

Chief Executive Officer
Ryan Harris



Board of Directors
Abe Hathaway, President
Jeanne Utterback, Vice President
Tami Humphry, Treasurer
Lester Cufaude, Director

Board of Directors
Regular Meeting Agenda
February 28, 2024 @ 1:00 PM
Mayers Memorial Healthcare District
Burney Boardroom
20647 Commerce Way
Burney, CA 96013

Mission Statement
Leading rural healthcare for a lifetime of wellbeing.

In observance of the Americans with Disabilities Act, please notify us at 530-336-5511, ext 1264 at least 48 hours in advance of the meeting so that we may provide the agenda in alternative formats or make disability-related modifications and accommodations. The District will make every attempt to accommodate your request.

				Approx. Time Allotted	
1	CALL MEETING TO ORDER				
2	2.1 CALL FOR REQUEST FROM THE AUDIENCE - PUBLIC COMMENTS OR TO SPEAK TO AGENDA ITEMS	Persons wishing to address the Board are requested to fill out a "Request Form" prior to the beginning of the meeting (forms are available from the Clerk of the Board, 43563 Highway 299 East, Fall River Mills, or in the Boardroom). If you have documents to present for the members of the Board of Directors to review, please provide a minimum of nine copies. When the President announces the public comment period, requestors will be called upon one-at-a time, please stand and give your name and comments. Each speaker is allocated five minutes to speak. Comments should be limited to matters within the jurisdiction of the Board. Pursuant to the Brown Act (Govt. Code section 54950 et seq.) action or Board discussion cannot be taken on open time matters other than to receive the comments and, if deemed necessary, to refer the subject matter to the appropriate department for follow-up and/or to schedule the matter on a subsequent Board Agenda.			
3	APPROVAL OF MINUTES				
	3.1 Regular Meeting –January 31, 2024	<i>Attachment A</i>	Action Item	1 min.	
4	DEPARTMENT/QUARTERLY REPORTS/RECOGNITIONS:				
	4.1 Resolution 2024.03 – January Employee of the Month	<i>Attachment B</i>	Action Item	2 min.	
	4.2 Hospice Quarterly	Lindsey Crum	<i>Attachment C</i>	Report	2 min.
	4.3 Mayers Healthcare Foundation Quarterly	Val Lakey	<i>Attachment D</i>	Report	2 min.
	4.4 Quality & Risk	Jack Hathaway	<i>Attachment E</i>	Report	2 min.
	4.5 Skilled Nursing Facility	Cassandra & Britany	<i>Attachment F</i>	Report	2 min.
	4.6 Maintenance & Engineering	Alex Johnson	<i>Attachment G</i>	Report	2 min.
5	BOARD COMMITTEES				
	5.1 Finance Committee				
	5.1.1 Committee Meeting Report: Chair Humphry		Report	5 min.	
	5.1.2 January 2024 Financial Review, AP, AR and Acceptance of Financials		Action Item	5 min.	
	5.1.3 Board Quarterly Finance Review		Action Item	2 min.	
	5.1.4 Acceptance of Annual Audit Summary prepared by Wipfli		Action Item	2 min.	

5.1.5	Proposal for HVAC Project in FR Dietary	Attachment H	Action Item	10 min.
5.1.6	Solar Project – TX Upgrade Cost	Attachment I	Action Item	10 min.
5.1.7	Master Planning Update – FR Rural Health Clinic	Attachment J	Discussion/ Action Item	10 min.
5.2	Strategic Planning Committee – No February Meeting			
5.3	Quality Committee –February 21st Report			
5.3.1	DRAFT Minutes Attached	Attachment K	Report	5 min.
6	NEW BUSINESS			
	Policies & Procedures: Ivenix SMART Infusion Pump Use Swing Bed Criteria and Pre-Admission Processes ABO/RH Confirmation of Patient Age Specific Guidelines Automated HDL Cholesterol Automated LDL Cholesterol Cholesterol Collection and Arm Band Policy Critical Values with Read Back Emergency Release of Blood Handling and Processing Specimens High Sensitivity Troponin I Ordering Protocol to Rule Out acute Myocardial Infarction Laboratory Environment Health and Safety Loci Thyroid Stimulating Hormone Loci Vitamin B12 Loci Vitamin D Total Assay Millipore Water Culture Total Prostate Specific Antigen Total Protein Triglycerides Uric Acid Urinary/Cerebrospinal Fluid Protein			
6.1		Attachment L	Action Item	5 min.
6.2	Organizational Chart Approval	Attachment M	Action Item	5 min.
6.3	New Board Member Appointment		Information	5 min.
6.4	Board Member Education Plans & Options		Discussion	5 min.
7	ADMINISTRATIVE REPORTS			
7.1	Chief's Reports – <i>Written reports provided. Questions pertaining to written report and verbal report of any new items</i>			
7.1.1	Chief Financial Officer – Travis Lakey		Report	5 min.
7.1.2	Chief Human Resources Officer – Libby Mee		Report	5 min.
7.1.3	Chief Public Relations Officer – Val Lakey	Attachment N	Report	5 min.
7.1.4	Chief Clinical Officer – Keith Earnest		Report	5 min.
7.1.5	Chief Nursing Officer – Theresa Overton		Report	5 min.
7.1.6	Chief Executive Officer – Ryan Harris		Report	5 min.
8	OTHER INFORMATION/ANNOUNCEMENTS			
8.1	Board Member Message: Points to highlight in message		Discussion	2 min.
9	MOVE INTO CLOSED SESSION			

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10 **CLOSED SESSION ITEMS**

Hearing (Health and Safety Code § 32155) – Medical Staff Credentials

AHP Appointment: Paula Amacker, NP – Oncology (Dignity)

10.1

Medical Staff Appointment:
Ross Mandeville, MD – Neurologist (Telemed2U)
Galen Church, DO – Emergency Medicine

Action Item

2 min.

11 **RECONVENE OPEN SESSION**

12 **ADJOURNMENT: Next Meeting March 27, 2024**

Posted 02/23/2024

Chief Executive Officer
Chris Bjornberg



Board of Directors
Abe Hathaway, President
Jeanne Utterback, Vice President
Tom Guyn, M.D., Secretary
Tami Humphry, Treasurer
Lester Cufaude, Director

Board of Directors
Regular Meeting
Minutes
January 31, 2024 – 1:00 pm
MMHD FR Boardroom

These minutes are not intended to be a verbatim transcription of the proceedings and discussions associated with the business of the board's agenda; rather, what follows is a summary of the order of business and general nature of testimony, deliberations and action taken.

CALL MEETING TO ORDER: Abe Hathaway called the regular meeting to order at 1:00 PM on the above date.

BOARD MEMBERS PRESENT:

Abe Hathaway, President
Jeanne Utterback, Vice President
Tami Humphry, Treasurer
Lester Cufaude, Director

ABSENT:

STAFF PRESENT:

Ryan Harris, CEO
Travis Lakey, CFO
Theresa Overton, CNO
Valerie Lakey, CPRO
Keith Earnest, CCO
Libby Mee, CHRO
Jessica DeCoito, Board Clerk

2 CALL FOR REQUEST FROM THE AUDIENCE - PUBLIC COMMENTS OR TO SPEAK TO AGENDA ITEMS:

- 3 Special Presentation:** Wipfli Annual Audit Summary – David Imus, Eric Volk, David Imus: Summary presentation of the Required Communication, Financial Statement Review, Financial Analysis, and Accounting Standards update was provided. Another clean audit with no findings and Mayers continues to better its financial ratios to increase financial stability. Thank you to Eric Volk, David Imus, and Dang Ta from Wipfli for the presentation. And a thank you to the Wipfli team for helping Mayers get to our financial standings today.

4 APPROVAL OF MINUTES

- | | | | |
|-----|---|-------------------------------|----------------------------|
| 4.1 | A motion/second carried; Board of Directors accepted the minutes of December 6, 2023. | Humphry,
Utterback | Approved by
All |
|-----|---|-------------------------------|----------------------------|

5 DEPARTMENT/OPERATIONS REPORTS/RECOGNITIONS

- | | | | |
|-----|---|-------------------------------|----------------------------|
| 5.1 | A motion/second carried; Stefanie Hawkins was recognized as December Employee of the Month. Resolution 2024-01. Stefanie is the first person to meet our patients for our Cardiac Rehab and Physical Therapy departments. Stefanie was a champion during the Cerner transition, even when the moments were difficult. She is a huge asset to our team, providing our patients with utmost care. | Utterback,
Cufaude | Approved by
All |
| 5.2 | A motion/second carried; Resolution 2024.02 Authority to Sign was approved. | Cufaude,
Utterback | Approved by
All |
| 5.3 | Safety Quarterly: written report submitted. Function drill originally scheduled for April will now be in May, due to Cerner LTC implementation. | | |
| 5.4 | IT: written report submitted. Review of strategic planning priorities. | | |
| 5.5 | Infection Control: written report submitted. Review of strategic planning priorities. New Infection Preventionist will begin on February 12 th . Root Cause Analysis is being done with the issues presented at the Burney Annex SNF and findings will help us establish better processes to mitigate issues happening again. | | |

6 BOARD COMMITTEES

6.1	Finance Committee		
6.1.1	Committee Report: Audit findings were great. In Finance we discussed our AR status. RevCycle Consultant was onsite last week to help us understand better workflows and build corrections in our new Cerner program that have caused an increase in AR days. A clinical consultant will be coming onsite in March to provide the same input from the clinical perspective.		
6.1.2	December 2023 Financials: motion moved, seconded and carried to approve financials.	<i>Humphry, Utterback</i>	<i>Approved by All</i>
6.1.3	Tri Counties Bank Signers Change: remove Chris Bjornberg and add Ryan Harris	<i>Cufaude, Humphry</i>	<i>Approved by All</i>
6.2	Strategic Planning Committee Chair Utterback: No Meeting held in December		
6.3	Quality Committee: DRAFT Minutes attached. Team has seen that we could use consultants to help get the ACHC Accreditation. So far, Jack and Ryan have entertained three different vendors and are awaiting bids. There is a lot more to the process that previously understood. Discussion about ACHC Academy and what was learned at the conference took place.		

7 NEW BUSINESS

7.1	Policy & Procedures Summary 12-31-2023 Moved, seconded and carried.	<i>Cufaude, Utterback</i>	<i>Approved by All</i>
7.2	Policy & Procedures: <ol style="list-style-type: none">1. Bladder Irrigation – Continuous2. Financial Obligations, Swing Bed3. General Laboratory Specimen Collection4. Anesthesia Privileges5. Hospice and Palliative Care Core Privileges6. Nurse Practitioner Core Privileges in Neurology 10-20237. Surgery, General Core Privileges Moved, seconded and carried.	<i>Cufaude, Humphry</i>	<i>Approved by All</i>
7.2	Board Vacancy Process: Motion moved, seconded and carried to fill vacancy by appointment. Post vacancy immediately, application & letter due by February 21 st , Special Board Meeting to conduct interviews on February 26 th , with the appointment to be made at the February 28 th Regular Board Meeting.	<i>Utterback, Humphry</i>	<i>Approved by All</i>
7.3	Board Committee Re-assignments: Tami Humphry volunteered to fill the empty Quality seat. Motion moved, seconded and carried.	<i>Humphry, Utterback</i>	<i>Approved by All</i>
7.4	May Board Meeting Date Change: motion moved, seconded and carried to move the May Board meeting to the 22 nd .	<i>Utterback, Humphry</i>	<i>Approved by All</i>

8 ADMINISTRATIVE REPORTS

8.1	Chief's Reports: written reports provided in packet		
8.1.1	CFO: Audit summary figures were compared to other critical access hospitals.		
8.1.2	CHRO: Spending time on provider recruiting and provider contract reviews. We will be spending more time on the legislative changes that have gone into effect and keeping in touch with those new bills coming forward that affect us. Plans to attend as many HR conferences and workshops to stay on top of things.		
8.1.3	CPRO: TCCN Center – hired an Executive Director to start on Monday. We are planning on hosting the March Quarterly Event in the TCCN space. A lot of work is going into the preparation for staff and business in the space. The Denim and Diamonds Gala was awesome! So proud of our team for going above and beyond for the night and the cause. We are looking at a net around \$35,000.		
8.1.4	CCO: We are working through physical therapy's problems with Cerner – not allowing more than 6 patients per therapist. 309 prescriptions filled in one day on January 8 th – new RECORD, with 69 left in the queue that just weren't able to get filled within the day. We are in an exploratory stage for Visiting Nurse services – a version of home health services.		

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8.1.5 **CNO:** We are in the midst of our Cerner LTC implementation. The team has concerns about the implementation and are making sure we are getting the attention, communication, training, etc we need to have a successful implementation. We are doing additional process efficiencies for our CNA continuing education units to help them meet their requirements every 2 years.

8.1.6 **CEO:** The FR clinic would be better as a brick and mortar set up, rather than the mobile clinic. Reviewing the Master Plan for the FR clinic is being worked on. Design in dietary for new cabinetry is \$20,000 and doesn't include unforeseen design changes. Just the design fees for the HVAC units in the space is \$85,000 and approximately \$750,000 to \$1,000,000 to replace and update the units. And these units can be reused in the Master Planning updates.

9 OTHER INFORMATION/ANNOUNCEMENTS

9.1 Board Member Message: 2023 Annual Audit Summary, Employee of the Month, TCCN Update, Spring Class for CNA's, Thank you to Gala Volunteers, Denim & Diamond Gala success, Board Vacancy

10 MOVE INTO CLOSED SESSION: 3:33 PM

10.1 **Closed Session Minutes Approval** **Approved by All**
December 1st, December 8th, December 22nd, December 29th
Hearing (Health and Safety Code §32155) – Medical Staff Credentials

10.2 **AHP Appointment:** Benjamin Weaver, CRNA
Medical Staff Appointment: Christopher Campos, DO (UCD) – Neurology **Approved by All**
Medical Staff Reappointment:
Edward Richert, MD
Alreza Abdolmohammadi, MD
William Dykes, MD

11 RECONVENE OPEN SESSION

12 ADJOURNMENT: 4:25 PM
Next Meeting February 28, 2024

I, _____, Board of Directors _____, certify that the above is a true and correct transcript from the minutes of the regular meeting of the Board of Directors of Mayers Memorial Healthcare District

Board Member

Board Clerk

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RESOLUTION NO. 2024-03

**A RESOLUTION OF THE BOARD OF TRUSTEES
OF MAYERS MEMORIAL HEALTHCARE DISTRICT RECOGNIZING**

Milca Estrada

As January 2024 EMPLOYEE OF THE MONTH

WHEREAS, the Board of Trustees has adopted the MMHD Employee Recognition Program to identify exceptional employees who deserve to be recognized and honored for their contribution to MMHD; and

WHEREAS, such recognition is given to the employee meeting the criteria of the program, namely exceptional customer service, professionalism, high ethical standards, initiative, innovation, teamwork, productivity, and service as a role model for other employees; and

WHEREAS, the MMHD Employee Recognition Committee has considered all nominations for the MMHD Employee Recognition Program;

NOW, THEREFORE, BE IT RESOLVED that, Milca Estrada is hereby named Mayers Memorial Healthcare District Employee of the Month for January 2024; and

DULY PASSED AND ADOPTED this 28th day of February by the Board of Trustees of Mayers Memorial Healthcare District by the following vote:

- AYES:
- NOES:
- ABSENT:
- ABSTAIN:

Abe Hathaway, President
Board of Trustees, Mayers Memorial Healthcare District

ATTEST:

Jessica DeCoito
Clerk of the Board of Directors

Hospice Quarterly Report

Hospice held a candlelight ceremony on December 7, 2024. It was a good turnout of community members. Our wonderful chaplain Alison Maki held prayer and Keith Earnest helped with opening speeches. We also did the Christmas tree lighting with long-term care in the lobby a couple of days later. Drinks and cookies were supplied by the kitchen. There were a couple of songs that were sung as a group and residents helped hang ornaments on the tree.

MHF reported a net profit of around \$35,000 for the Denim and Diamonds Hospice Gala. Per MHF policy Hospice will not know the total profit directed to us until they have decided what percent of profits will go to designated fundraiser designees.

Since the last update on Hospice billing, we have finally begun to bill and see payment since the transition to Matrix in August. As of 02/20/2024, we have received nearly \$31,000 in payment between private pay and Medicare. Private pay until now has been an eaten cost, we have been spending copious amounts of time making sure each step for repayment is being taken. We continue through growing pains with our billing process and pushing through claims holds within the new system. Danielle Olson has been a fantastic help throughout the entire process.

The new matrix system has allowed for much more quality tracking than our last system allowed. With this tracking we have been able to take a deeper look into our current referrals and where they come from. We can use this towards education on Hospice to the sources that have not made as many referrals. With those referrals, we are hoping to continue to increase our length of service with our patients. As of Fiscal year 2022, the national average LOS is 79 days, and our hospice has an average of 74.88 days which is something to be very grateful for. We will continue to work towards reaching these achievements through the education of providers and the community.

The Hospice Regulatory boot camp was a success. Many things have changed since the last Bootcamp that was attended in 2018. It was my first time as manager to go to a boot camp and it was a knowledge overload. We have many things to continue to change and tweak. Along with many things that we are already doing great.

Thank you,

Lindsey Crum, RN Hospice Manager



People Pillar



Name: Lindsey Crum
Supervisor: Keith Earnest
Department: Hospice

Last Updated:

FY24 (July 1, 2023 - June 30, 2024)							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
Bring in pet therapy run by volunteer/staff for hospice patients. Add 3 new volunteers in the area				Lindsey Crum	Three new volunteer applications placed through Mayers for Hospice on 11/15/23		
					02/06/24 follow up with volunteers and hiring process		
Priority Ideas for Next Year 2.							

For Completion at Beginning of Fiscal Year		
_____ Name	_____ Signature	_____ Date
_____ Supervisor	_____ Signature	_____ Date
_____ Executive Leader	_____ Signature	_____ Date

CEO Approval at End of Fiscal Year		
_____ Ryan Harris CEO	_____ Signature	_____ Date



Growth Pillar



Name: Lindsey Crum
Supervisor: Keith Earnest
Department: Hospice

Last Updated: 02/20/2024

FY24							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
Increase length of stay to 80% of national average.				Lindsey Crum	Continued education given to the Hospice Medical Director over early admission.		
				Lindsey Crum	Current National Average LOS is 79 days. Intermountain Hospice is at 74.88 days for Fiscal Year 2022		
Priority Ideas for Next Year							

For Completion at Beginning of Fiscal Year		
_____ Name	_____ Signature	_____ Date
_____ Supervisor	_____ Signature	_____ Date
_____ Executive Leader	_____ Signature	_____ Date

CEO Approval at End of Fiscal Year		
_____ Ryan Harris CEO	_____ Signature	_____ Date



Communication Pillar



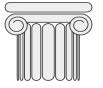
Name: Lindsey Crum
Supervisor: Keith Earnest
Department: Hospice

Last Updated: 02/20/2024

FY24 (July 1, 2023 - June 30, 2024)							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
Complete outreaches quarterly to achieve earlier referral.				Lindsey Crum	Meetings with different outreach programs to educate about hospice		
				Lindsey Crum	Tracking referral sources on new EMR system		
Priority Ideas for Next Year							

For Completion at Beginning of Fiscal Year		
_____	_____	_____
Name	Signature	Date
_____	_____	_____
Supervisor	Signature	Date
_____	_____	_____
Executive Leader	Signature	Date

CEO Approval at End of Fiscal Year		
_____	_____	_____
Ryan Harris	Signature	Date
CEO		



Finance Pillar

Name: Lindsey Crum
Supervisor: Keith Earnest
Department: Hospice

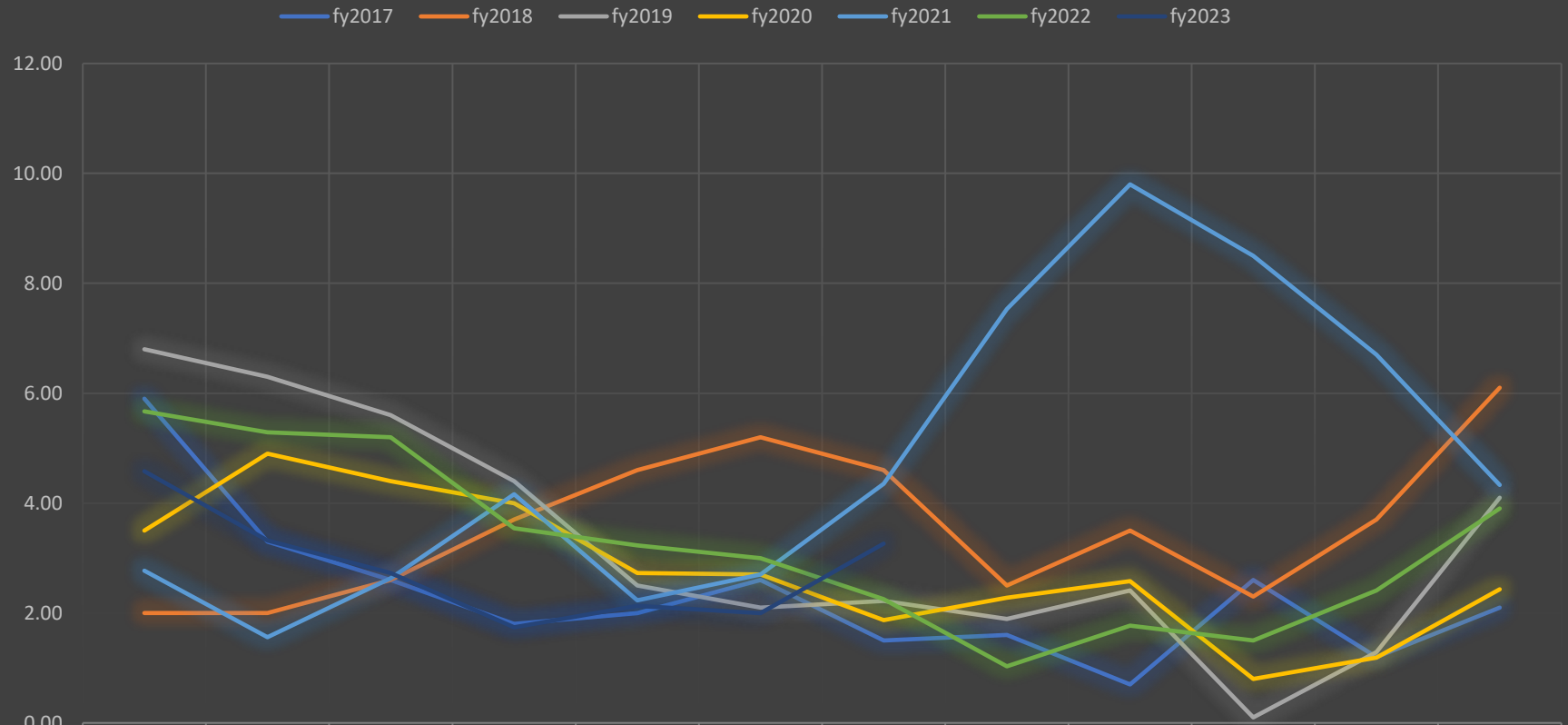
Last Updated: 02/20/2024

FY24 (July 1, 2023 - June 30, 2024)							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
1. Create Medicare Advantage admission form process to be used prior to admission into Hospice to receive payment on 70% of Medicare patients.				Lindsey Crum	Pre approvals through different private insurances and medicare advantage programs worked through		
				Lindsey Crum	10/13/23 Successful payment from private Blue Shield insurance		
Priority Ideas for Next Year							

For Completion at Beginning of Fiscal Year		
_____ Name	_____ Signature	_____ Date
_____ Supervisor	_____ Signature	_____ Date
_____ Executive Leader	_____ Signature	_____ Date

CEO Approval at End of Fiscal Year		
_____ Ryan Harris CEO	_____ Signature	_____ Date

Average Patient Days



	1	2	3	4	5	6	7	8	9	10	11	12
fy2017	5.90	3.30	2.60	1.80	2.00	2.60	1.50	1.60	0.70	2.60	1.20	2.10
fy2018	2.00	2.00	2.60	3.70	4.60	5.20	4.60	2.50	3.50	2.30	3.70	6.10
fy2019	6.80	6.30	5.60	4.40	2.50	2.10	2.22	1.89	2.41	0.10	1.29	4.10
fy2020	3.50	4.90	4.40	4.00	2.73	2.70	1.87	2.28	2.58	0.80	1.19	2.43
fy2021	2.77	1.56	2.63	4.16	2.23	2.70	4.35	7.53	9.80	8.50	6.70	4.33
fy2022	5.67	5.29	5.20	3.54	3.23	3.00	2.25	1.03	1.77	1.50	2.41	3.90
fy2023	4.58	3.32	2.73	1.74	2.13	2.00	3.26					



**Report to the MMHD Board
February 2024 Regular Board Meeting**

The Mayers Healthcare Foundation ended 2023 with a lot of successes and is looking forward to 2024.

Financial Reports:

- The finance committee met with Edward B. Jones and discussed our CD's. We renewed a CD at a rate of 5.5%. We are working with the firm to strategize our CD's.
- The finance committee met to establish a budget for the 2024 calendar year. They also worked on revising the chart of accounts.

Events:

- MHF "On the Green" – a check for \$18,653.37 was presented to the MMHD Ambulance. This was a result of the successful golf tournament. The amount is 75% of the net proceeds.
- **NSGT** – November 28, 2023, was a HUGE success! We raised \$25,705 from over 90 donors! This includes a prize of \$1,000 from the Community Foundation of the North State for all of our Foundation board members donating. This year saw the most donors we have had and the most MMHD staff! Thank you to the 43 staff, MMHD board and MHF board members that generously gave. We also received an additional \$2000 +/- for the Power Hour Giving. Thank you to Laura Beyer for all her efforts in organizing the event and to the staff, MHF Board, MMHD Board and volunteers for making this event such a success.
- **Denim & Diamonds Hospice Winter Gala** – January 27, 2024. This event was a HUGE success! We sold out the dinner, sold all 10 sponsor tables and sold 481 tickets for the 1965 Mustang. You will find a summary attached, but the bottom line is that it was a fantastic evening and we netted about \$35,000. We had a meeting last week to review the event and did a lot of brainstorming to make it even better next year. Thank you to Michele and all of the MHF team, board and volunteers for the time and effort put in to make this such a great evening.
- **Health Fair** - As discussed at our last board meeting, we are looking at some different ways to reinvigorate the Health Fair. There are some good ideas floating around. We had a planning meeting and are looking at doing the event (completely new and refreshed!) on June 22, 2024.

Thrift Store Update: Some of the biggest news comes out of the Thrift Store. Mary Rainwater has accepted a new position at Mayers and stepped down from the Thrift Store. We are trying something new at the request of the volunteers. We are going back to the original model of the thrift store and making it a volunteer run store. We closed the store for a week and the volunteers cleaned, reorganized, and refreshed the store. They did an amazing job! The store re-opened on February 21 and had a very successful day. We are keeping the position open and will see how things go with the new model. If we need to, we will hire someone. I am very optimistic this will work out very well given the enthusiasm and dedication of the volunteers. As always, we welcome new volunteers and are always in need of donations.

Volunteers:

The Volunteer Luncheon at the Pit River Lodge was a great success. Thank you to Shay for organizing and to Joey and Carol for hosting. This was a fun event, and the location was perfect! We truly appreciate the many volunteers we have working in Hospice, taking care of the hospital gardens, at the Thrift Store, SNF activities and more. As always, we can use more volunteers – even for short amounts of time here and there.

We have a few new volunteers and we have been able to have extra help cleaning at the TCCN building as well as other regular volunteer activities.

Awards and Scholarships:

Department Award Grant applications were received. There were 13 applications received. Letters to the Department Grant recipients were sent. MHF is proud to have awarded \$80,480.99 to MMHD departments.

We have been working on grant applications. We are also getting ready to start the scholarship cycle. We would like to consider offering scholarships in the Spring and Fall.

MHF Committee Updates:

Finance Committee met to develop budget and review chart of accounts.

Other News:

- The Annual Appeal brought in over \$20,000. The Annual Appeal went out to all local boxholders as well as an additional 300 to out of the area people who have previously supported the foundation. We have seen many donations from the appeal. It was also a great opportunity to show the community what we do at MHF! You can also view the appeal on our website [HERE](#)

NEXT INPERSON BOARD MEETING: – March 18, 2024, Fall River Mayers Campus Board Room or Zoom – 4:00 – 5:00 p.m.



Attachment E

QUALITY REPORT FEBUARY 2024

Quality is not an act, it is a habit.

- Aristotle

Mayers Memorial Healthcare District

Jack Hathaway | Director of Quality

Mayers Memorial Healthcare District – Quality Update.

ACHC

As the Board is aware - Cindy Segar-Miller is on board and has started the work for assessment towards accreditation readiness. The work will be a heavier lift for some than others, luckily (as I would view it), we are starting the work in a very standardized process with departments that are not as heavily impacted by Cerner's Great Adventure. Cindy is methodically walking us through the most important application documents and requirements step-by-step, weekly meetings and lists for accountability. Ryan has emphasized that results should be the highest measure of our success, to allow us some room in the timeline that was previously established. At the end of the ACHC work the hospital and the community we serve will be in a better position concerning healthcare.

DHCS-QIP

Quality is currently auditing populations to see where we could potentially find success for PY6 (Performance Year 6 - Calendar Year 2023). Traditionally DHCS-QIP has been a look back program, in the previous versions of QIP - all of the years prior to COVID - looking back over the year we were able to find some measure of success. However, a few policy changes in the program itself and an increased focus on outcomes and gap closure in metric measurements for success made the program more difficult. To be fully transparent from Quality's perspective as long as metrics were found for success there was never a problem with how the look back process in the program was managed. However, it never met the transformative purpose of QIP as a look back program.

I have attached a brief OIP Data overview of the recent QIP data and measure selection that we have used and a show of success or failure as reference for our conversation moving forward.

Partnership QIP

The Partnership QIP has been a largely passive QIP program as well - with Long Term Care, Clinic, and Hospital, programs that have been largely managed and paid on performance based on data that Partnership had provided to us. For reference in FY22/23 we received \$15,750 from the HQIP program and in CY2022 we received \$62,929.31 from the LTC QIP program. Partnership QIP programs are very user friendly and as we work to align the Clinic Partnership QIP and the DHCS QIP where they have overlapping measures, we may find added success in both programs.

Internal Quality Measures

Our internal quality work is progressing; however, I know that there will be changes coming - around the annual report I provide to the Board, and the way that the board is updated on our internal measures, and the direction we receive back around that data. So, look for that in the near future. I have provided some graphs and basic data that will be part of those reports moving forward as they are specifically called out in the ACHC manual as measures that are to be reported to the Board as a part of the District's QAPI (Quality Assurance and Performance Improvement) program.

Other than that the work continues, and as with everything we do in healthcare it will continue to evolve and we will continue to improve our response to those changes.

Thank you,

Jack Hathaway | Director of Quality

QIP Data overview:

PY 3.5 Jan 2020 - Dec 2020 (COVID Allowances in place for success)									
Number	Abbreviation	Title	Report Status	Baseline Rate	Target Rate	Numerator	Denominator	Achievement Rate	Achievement Value
Q-PC9	Q-PC9	Immunization for Adolescents	No Data Entered						1
Q-PC10	Q-PC10	Childhood Immunization Status	No Data Entered						1
Q-PC15	Q-CMS147	Preventive Care and Screening Influenza Immunizations	No Data Entered						1

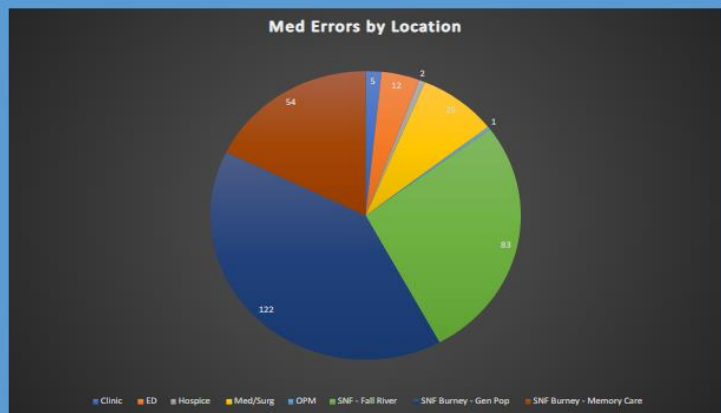
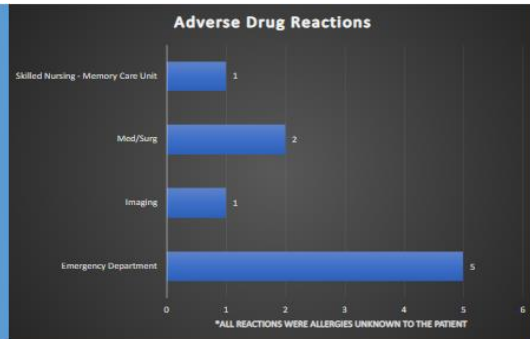
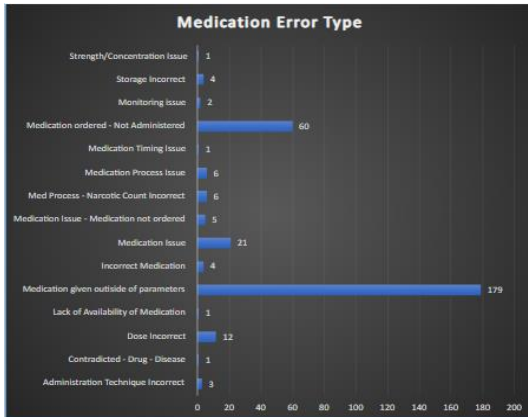
PY 4 Jan 2021 - Dec 2021 (COVID Allowances in place for success)									
Number	Abbreviation	Title	Report Status	Baseline Rate	Target Rate	Numerator	Denominator	Achievement Rate	Achievement Value
Q-PS3	Q-QPP76	Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections	Report Made	0.00	0.4485	1	1	1	1
Q-CDI	Q-CDI	Reduction in Hospital Acquired Clostridium Difficile Infections	Report Made	0.00	0.79	0.00	0.485	0.00	1

PY 5 Jan 2022 - Dec 2022 (No COVID Allowances moving forward)									
Number	Abbreviation	Title	Report Status	Baseline Rate	Target Rate	Numerator	Denominator	Achievement Rate	Achievement Value
Q-PC12	Q-CMS147	Preventive Care and Screening Influenza Immunizations	Report Made	0.811	0.7182	70	167	0.419	0
Q-CDI	Q-CDI	Reduction in Hospital Acquired Clostridium Difficile Infections	Report Made	0.00	0.00	0.00	0.652	0.00	0

PY 6 Jan 2023 - Dec 2023 ("Normal" Performance requirements)									
Number	Abbreviation	Title	Report Status	Baseline Rate	Target Rate	Numerator	Denominator	Achievement Rate	Achievement Value
Q-PC12	Q-CMS147	Preventive Care and Screening Influenza Immunizations	Report Audit in Process	0.419	0.4525	TBD	TBD	TBD	TBD
TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD

Internal Quality Measures:

This is a look at the Medication Error tracking that we will be continuing - internally we monitor all of this more closely in Medication, Pharmacy and Therapeutics - however, at this level it will be a more general less specific overview of these measures and our progress on them. This is a 2023 baseline for future work.



This is a look at the measures we are currently following from the Acute floor - there may be some changes as Cindy continues on her work to help us become ACHC survey ready - but the measures and the issues with the data capture in our systems will all be followed and we will continue to work on this pathway as well.



SNF BOARD REPORT

February 2024

SNF Update

- The current census is at 77 - Fall River is 31 and Burney 46.
- We have 2 female beds and 1 male bed available in Burney. In Fall River we have 3 female and 2 male beds available.
- Admissions continue to be on hold at this time.
- We have 3 CNA students that completed class on February 20th. Their state test is scheduled for March 21st. These students will train on the Acute Care floor until they are cleared by CDPH. Then they will start their SNF on the floor orientation.
- We have 6 unit assistants working on the floor currently who will be added to the next CNA class. The next class start date is pending at this time.
- Currently in Fall River we have 5 CNA vacancies and 7 Nurse vacancies. In Burney we have 10 CNA vacancies and 8 Nurse vacancies. With these additional staff members, we would have a fully covered schedule with no overtime.
- These vacancies do not include the four CNA staff members out at this time pending retesting due to a lapse in certification. Two have test dates scheduled. Two are awaiting clearance to test from the licensing board. The team has discussed monitoring and communication processes to mitigate future lapses in certification.
- Staff interest in attending an in-house VN (Vocational Nurse) program continues to be a hot topic. Several staff members have taken the initiative to start their prerequisite classes, so they are ready to go when a program is established.
- The Burney Fire Alarm Panel replacement project continues.
- The SNF Cerner Super Users are currently undergoing training. At this time, they are not feeling adequately prepared to train others. Requests have been made for additional training and onsite support from Cerner during go live.
- On 2/12/24 the state returned to the Burney campus to survey the facility on our directed plan of correction regarding C difficile management. On exit, the surveyor said he found the facility complied with the plan and complimented the nursing and environmental staff for their hard work. Additionally on the same date the surveyor reviewed two falls with injury and one resident to resident altercation with no deficiencies cited. In Fall River one case of norovirus was reviewed with no deficiencies cited.
- Implementation of the SNF's response to those items identified in the facility root cause analysis leading to an immediate jeopardy tag are ongoing.
- On 2/16/24 a state surveyor came to the Burney campus for a complaint survey with no deficiencies cited.

SNF 2024 Priorities

- Establish staff competence on mechanical lifts. Educate a minimum of 80% of staff initially. Competency training is completed annually by all staff. Facility alignment with Safe Patient Handling guidelines.
 - Three sit-to-stands, two full-body mechanical lifts and lift slings have been purchased and are on site. This new equipment will be able to be utilized on the floor pending BioMed inspection.
 - Staff training on new lift equipment will start in March.
- Initiate 14-day Physical Therapy resident evaluation. Establish a 3-month baseline. Maintain a success rate of 80% or higher.
 - Physical Therapy evaluation workflow is in the process of being built.
- Establish a new resident mobility assessment tool to align with best practice guidelines. Educate 80% of staff initially. Competency training is completed annually by all staff.
 - Mobility assessment tool has been established. A ticket has been placed to intergrade tool into Cerner for use.

SNF Activities Update

- The resident family's Christmas party went great. All the residents received multiple presents between staff donations and the giving tree placed in the community. Mrs. Clause and the Grinch also made a special appearance.
- Due to an outbreak at the Burney Campus, their family party was delayed until January. However, their party was also well attended. All in all, the residents and their families were overjoyed to see the return of these special events.
- Although the Superbowl Champion was not the favored team among our residents, they did enjoy watching the game and the snacks provided.
- Burney 4-H handed out Valentines Day cards and brought smiles and laughter to our residents.
- The Activities Director was able to secure a Preacher for the Fall River Campus monthly. Bible study is also being provided twice weekly and is a big hit.
- We are happy to welcome a new volunteer as well. He will be splitting his time between both campuses while he works towards entering medical school.
- The mural on the fence in Memory Care is complete. This was completed by a student for their senior project.
- The Activities Department's next project will be organizing a cruise for our residents during hospital week. More details to be announced.
- The Activities Department continues to be fully staffed on the floor as well as with a Van Driver and Hairdresser.



People Pillar



Executive Leader: Ryan Harris
 Director or Manager: Alex Johnson
 Department: Maintenance

Last Updated: 7.6.2023

FY24 (July 1, 2023 - June 30, 2024)							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
Employment turnover rate in the maintenance department including facilities, engineering, and maintenance will be less than 17.52 percent or two employees or less by FYE 2024.				Alex Johnson	We are fully staffed with 0 turnover.		
Priority Ideas for Next Year							

For Completion at Beginning of Fiscal Year		
Name	Signature	Date
Supervisor	Signature	Date
Executive Leader	Signature	Date

CEO Approval at End of Fiscal Year		
Ryan Harris	Signature	Date
CEO	Signature	Date



Quality Service Pillar



Executive Leader: Ryan Harris
 Director or Manager: Alex Johnson
 Department: Maintenance

Last Updated: 7.6.2023

FY24 (July 1, 2023 - June 30, 2024)							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
Pass ACHC accreditation in the maintenance department by FY24.			Meet ACHC standards from a physical plant and log keeping perspective by the end of fiscal year	Alex Johnson	Rewriting logs to meet ACHC standards. We are 75% complete.		
					Working above the ceiling to fix penetrations in fire walls and do cable management. We are also making sure we don't have anything touching fire sprinkler lines. 25% complete.		
					Working with Aspen street architects on Fire Life Safety Drawings. 25% complete.		
					Working on Building Demographic Report. 75% complete.		
					Helping Dana with information related to the facility for Safety Management.		
Pass the ASHE Certified Healthcare Facility manager exam by FYE 2024.				Alex Johnson	I am studying for the test and plan on taking it prior to the end of the fiscal year.		
Priority ideas for Next Year							

For Completion at Beginning of Fiscal Year		
_____ Name	_____ Signature	_____ Date
_____ Supervisor	_____ Signature	_____ Date
_____ Executive Leader	_____ Signature	_____ Date

CEO Approval at End of Fiscal Year		
_____ Ryan Harris CEO	_____ Signature	_____ Date



Communication Pillar

Executive Leader: Ryan Harris
Director or Manager: Alex Johnson
Department: Maintenance

Last Updated: 7.6.2023

FY24 (July 1, 2023 - June 30, 2024)							
Priority:	Weight	Bonus Amount	Specific Plan & Estimated Completion Date	Driver	Current Actions	% Complete By FY End	Bonus Amount Awarded
Provide maintenance support for at least 3 monthly community events and participate in at least 1 quarterly event.				Alex Johnson	We have supported the golf tournament, Fair booth, Denim and Diamonds and a recent community event at Ray's Market.		
					I attended the community outreach event about the proposed master plan that was held in the Hospital Lobby.		
Priority Ideas for Next Year							

For Completion at Beginning of Fiscal Year

_____ Name	_____ Signature	_____ Date
_____ Supervisor	_____ Signature	_____ Date
_____ Executive Leader	_____ Signature	_____ Date

CEO Approval at End of Fiscal Year

_____ Ryan Harris CEO	_____ Signature	_____ Date
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Aspen Street ARCHITECTS

Architecture • Planning • Feasibility Studies

February 1, 2023

John Morris, Project Manager
 Mayers Memorial Hospital
 PO Box 459 / 43563 Highway 299E
 Fall River Mills, CA 96028
 (530) 519-5041

Project Title: **Hospital Dietary HVAC Replacement, Design Proposal**

John,

Aspen Street Architects is pleased to submit this proposal for professional design services related to proposed HVAC project in the Dietary and surrounding area at the hospital in Fall River. This will be an OSHPD-1 project.

Scope of Work:

Design services for the following:

The installation of a new exterior ground mounted HVAC system to supply the kitchen, adjacent dining, and office area. The Kitchen currently has a swamp cooler on the roof. The are to be served is the Kitchen zone, and zones 9, 10 and 11 from the facilities HVAC zone map.

Whereas this is solely a mechanical project, accessibility upgrades within the area of work are excluded from the scope.

Consultant includes the following engineering subconsultants; structural, mechanical, and electrical.

One site visit by architectural PM and required engineers is included in scope of work, to review existing conditions and obtain readily available site information.

Electrical scope includes PIN-70 short circuit coordination, as necessary.

Any required Fire Alarm or Fire Sprinkler design work to be by Client, as deferred approval, or integrated with design by Consultant if possible.

The unpermitted HVAC unit in the Kitchen to be removed and is not part of the subject project.

Additional scope beyond that identified in this proposal will be additional services if required, such as change of use for associated space, accessibility upgrades to areas outside the immediate area of work, overall accessibility reviews, etc. Assistance with licensing agencies is excluded from scope of services but can be provided as additional services if required by Client.

Client to provide required electrical load readings, air balances, existing building plans/reference drawings, as-builts, AutoCAD base plans, etc., as may be required for design.

Plans to be submitted to HCAI for plan review and permitting. Consultant to respond to HCAI plan review comments to receive approval and make submittal for permitting.

Bidding services are included, to include coordination with Client selected contractor on RFIs. Formal public bidding services can be provided as additional services if requested.

Construction Administration (CA) to be provided, as required by jurisdictional authority.

It is assumed the HVAC piece will be run continuously once started.

Typical CA services included, to assume participation in regular Owner/Architect/Contractor meetings (virtual), responding to RFIs and review of submittals, completion of required HCAI paperwork, and administration of ACDs and NMAs. Any change due to unforeseen conditions, owner requested changes, or contractor requested changes can be handled as additional services as may be needed.

One site visit in CA is assumed by architectural PM and required engineers for final verified reports – additional visits can be provided as needed (additional fee may be warranted).

Client to pay all fees, including plan review, permitting, and bidding.

Fee Proposal

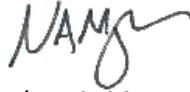
Consultant to proceed on a fixed fee basis for design as detailed in below chart, exclusive of reimbursable expenses, which will be billed per the attached rate schedule.

		design	agency review	con admin	subtotal
architectural	Aspen Street	\$ 16,170	\$ 5,280	\$ 11,880	\$ 33,330
subconsultants					
structural	Axiom	\$ 4,000	included	included	\$ 4,000
mechanical	NEXUS	\$ 22,000	included	included	\$ 22,000
electrical	Edge	\$ 19,000	included	included	\$ 19,000
subconsultant subtotal					\$ 45,000
consultant markup	15%				\$ 6,750
TOTAL					\$ 85,080

This proposal is valid for the next 90 days. Please provide a written authorization to proceed with work if the above meets your approval.

Thank you for considering Aspen Street Architects for this project. We look forward to working with you.

Respectfully,

A handwritten signature in black ink, appearing to read 'N.A.M.', with a stylized flourish extending from the end.

Nathan A. Morgan
President



**Aspen Street Architects, Inc.
Rate Schedule**

Hourly Rates for Professional Personnel

Principal/Architect	240.00	Certified Access Specialist (CASp)	200.00
Senior Architect	230.00	Senior Planner	240.00
Architect IV	210.00	Facilities Manager	180.00
Architect III	180.00	Sr Project Manager	185.00
Architect II	160.00	Project Manager	165.00
Architect I	150.00		
Architect Intern II	145.00	Construction Contract Administrator	130.00
Architect Intern I	135.00	Project Administrator	100.00
Sr. Job Captain	135.00		
Job Captain	120.00		
Senior Production	120.00		
Production	105.00		

Consultants Fees Under Contract:

Billed per consultant's invoice, plus 15% coordination fee.

Reimbursable Expenses Not Included in Contract:

Engineering Xeroxes (white 24" x 36")	\$ 5.00/each
Engineering Xeroxes (white 30" x 42")	\$ 7.50/each
Color Printing (8.5"x11")	\$ 1.50/page
Color Printing (11"x17")	\$ 2.75/page
Photocopies	\$ 0.20/each
Data Disc	\$ 2.50/each
Report Binding	\$ 5.50/each

Miscellaneous reimbursable charges, including but not limited to, photographs, outside printing, maps, renderings, postage and freight will be billed at actual cost plus 15%. Travel expenses will be billed at actual cost plus 15%.

Clients will be billed monthly for services rendered. Payment is due upon receipt of invoice. Invoices which remain unpaid after thirty days are considered past due and subject to a service charge of 1.5% per month, which is an annual rate of 18%. If Client believes a billing error has occurred, or if Client requires additional information regarding an invoice, Client agrees to inform Aspen Street Architects in writing within ten days of invoice date. If Client does not inform Aspen Street Architects of any disputes within ten days, charges will be deemed correct.

The rates will remain in effect until December 31, 2024 and are subject to adjustment thereafter.



Electric Sample Form No. 79-1220-02

Sheet 1

Interconnection Agreement for Net Energy Metering 2 (NEM2) of a Renewable Electric Generating Facility of 1,000 kW or Less, Except NEM2 Solar or Wind Facilities of 30 kW or Less, and Virtual Net Energy Metering (NEM2V) of a Renewable Electric Generating Facility of 1,000 kW or Less

Please Refer to Attached Sample Form

(Continued)

Advice Decision 6976-E

Issued by
Meredith Allen
Vice President, Regulatory Affairs

Submitted June 30, 2023
Effective June 30, 2023
Resolution _____



INTERCONNECTION AGREEMENT FOR NET ENERGY METERING 2 (NEM2) OF A RENEWABLE ELECTRIC GENERATING FACILITY OF 1,000 KW OR LESS, EXCEPT NEM2 SOLAR OR WIND FACILITIES OF 30 KW OR LESS, AND VIRTUAL NET ENERGY METERING (NEM2V) OF A RENEWABLE ELECTRIC GENERATING FACILITY OF 1,000 KW OR LESS

This INTERCONNECTION AGREEMENT FOR NET ENERGY METERING 2 (NEM) OF A RENEWABLE ELECTRIC GENERATING FACILITY OF 1,000 KW OR LESS, EXCEPT NEM2 SOLAR OR WIND FACILITIES OF 30 KW OR LESS, AND VIRTUAL NET ENERGY METERING (NEM2V) OF A RENEWABLE ELECTRIC GENERATING FACILITY OF 1,000 KW OR LESS (Agreement)¹ is entered into by and between _____ (Customer-Generator), and Pacific Gas and Electric Company (PG&E), a California Corporation. Customer-Generator and PG&E are sometimes also referred to in this Agreement jointly as “Parties” or individually as “Party.” In consideration of the mutual promises and obligations stated in this Agreement and its attachments, the Parties agree as follows:

1. SCOPE AND PURPOSE

1.1 This Agreement provides for Customer-Generator to interconnect and operate a Renewable Electrical Generation Facility as defined in Schedule NEM2 (if this is a NEM2 Solar or Wind Generating Facility less than 30 kW, please use form 79-1151A-02) (Generating Facility) in parallel with PG&E’s Electric System to serve the electrical loads connected to the electric service account that PG&E uses to interconnect Customer-Generator’s Generating Facility. Customer-Generator’s Generating Facility is intended primarily to offset part or all of the Customer-Generator’s own electrical requirements. Consistent with, and in order to effectuate, the provisions of Sections 2827 of the California Public Utilities Code and PG&E’s electric rate Schedule NEM2 (NEM2), Parties enter into this Agreement. This Agreement applies to the Customer-Generator’s Generating Facilities identified below with the specified characteristics and generating capacity, and does not allow interconnection or operation of facilities different than those described.

2. SUMMARY AND DESCRIPTION OF CUSTOMER-GENERATOR’S GENERATING FACILITY AND DESIGNATION OF OTHERWISE-APPLICABLE RATE SCHEDULE

2.1 A description of the Generating Facility, including a summary of its significant components, and a single-line diagram showing the general arrangement of how Customer-Generator’s Generating Facility and loads are interconnected with PG&E’s Electric System, is attached to and made a part of this Agreement. (This description is supplied by Customer-Generator as Appendix A).

2.2 Generating Facility identification number: _____ (Assigned by PG&E).

¹ Additional forms are available on PG&E’s website at <http://www.pge.com/gen>).

† Information collected on this form is used in accordance with PG&E’s Privacy Policy. The Privacy Policy is available at pge.com/privacy.



**INTERCONNECTION AGREEMENT FOR
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FACILITIES OF 30 KW OR LESS, AND VIRTUAL NET
ENERGY METERING (NEM2V) OF A RENEWABLE
ELECTRIC GENERATING FACILITY OF 1,000 KW OR
LESS**

2.3 Customer-Generator's electric service agreement ID number: _____
(Assigned by PG&E).

2.4 Name and address used by PG&E to locate the electric service account used to interconnect the Generating Facility with PG&E's Electric System:

Name: _____

Address: _____

City/Zip Code: _____

2.5 The Gross Nameplate Rating of the Generating Facility: _____ kW.

2.6 The Net Nameplate Rating of the Generating Facility: _____ kW.

2.7 The expected annual energy production of the Generating Facility is _____ kWh.

2.8 Customer-Generator's otherwise-applicable rate schedule as of the execution of this Agreement is _____.

2.9 The Generating Facility's expected date of Initial Operation is _____.
The expected date of Initial Operation shall be within two years of the date of this Agreement.

2.10 Smart Inverters - For Customer-Generator applications received on or after September 9, 2017, the Customer-Generator certifies that their inverter-based Generating Facilities fully comply with Section Hh of Rule 21, including configuration of protective settings and default settings, in accordance with the specifications therein.

Distribution Provider may require a field verification of the Customer-Generator's inverter. Customer-Generator further agrees to cooperate fully with any such request and make their inverter available to the Distribution Provider for such verification. Customer-Generator understands that in the event the inverter is not set in accordance with Section Hh of Rule 21, Customer-Generator will need to cease operation of generating facility until verification is confirmed by Distribution Provider.

(Solar inverter models and firmware versions that comply with Rule 21 Section Hh can be found at <https://www.energy.ca.gov/programs-and-topics/topics/renewable-energy/solar-equipment-lists>.)

Verification of compliance with such requirements shall be provided by the Customer-Generator upon request by PG&E in accordance with PG&E's Electric Rule 21.

An "existing inverter" is defined as an inverter that is a component of an existing Generating Facility that meets one or more of the following conditions:

- (a) it is already approved by PG&E for interconnection prior to September 9, 2017
- (b) the Customer-Generator has submitted the interconnection application prior to September 9, 2017,
- (c) the Customer-Generator provides evidence of having applied for an electrical permit for the Generating Facility installation that is dated prior to September 9,



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LESS**

2017 and submitted a complete interconnection application² no later than March 31, 2018, or

(d) the Customer-Generator provides evidence of a final inspection clearance from the governmental authority having jurisdiction over the Generating Facility prior to September 9, 2017.

All “existing inverters” are not required to be Smart Inverters and are only subject to Section H of Rule 21. Customer-Generator replacing an “existing inverter” certifies it is being replaced with either:

- (i) inverter equipment that complies with Section Hh of Rule 21, (encouraged); or
- (ii) a conventional inverter that is of the same size and equivalent ability to that of the inverter being replaced, as allowed in Rule 21 Section H.3.d.ii.

3. DOCUMENTS INCLUDED AND DEFINED TERMS

3.1 This Agreement includes the following exhibits that are specifically incorporated herein and made a part of this Agreement.

- Appendix A Description of Generating Facility and Single-Line Diagram (Supplied by Customer-Generator).
- Appendix B *A Copy of PG&E’s Agreement for Installation or Allocation of Special Facilities (Forms 79-255, 79-280, 79-702) or Agreements to Perform Any Tariff Related Work (62-4527), if applicable (Formed by the Parties).*
- Appendix C Schedule NEM2 / NEM2V Customer-Generator Warranty That it Meets the Requirements for an Eligible Customer-Generator and Is an Eligible Renewable Electrical Generation Facility Pursuant to Section 2827 of the California Public Utilities Code (if applicable).
- Appendix D NEM2 Load Aggregation Customer-Generator Declaration Warranting NEM2 Aggregation Is Located On Same or Adjacent or Contiguous Property to Generator Parcel (if applicable)
- Appendix E Customer-Generator Affidavit Warranting That NEM2V Arrangement Is Sized to Load (if applicable)
- Appendix F NEMV, NEM2V, Storage (if applicable)

² A complete application consists all of the following without deficiencies:

- 1. A completed Interconnection Application including all supporting documents and required payments, (continued next page)
- 2. A completed signed Interconnection Agreement,
- 3. Evidence of the Customer-Generator final inspection clearance from the governmental authority having jurisdiction over the generating system.



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ENERGY METERING (NEM2V) OF A RENEWABLE
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LESS**

Appendix G Operating Requirements for Energy Storage Device(s) (when applicable)

In addition, PG&E Electric Tariff Rules and Rates, including but not limited to Electric Rules 2, 14, 15, 16, and 21, Schedule NEM2 (if applicable), Schedule NEM2V (if applicable) and Customer-Generator's otherwise-applicable rate schedule, available at PG&E's website at www.pge.com or by request, are specifically incorporated herein and made part of this Agreement.

- 3.2 When initially capitalized, whether in the singular or in the plural, the terms used herein shall have the meanings assigned to them either in this Agreement or in PG&E's Electric Rule 21, Section C.

4. TERM AND TERMINATION

- 4.1 This Agreement shall become effective as of the last date entered in Section 20 below. The Agreement shall continue in full force and effect until the earliest date that one of the following events occurs:
- (a) The Parties agree in writing to terminate the Agreement.
 - (b) Unless otherwise agreed in writing by the Parties, at 12:01 A.M. on the day following the date the electric service account through which Customer-Generator's Generating Facility is interconnected to PG&E is closed or terminated.
 - (c) At 12:01 A.M. on the 61st day after Customer-Generator or PG&E provides written Notice pursuant to Section 10 below to the other Party of Customer-Generator's or PG&E's intent to terminate this Agreement.
- 4.2 Customer-Generator may elect to terminate this Agreement pursuant to the terms of Section 4.1(c) for any reason. PG&E may elect to terminate this Agreement pursuant to the terms of Section 4.1(c) for one or more of the following reasons:
- (a) A change in applicable rules, tariffs, or regulations, as approved or directed by the Commission, or a change in any local, state or federal law, statute or regulation, either of which materially alters or otherwise affects PG&E's ability or obligation to perform PG&E's duties under this Agreement; or,
 - (b) Customer-Generator fails to take all corrective actions specified in PG&E's Notice that Customer-Generator's Generating Facility is out of compliance with the terms of this Agreement within the time frame set forth in such Notice; or,
 - (c) Customer-Generator abandons the Generating Facility. PG&E shall deem the Generating Facility to be abandoned if PG&E determines, in its sole opinion, the Generating Facility is nonoperational and Customer-Generator does not provide a substantive response to PG&E Notice of its intent to terminate this Agreement as a result of Customer-Generator's apparent abandonment of the Generating Facility affirming Customer-Generator's intent and ability to continue to operate the Generating Facility; or,
 - (d) Customer-Generator's Generating Facility ceases to meet all applicable safety and performance standards set out in Section 5.



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LESS**

- 4.3 Notwithstanding any other provisions of this Agreement, PG&E shall have the right to unilaterally file with the Commission, pursuant to the Commission's rules and regulations, an application to terminate this Agreement.
- 4.4 Any agreements attached to and incorporated into this Agreement shall terminate concurrently with this Agreement unless the Parties have agreed otherwise in writing.

5. GENERATING FACILITY REQUIREMENTS

- 5.1 Customer-Generator's Generating Facility must meet all applicable safety and performance standards established by the National Electrical Code, the Institute of Electrical and Electronics Engineers, and accredited testing laboratories such as Underwriters Laboratories and, where applicable, rules of the Commission regarding safety and reliability including Rule 21.
- 5.2 Customer-Generator shall: (a) maintain the Generating Facility and Interconnection Facilities in a safe and prudent manner and in conformance with all applicable laws and regulations including, but not limited to, Section 5.1, and (b) obtain any governmental authorizations and permits required for the construction and operation of the Generating Facility and Interconnection Facilities. Customer-Generator shall reimburse PG&E for any and all losses, damages, claims, penalties, or liability it incurs as a result of Customer-Generator's failure to obtain or maintain any governmental authorizations and permits required for construction and operation of Customer-Generator's Generating Facility.
- 5.3 Customer-Generator shall not commence parallel operation of the Generating Facility until PG&E has provided express written approval. Such approval shall normally be provided no later than thirty (30) business days following PG&E's receipt of: (1) a completed *Rule 21 Generator Interconnection Application* (Form 79-1174-02), including all supporting documents and payments as described in the Application; (2) a signed and completed *INTERCONNECTION AGREEMENT FOR A NET ENERGY METERING (NEM2/NEM2V) OF A RENEWABLE ELECTRICAL GENERATION FACILITY OF 1,000 KW OR LESS, EXCEPT SOLAR OR WIND* (Form 79-XXXX-02); and (3) a copy of the Customer-Generator's final inspection clearance from the governmental authority having jurisdiction over the Generating Facility. Such approval shall not be unreasonably withheld. PG&E shall have the right to have representatives present at the Commissioning Test as defined in Rule 21. Customer-Generator shall notify PG&E at least five (5) business days prior to the initial testing.
- 5.4 In order to promote the safety and reliability of the customer Generating Facility, the applicant certifies that as a part of each interconnection request for NEM2, that all major solar system components are on the verified equipment list maintained by the California Energy Commission and certifies that other equipment, as determined by PG&E, has safety certification from a nationally recognized testing laboratory.
- 5.5 Applicant certifies as a part of each interconnection request for NEM2 that
 - (i) a warranty of at least 10 years has been provided on all equipment and on its installation, or
 - (ii) a 10-year service warranty or executed "agreement" has been provided ensuring proper maintenance and continued system performance.



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LESS**

5.6 Customers on this tariff must pay for the interconnection of their Generation Facilities as provided in Electric Rule 21, pursuant to Decision 16-01-044.

6. INTERCONNECTION FACILITIES

- 6.1 Customer-Generator and/or PG&E, as appropriate, shall provide Interconnection Facilities that adequately protect PG&E's Electric System, personnel, and other persons from damage or injury, which may be caused by the operation of Customer-Generator's Generating Facility.
- 6.2 Customer-Generator shall be solely responsible for the costs, design, purchase, construction, permitting, operation, and maintenance of the Interconnection Facilities that Customer-Generator owns.
- 6.3 If the provisions of PG&E's Electric Rule 21, or any other tariff or rule approved by the Commission, require PG&E to own and operate a portion of the Interconnection Facilities, Customer-Generator and PG&E shall promptly execute a Special Facilities Agreement that establishes and allocates responsibility for the design, installation, operation, maintenance, and ownership of the Interconnection Facilities. This Special Facilities Agreement shall be attached to and made a part of this Agreement as Appendix B.

7. LIMITATION OF LIABILITY

Each Party's liability to the other Party for any loss, cost, claim, injury, liability, or expense, including reasonable attorney's fees, relating to or arising from any act or omission in its performance of this agreement, shall be limited to the amount of direct damage actually incurred. In no event shall either Party be liable to the other Party for any indirect, special, consequential, or punitive damages of any kind whatsoever.

8. INSURANCE

- 8.1. Customer-Generator Facility is required to comply with standards and rules set forth in Section 5 and provide the following for insurance policies in place.
 - (a) For NEM2V Customer-Generators only, to the extent that Customer-Generator has currently in force property insurance and commercial general liability or personal liability insurance, Customer-Generator agrees that it will maintain such insurance in force for the duration of this Agreement in no less amounts than those currently in effect. Pacific Gas and Electric Company shall have the right to inspect or obtain a copy of the original policy or policies of insurance prior to commencing operation. As long as Customer-Generator meets the requirements of this Section 8.1(a), Customer-Generator shall not be required to purchase any additional liability insurance.

I have insurance. I hereby certify that there is presently insurance coverage in the amount of \$_____ for the Schedule NEM2V Generating Facility location.



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Insuring Company's Name: _____

Insurance Policy # _____

I do not have insurance. I hereby certify that there is presently \$0 (zero) dollars of insurance for the Schedule NEM2V Generating Facility location.

- 8.2. Customer-Generator shall furnish the required certificates and all endorsements to PG&E prior to Parallel Operation.
- 8.3. The certificate shall provide thirty (30) calendar days' written notice to PG&E prior to cancellation, termination, alteration, or material change of such insurance.
- 8.4. PG&E shall have the right to inspect or obtain a copy of the original policy or policies of insurance.

If at any time during this agreement the Customer-Generator fails to meet the requirements in Section 5, the following insurance shall apply:

Customer-Generator shall procure and maintain a commercial general liability insurance policy at least as broad as the Insurance Services Office (ISO) commercial general liability coverage "occurrence" form; or, if Customer-Generator is an individual, then liability coverage with respect to premises and use at least as broad as the ISO homeowners' or personal liability Insurance occurrence policy form, or substitute, providing equivalent coverage no less than the following limits, based on generator size:

- (a) Two million dollars (\$2,000,000) for each occurrence if the Gross Nameplate Rating of the Generating Facility is greater than one hundred (100) kW; or
- (b) One million dollars (\$1,000,000) for each occurrence if the Gross Nameplate Rating of the Generating Facility is greater than twenty (20) kW and less than or equal to one hundred (100) kW; or
- (c) Five hundred thousand dollars (\$500,000) for each occurrence if the Gross Nameplate Rating of the Generating Facility is twenty (20) kW or less;
- (d) Two hundred thousand dollars (\$200,000) for each occurrence if the Gross Nameplate Rating of the Generating Facility is ten (10) kW or less and the Generating Facility is connected to an account receiving residential service from PG&E.

The insurance shall, by endorsement:

- (a) Add PG&E as an additional insured;
- (b) State that coverage provided is primary and is not in excess to or contributing with any insurance or self-insurance maintained by PG&E.
- (c) Contain a severability of interest clause or cross-liability clause



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LESS**

- 8.5. If Customer-Generator's Generating Facility is connected to an account receiving residential service from PG&E and the requirement of Section 8.1 prevents Customer-Generator from obtaining the insurance required in this Section, then upon Customer-Generator's written Notice to PG&E in accordance with Section 10.1, the requirements of Section 8.1 may be waived.
- 8.6. Customer-Generator may self-insure with approval from PG&E. Evidence of an acceptable plan to self-insure, at least thirty (30) calendar days' prior to operations shall be submitted. Customer-Generators such as state agencies that self-insure under this section are exempt from Section 8.1.

If Customer-Generator ceases to self-insure to the level required hereunder, or if Customer-Generator is unable to provide continuing evidence of Customer-Generator's ability to self-insure, Customer-Generator agrees to immediately obtain the coverage required under agreement.

- 8.7. All required certificates, endorsements or letters of self-insurance shall be issued and submitted via email or mail to the following:

Pacific Gas and Electric Company
Attn: Electric Grid Interconnection – Contract Management
300 Lakeside Drive, Suite 210
Oakland, CA 94612
Email: EGContractMgmt@pge.com

9. INDEMNITY FOR FAILURE TO COMPLY WITH INSURANCE PROVISIONS

- 9.1 If Customer-Generator fails to comply with the insurance provisions of this Agreement, Customer-Generator shall, at its own cost, defend, save harmless and indemnify PG&E, its directors, officers, employees, agents, assignees, and successors in interest from and against any and all loss, liability, damage, claim, cost, charge, demand, or expense of any kind or nature (including attorney's fees and other costs of litigation) resulting from the death or injury to any person or damage to any property, including the personnel and property of the utility, to the extent that the utility would have been protected had Customer-Generator complied with all such insurance provisions. The inclusion of this Section 9.1 is not intended to create any expressed or implied right in Customer-Generator to elect not to provide any such required insurance.
- 9.2 The provisions of this Section 9 shall not be construed to relieve any insurer of its obligations to pay any insurance claims in accordance with the provisions of any valid insurance policy.



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10. NOTICES

10.1 Any written notice, demand, or request required or authorized in connection with this Agreement (Notice) shall be deemed properly given if delivered in person or sent by first class mail, postage prepaid, to the person specified below:

If to PG&E: Pacific Gas and Electric Company
Attention: Electric Grid Interconnection – Contract Management
300 Lakeside Drive, Suite 210
Oakland, CA 94612
Email: EGContractMgmt@pge.com

If to Customer-Generator:

Customer-Generator Name: _____
Address: _____
City: _____
Phone: (_____) _____
FAX:(_____) _____

10.2 A Party may change its address for Notices at any time by providing the other Party notice of the change in accordance with Section 10.1.

10.3 The Parties may also designate operating representatives to conduct the daily communications, which may be necessary or convenient for the administration of this Agreement. Such designations, including names, addresses, and phone numbers may be communicated or revised by one Party’s Notice to the other.

11. REVIEW OF RECORDS AND DATA

11.1 PG&E shall have the right to review and obtain copies of Customer-Generator’s operations and maintenance records, logs, or other information such as Generating Facility availability, maintenance outages, circuit breaker operation requiring manual reset, relay targets and unusual events pertaining to Customer-Generator’s Generating Facility or its interconnection to PG&E.

11.2 Customer-Generator authorizes to release to the California Energy Commission (CEC) information regarding Customer-Generator’s facility, including customer name and Generating Facility location, size, and operational characteristics, as requested from time to time pursuant to the CEC’s rules and regulations.

12. ASSIGNMENT

Customer-Generator shall not voluntarily assign its rights nor delegate its duties under this Agreement without PG&E’s written consent. Any assignment or delegation Customer-Generator makes without PG&E’s written consent shall not be valid. PG&E shall not unreasonably withhold its consent to Customer-Generator’s assignment of this Agreement.



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13. NON-WAIVER

None of the provisions of this Agreement shall be considered waived by a Party unless such waiver is given in writing. The failure of a Party to insist in any one or more instances upon strict performance of any of the provisions of this Agreement or to take advantage of any of its rights hereunder shall not be construed as a waiver of any such provisions or the relinquishment of any such rights for the future, but the same shall continue and remain in full force and effect.

14. DISPUTES

14.1 Dispute Resolution

Any dispute arising between the Parties regarding a Party's performance of its obligations under this Agreement or requirements related to the interconnection of the Generating Facility shall be resolved according to the procedures in Rule 21.

15. REVIEW OF RECORDS AND DATA

15.1 Applicable Tax Laws and Regulation

The Parties agree to follow all applicable tax laws and regulations, consistent with CPUC policy and Internal Revenue Service requirements.

15.2 Maintenance of Tax Status

Each Party shall cooperate with the other to maintain the other Party's tax status. Nothing in this Agreement is intended to adversely affect the Distribution Provider's tax exempt status with respect to the issuance of bonds including, but not limited to, local furnishing bonds

16. GOVERNING LAW, JURISDICTION OF COMMISSION, INCLUSION OF PG&E's TARIFF SCHEDULES AND RULES

16.1 This Agreement shall be interpreted, governed, and construed under the laws of the State of California as if executed and to be performed wholly within the State of California without giving effect to choice of law provisions that might apply to the law of a different jurisdiction.

16.2 This Agreement shall, at all times, be subject to such changes or modifications by the Commission as it may from time to time direct in the exercise of its jurisdiction.

16.3 The interconnection and services provided under this Agreement shall at all times be subject to the terms and conditions set forth in the Tariff Schedules and Rules applicable to the electric service provided by PG&E, which Tariff Schedules and Rules are hereby incorporated into this Agreement by this reference.

16.4 Notwithstanding any other provisions of this Agreement, PG&E shall have the right to unilaterally file with the Commission, pursuant to the Commission's rules and regulations, an application for change in rates, charges, classification, service, tariff or rule or any agreement relating thereto.



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17. CRD POWER CONTROL SYSTEM CERTIFICATION

When applicable, Customer-Generator confirms that the Renewable Electrical Generation Facility including Energy Storage over 10 kW that has received UL 1741 CRD for Power Control Systems (PCS) certification will comply with either No Grid Charge or No Storage Export as defined in Schedule NEM2.

18. AMENDMENT AND MODIFICATION

This Agreement can only be amended or modified in writing, signed by both Parties.

19. ENTIRE AGREEMENT

This Agreement, including any incorporated Tariff Schedules and Rules, contains the entire Agreement and understanding between the Parties, their agents, and employees as to the subject matter of this Agreement. Each party also represents that in entering into this Agreement, it has not relied on any promise, inducement, representation, warranty, agreement or other statement not set forth in this Agreement or in the incorporated Tariff Schedules and Rules.

20. SIGNATURES

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives. This Agreement is effective as of the last date set forth below.

<i>(Customer-Generator's Name)</i>	PACIFIC GAS AND ELECTRIC COMPANY
<i>(Signature)</i>	<i>(Signature)</i>
<i>(Print Name)</i>	<i>(Print Name)</i>
<i>(Title)</i>	<i>(Title)</i>
<i>(Date)</i>	<i>(Date)</i>



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APPENDIX A

DESCRIPTION OF GENERATING FACILITY
AND SINGLE-LINE DIAGRAM

(Provided by Customer-Generator)



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APPENDIX B (If Applicable)

Any Rule 2 or Rule 21 Agreements for the Installation or Allocation of
Special Facilities (Forms 79-255, 79-280, 79-702) or Agreements to
Perform Any Tariff Related Work (62-4527)
(Formed between the Parties)



February 9, 2024

John Morris, Project Manager
Mayers Memorial Hospital
PO Box 459 / 43563 Highway 299E
Fall River Mills, CA 96028
(530) 519-5041

Project Title: **Fall River RHC Tenant Improvement, Design Proposal**

John,

Aspen Street Architects is pleased to submit this proposal for professional design services related to a remodel within the Clinic Building on the Fall River campus to convert the business side to a rural health clinic (RHC).

It is understood that the building currently houses a PT clinic and business offices. The building is not currently OSHPD-3. The building was built circa 1986 as the new Medical Office Building. At some point portions were converted for the current uses. No major remodel has been completed, beyond typical maintenance. Approximately half of the building is currently utilized as business offices. This half is what the hospital is proposing for conversion to an RHC. The half would not include the original X-Ray room (current PT gym) that is central in the building.

Scope of Work:

Design services. Consultant to develop construction documents for the conversion of the business office area into an RHC. The program is to maximize exam room quantities, which per initial concept review was determined to be possible to obtain 2 exam rooms and a procedure room.

Area of remodel (approximately 1,300 square feet) will require OSHPD-3 certification. Project is to be submitted to local jurisdiction as an OSHPD-3 project.

Consultant includes mechanical/plumbing and electrical engineering. Scope assumes minor structural support for any new equipment anchorage support as needed. Engineers and Architect have previously made a site visit to obtain existing readily available as-built observations. Electrical assumes the existing electrical infrastructure is sufficient to accommodate these renovations. Mechanical assumes for regulatory compliance that the HVAC units serving the area of the work will be replaced with compliant units. All Title 24 required energy compliance forms are included in design scope.

No changes the building exterior are currently assumed, but can be included if required as additional services, such as site accessibility if required by local jurisdiction.

Interior design to utilize existing facility standards, and product/material requirements will be noted, with exact color/finish to be selected by Owner during construction.

Client standard accessories to be indicated were applicable, and any new medical equipment information to be provided by Client.

Automatic fire sprinkler and fire alarm to be provided by Client’s vendor if required. To be incorporated in to the design documents and coordinated by Consultant.

Client to provide required electrical load readings, air balances, existing building plans/reference drawings (previously received), etc., as may be required for design.

Consultant to make submittal to local jurisdiction for plan review and permitting.

Bidding services. Consultant to include responses to prospective general contractor questions during Client run bid period as needed. If Client requests Consultant run the bid process, this can be provided as additional services.

Construction Administrative (CA) services. Consultant to provide, as required by jurisdictional authority.

Typical CA services included, to assume participation in regular Owner/Architect/Contractor meetings (virtual), responding to RFIs and review of submittals, completion of required CA paperwork, and administration of changes. Any change due to unforeseen conditions, owner requested changes, or contractor requested changes can be handled as additional services as may be needed.

A three month construction period is assumed for generation of CA fee. If actual construction duration is in excess of this, additional services may be warranted.

One site visit in CA is assumed by architectural PM for punch-walk at substantial completion – additional visits can be provided as needed (additional fee may be warranted).

Client to pay all fees, including plan review, permitting, and bidding.

Fee Proposal

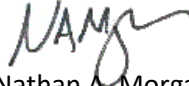
Consultant to proceed on a fixed fee basis for design as detailed in below chart, exclusive of reimbursable expenses, which will be billed per the attached rate schedule.

		design	agency review	con admin	subtotal
architectural	Aspen Street	\$ 23,100	\$ 3,960	\$ 10,560	\$ 37,620
subconsultants					
structural	Axiom	\$ 5,000		included	\$ 5,000
mechanical	NEXUS	\$ 8,100		\$ 900	\$ 9,000
electrical	Edge	\$ 10,500		\$ 5,000	\$ 15,500
subconsultant subtotal					\$ 29,500
consultant markup	15%				\$ 4,425
Total					\$ 71,545

This proposal is valid for the next 90 days. Please provide a written authorization to proceed with work if the above meets your approval.

Thank you for considering Aspen Street Architects for this project. We look forward to working with you.

Respectfully,

A handwritten signature in black ink, appearing to read 'N.A.M.', with a stylized flourish extending to the right.

Nathan A. Morgan
President



**Aspen Street Architects, Inc.
Rate Schedule**

Hourly Rates for Professional Personnel

Principal/Architect	240.00	Certified Access Specialist (CASp)	200.00
Senior Architect	230.00	Senior Planner	240.00
Architect IV	210.00	Facilities Manager	180.00
Architect III	180.00	Sr Project Manager	185.00
Architect II	160.00	Project Manager	165.00
Architect I	150.00		
Architect Intern II	145.00	Construction Contract Administrator	130.00
Architect Intern I	135.00	Project Administrator	100.00
Sr. Job Captain	135.00		
Job Captain	120.00		
Senior Production	120.00		
Production	105.00		

Consultants Fees Under Contract:

Billed per consultant's invoice, plus 15% coordination fee.

Reimbursable Expenses Not Included in Contract:

Engineering Xeroxes (white 24" x 36")	\$ 5.00/each
Engineering Xeroxes (white 30" x 42")	\$ 7.50/each
Color Printing (8.5"x11")	\$ 1.50/page
Color Printing (11"x17")	\$ 2.75/page
Photocopies	\$ 0.20/each
Data Disc	\$ 2.50/each
Report Binding	\$ 5.50/each

Miscellaneous reimbursable charges, including but not limited to, photographs, outside printing, maps, renderings, postage and freight will be billed at actual cost plus 15%. Travel expenses will be billed at actual cost plus 15%.

Clients will be billed monthly for services rendered. Payment is due upon receipt of invoice. Invoices which remain unpaid after thirty days are considered past due and subject to a service charge of 1.5% per month, which is an annual rate of 18%. If Client believes a billing error has occurred, or if Client requires additional information regarding an invoice, Client agrees to inform Aspen Street Architects in writing within ten days of invoice date. If Client does not inform Aspen Street Architects of any disputes within ten days, charges will be deemed correct.

The rates will remain in effect until December 31, 2024 and are subject to adjustment thereafter.

Chief Executive Officer
Ryan Harris



Board of Directors
Abe Hathaway, President
Jeanne Utterback, Vice President
Tami Humphry, Treasurer
Lester Cufaude, Director

Board of Directors
Quality Committee
Minutes

February 21, 2024 @ 4:30 PM
Microsoft Teams Meeting

These minutes are not intended to be a verbatim transcription of the proceedings and discussions associated with the business of the board's agenda; rather, what follows is a summary of the order of business and general nature of testimony, deliberations and action taken.

1	CALL MEETING TO ORDER: Les Cufaude called the meeting to order at 4:30 pm on the above date.		
	BOARD MEMBERS PRESENT:	STAFF PRESENT:	
	Les Cufaude, Director Tami Humphry, Director	Ryan Harris, CEO Jack Hathaway, Director of Quality Jessica DeCoito, Board Clerk	
	Excused ABSENT:		
2	CALL FOR REQUEST FROM THE AUDIENCE – PUBLIC COMMENTS OR TO SPEAK TO AGENDA ITEMS		
	None		
3	APPROVAL OF THE MINUTES		
	3.1	Regular Meeting – January 24, 2024	Harris, Cufaude Approved by All
4	HOSPITAL QUALITY COMMITTEE REPORT: the departments meet monthly to review measures that they feel are necessary to the success in their patient or resident care, efficiencies, etc. While these could be measures aligned with ACHC, some may not but are not discounted in their importance to the department.		
5	DIRECTOR OF QUALITY: Hired a consultant to help with ACHC Accreditation and she has been great so far. She has set weekly goals to meet. This committee also needs 9 to 11 measures to understand, measure and report on to the full board. These include medication theory, infection control, surgical/invasive and manipulative procedures, blood product usage, data management, discharge planning, utilization management, complaints, restraint/seclusion use and mortality review. The vision is that we provide you with dashboards and graphs and narratives on the measures. Add in Plan on Action or Correction into the charts for measures requiring it. First step in our ACHC accreditation process is to get our physical environment up to par, establish risk assessments for the areas of concern, and evaluate the construction/remodel projects for current use versus master planning. QIP program will be more transparent with our staff and board members. It has been made a priority to make everyone more aware of each measure, how to meet them, and what kind of funds we could receive for meeting those measures. Physicians and staff will be at the table to help pick out the quality measures and incentives will be applied to meeting those measures to get the buy in and dedication from staff. We will have a list of those measures for the next Quality meeting.		
6	9XMed Discussion: Company with remote patient monitoring. Previous discussions brought about a proposal that will be shared with the Physicians in a meeting next week. Essentially, MMHD would be a pilot program for 9XMed.		
7	OTHER INFORMATION/ANNOUNCEMENTS: Community complaints received by Board members with regards to referrals not being sent properly, and records requested not being sent. MMHD team will take these complaints will work on process improvements and submit tickets to Cerner for functionality fixes.		
8	MOVE INTO CLOSED SESSION		
	8.1	HEARING – (Health and Safety Code §32155) – Medical Staff Credentials Staff Status Change: Jody Crabtree, PA to Inactive Kyung Lee, NP to Inactive Christopher Louisell, MD to Inactive Julia Mooney, MD to Inactive	Approved by All

	Tommy Saborido, MD to Inactive Tyler Barr, MD to Inactive AHP Appointment Paula Amacker, NP – Oncology (Dignity) Medical Staff Appointment Ross Madeville, MD – Neurologist (Telemed2U) Galen Church, DO – Emergency Medicine	
9	RECONVENE OPEN SESSION	
10	ADJOURNMENT: at 5:36 pm Next Meeting is March 20, 2024 at 1:00 pm	

DRAFT

Public records which relate to any of the matters on this agenda (except Closed Session items), and which have been distributed to the members of the Board, are available for public inspection at the office of the Clerk to the Board of Directors, 43563 Highway 299 East, Fall River Mills CA 96028. This document and other Board of Directors documents are available online at www.mayersmemorial.com.

SUBJECT/TITLE: Ivenix SMART Infusion Pump Use	POLICY #MS071
DEPARTMENT/SCOPE: Acute Care	Page 1 of 3
	EFFECTIVE: 10/12/2023
OWNER: M. Padilla	APPROVER: T. Overton

DEFINITIONS:

Care Profile – A grouping of drugs typically administered in a specific clinical area.

Dose Error Reduction Software (DERS) - computer software to prevent programming errors and warn users of potential over- or under-delivery of a medication or fluid by comparing programmed rates with preset limits.

Drug Library - A list of drugs stored in the smart pump's memory with parameters such as concentration, infusion rate and maximum and minimum dosages.

Hard Limits – the upper hard limit (UHL) and lower hard limit (LHL) rates that cannot be overridden.

Soft Limits - the upper (USL) and lower (LSL) soft limit rates that can be overridden when specific conditions are met.

Medication Administration Record (MAR) - the record used for documenting medication administration.

Safer Medication Administration Through Technology (SMART) Pump – a large volume infusion device with safety.

POLICY:

1. Use of the SMART infusion pump drug library is required if the medication and appropriate concentration are programmed, unless otherwise stated within this policy.
2. Units have a default care profile specific to unit location; users administer fluids and medications within their scope of practice, and if adequately trained, consistent with Mayers Memorial Healthcare District (MMHD) policy.
3. When patients move to a different clinical area, the user in the receiving area updates the care profile.
4. SMART infusion pumps will remain “unlocked” as standard practice, therefore; a PIN is not indicated for individualized use. In circumstances that devices need to be “locked” to ensure safety of patient care, nursing staff can do so individually. A PIN is required to “unlock” the device once this setting is initiated. This PIN can be found in the SMART Pump Reference Guide located at each unit and in the following locations:
 - a. Acute Care Med Room
 - b. Emergency Room Nursing Station
 - c. Outpatient Medical Med Room
 - d. Outpatient Surgery Nurse Station or Dictation Room
5. Users administering parenteral fluid and medications utilize a SMART pump with DERS for:

SUBJECT/TITLE: Ivenix SMART Infusion Pump Use	POLICY #MS071
DEPARTMENT/SCOPE: Acute Care	Page 2 of 3
	EFFECTIVE: 10/12/2023
OWNER: M. Padilla	APPROVER: T. Overton

- a. Pediatric patients, with the exception of patients in the operating room, or in an emergent situation in which the clinician determines there is an imminent threat to patient safety if the pump is used.
 - b. High alert medications.
 - c. Titratable medications.
5. Occlusion Pressures
- a. Note that increasing occlusion pressures delays occlusion alarm
 - b. Adult occlusion pressures are set at 525 mm Hg for adults and are nonadjustable.
 - c. Pediatric occlusion pressures are set at 300 mm Hg.
 - i. Nursing staff members within the Emergency Department or Operating Room that are trained to adjust occlusion pressures when using the SMART infusion pump may adjust pediatric occlusion pressures based on the clinical situation.
6. When medication administration is programmed at a dose/rate outside of established drug library limits, the user takes the following actions based on a yellow/soft limit notification:
- a. Re-check the order.
 - b. Re-program the pump (if the user made a keystroke error).
 - c. If intending to proceed with administration, confirm the dose with the provider and document the rationale for the override in the MAR comments.
7. When medication administration is programmed at a dose/rate outside of established drug library limits, the user takes the following actions based on a red/hard limit notification:
- a. Re-check the order
 - b. Re-program the pump (if the user made a keystroke error).
 - c. Discuss the hard limit violation with the ordering provider
 - i. In non-critical care areas, select a dose that does not exceed hard limits.
 - ii. In critical care areas, if the provider confirms the dose that exceeds a hard limit, contact Pharmacy (on site or remote) before using the “no drug selected” option.
 - iii. Document the rationale for the override in the MAR comments.
8. For intermittent infusions, the user hangs a primary solution to ensure infusion of all medication (“Infuse to Empty”):
- a. Check compatibility with the primary solution; if compatible, use the secondary administration set and back prime from the primary infusion bag.
 - b. When a continuous primary infusion is not ordered, attach a 100cc NS bag as primary infusion.
 - i. If unavailable, utilize alternative fluid available on unit, ensuring compatibility
9. Initial and ongoing SMART pump education:
- a. Pharmacists complete required drug library training before creating drug library entries.
 - b. Users complete assigned online training and/or successfully complete the in-person competency prior to using SMART infusion pumps.
 - c. Department leaders may review smart infusion pump reports, address barriers to DERS use, and coordinate additional training support for users as needed.

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SUBJECT/TITLE: Ivenix SMART Infusion Pump Use	POLICY #MS071
DEPARTMENT/SCOPE: Acute Care	Page 3 of 3
	EFFECTIVE: 10/12/2023
OWNER: M. Padilla	APPROVER: T. Overton

10. SMART infusion pump drug library creation and updates
 - a. A pharmacist creates each drug library entry
 - b. A second pharmacist and a clinician review and document agreement with each drug entry, including drug name, dosing units, concentration, dose limits, and clinical alerts (if applicable).
 - c. A pharmacist updates the drug library as needed.
 - i. The Pharmacy & Therapeutics Committee evaluates and approves routine requests.
 - ii. Pharmacist collaborates with providers to make decisions regarding the need for urgent updates due to drug shortages or newly available medications requiring timely approval.
11. Trouble Shooting SMART infusion pumps
 - a. Follow troubleshooting prompts on screen
 - b. Refer to FAQ (Frequently Asked Question) Sheet, located on each unit and within department Teams groups
 - c. Request assistance from super user
 - d. Submit IT ticket
 - e. Users discontinue use of infusion pumps suspected of malfunctioning
12. Users refer to manufacture instructions for general use and cleaning/disinfecting information.
13. SMART infusion pumps remain on site and cannot be sent with patients transported to another facility.

REFERENCES:

1. Agency for Healthcare Research and Quality (2017). Safe Medication Administration: Oxytocin.
2. <https://www.ahrq.gov/hai/tools/perinatal-care/modules/strategies/medication/tool-safe-oxytocin.html>.
3. Bacon, O. & Hoffman, L. (2020). System-Level Patient Safety Practices that Aim to Reduce Medication Errors Associated with Infusion Pumps: An Evidence Review, *Journal of Patient Safety* 16 (3), S42-S47
4. Infusion Nurses’ Society (2021). Infusion therapies. *Journal of Infusion Nursing* 44(15), S180-S183.
5. Institute for Safe Medication Practices (ISMP). (2020). Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps. <https://www.ismp.org/mode/972>.
6. The Joint Commission Patient Safety Advisory Group. (2021). Sentinel Event Alert 63: Optimizing smart infusion pump safety with DERS. *The Joint Commission Journal on Quality and Patient Safety* 47: 394-397.

COMMITTEE APPROVALS:

M/P&T: 11/22/2023
 P&P: 1/3/2024
 MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE:	Swing Bed Criteria and Pre-Admission Processes	POLICY #SB008
DEPARTMENT/SCOPE:	Swing Bed	Page 1 of 6
		EFFECTIVE: 10/5/2023
OWNER: M. Padilla		APPROVER: T. Overton

DEFINITIONS:

Daily Skilled Care

(Medicare Benefits Manual Chapter 8, 30.7)

In determining whether the daily skilled care needed by an individual can, as a “practical matter,” only be provided in a SNF on an inpatient basis, the A/B MAC (A) considers the individual’s physical condition and the availability and feasibility of using more economical alternative facilities or services. As a “practical matter,” daily skilled services can be provided only in a SNF if they are not available on an outpatient basis in the area in which the individual resides or transportation to the closest facility would be:

- An excessive physical hardship;
- Less economical; or
- Less efficient or effective than an inpatient institutional setting.

The availability of capable and willing family or the feasibility of obtaining other assistance for the patient at home should be considered. Even though needed daily skilled services might be available on an outpatient or home care basis, as a practical matter, the care can be furnished only in the SNF if home care would be ineffective because the patient would have insufficient assistance at home to reside there safely.

Skilled Nursing and/or Skilled Rehabilitation Services

(Medicare Benefits Manual Chapter 8, 30.2)

Skilled nursing and/or skilled rehabilitation services are those services, furnished pursuant to physician orders, that:

- Require the skills of qualified technical or professional health personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech-language pathologists or audiologists; and
- Must be provided directly by or under the general supervision of these skilled nursing or skilled rehabilitation personnel to assure the safety of the patient and to achieve the medically desired result.
- NOTE: “General supervision” requires initial direction and periodic inspection of the actual activity. However, the supervisor need not always be physically present or on the premises when the assistant is performing services. Skilled care may be necessary to improve a patient’s current condition, to maintain the patient’s current condition, or to prevent or slow further deterioration of the patient’s condition.

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Swing Bed Criteria and Pre-Admission Processes	POLICY #SB008
DEPARTMENT/SCOPE: Swing Bed	Page 2 of 6
	EFFECTIVE: 10/5/2023
OWNER: M. Padilla	APPROVER: T. Overton

POLICY:

1. All potential Swing Bed admissions from Mayers Memorial Healthcare District (MMHD) will be reviewed in advance to ensure that they meet swing bed criteria and that patient needs can be met.
2. All potential Swing Bed admissions from MMHD will be provided a choice of Swing Bed or skilled nursing post-acute providers.

PROCEDURES:

A. Admission Criteria

1. The patient must be medically stable.
2. Medicare Benefits Manual Chapter 8 includes the following general criteria which must **all be met** for care of a Medicare patient in a skilled nursing facility (swing bed) to be covered:
 - a. The patient requires skilled nursing services or skilled rehabilitation services.
 - b. Skilled nursing or skilled rehabilitation services are ordered by a physician.
 - c. Services are for the treatment of condition for which the beneficiary was receiving inpatient hospital services (including services of an emergency hospital) or a condition which arose while in a Swing Bed or SNF for treatment of a condition for which the beneficiary was previously hospitalized. In this context, the applicable hospital condition need not have been the principal diagnosis that actually precipitated the beneficiary's admission to the hospital but could be any one of the conditions present during the qualifying patient stay.
 - d. Skilled nursing services or skilled rehabilitation services (or a combination of these services) must be needed and provided on a "daily basis," i.e., on essentially a 7-days-a-week basis. A patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the "daily basis" requirement when they need and receive those services on at least 5 days a week.
 - e. As a practical matter, considering economy and efficiency, the daily skilled services can be provided only on an inpatient basis in a skilled nursing facility.
 - f. The services delivered are reasonable and necessary for the treatment of a patient's illness or injury, i.e., are consistent with the nature and severity of the individual's illness or injury, the individual's particular medical needs, and accepted standards of medical practice. The services must also be reasonable in terms of duration and quantity.
3. Additional criteria included in the Medicare Benefits Manual Chapter 8 include:

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DEPARTMENT/SCOPE:	Swing Bed	Page 3 of 6
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OWNER:	M. Padilla	APPROVER: T. Overton

- a. The individual must have been an inpatient of a hospital for a medically necessary stay of at least three consecutive calendar days. The 3 consecutive calendar day stay requirement can be met by stays totaling 3 consecutive days in one or more hospitals. In determining whether the requirement has been met, the day of admission, but not the day of discharge, is counted as a hospital inpatient day. Time spent in observation or in the emergency room prior to (or in lieu of) an inpatient admission to the hospital does not count toward the 3-day qualifying inpatient hospital stay, as a person who appears at a hospital’s emergency room seeking examination or treatment or is placed on observation has not been admitted to the hospital as an inpatient; instead, the person receives outpatient services.
- b. The individual must have been transferred to a participating skilled nursing facility within 30 days after discharge from the hospital except as noted below:
- c. A direct admission from home, long term care, or assisted living can also occur with physician hold / deferred covered treatment, with an elapsed period of more than 30-days under certain circumstances. Such is permitted only for swing bed admissions where the patient’s condition makes it medically inappropriate to begin an active course of treatment immediately after hospital discharge, and it is medically predictable at the time of the hospital discharge that he or she will require covered care within a predetermined time period.
- d. To be covered, the extended care services must have been for the treatment of a condition for which the beneficiary was receiving inpatient hospital services (including services of an emergency hospital) or a condition which arose while in the SNF for treatment of a condition for which the beneficiary was previously hospitalized. In this context, the applicable hospital condition need not have been the principal diagnosis that actually precipitated the beneficiary’s admission to the hospital, but could be any one of the conditions present during the qualifying hospital stay

B. Hospital Specific Admission Limitations

- 1. No patient with a primary psychiatric or mental retardation diagnosis will be admitted.
- 2. No patient will be admitted with the following needs as it is beyond the Swing Bed services offered at MMHD.
 - Drug and Alcohol Treatment / Rehabilitation
 - Ventilator Dependent or Ventilator Weaning
 - Patients who require a blood transfusion and are in an unstable condition
 - Patients requiring dialysis
 - Patients requiring radiation therapy
 - Patients requiring chemotherapy

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SUBJECT/TITLE: Swing Bed Criteria and Pre-Admission Processes	POLICY #SB008
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- Prisoners
 - Patients under the age of 18
 - Patients with no clear discharge plan
 - Patients requesting occupational or speech therapy
3. Patients with secondary psychiatric or mental retardation diagnosis shall be evaluated on a case-by-case basis to determine if their needs can be met.
 4. External referrals of patients with a communicable disease or diagnosis will be evaluated on the basis of diagnosis type, specific care requirements, availability of correct room to manage isolation if needed and as directed by the hospital’s policy on communicable disease.
 5. External referrals will be considered for admission based on the program’s capability to meet their medical and rehabilitation needs but also on bed availability.
 6. Care Management will determine if a Preadmission Screening and Resident Review (PASARR) has been completed for the patient and if so, will review the PASARR to ensure services can be provided.

C. Pre-Admission – In-Patients at MMHD

1. Care Management or designee will review all potential admissions to determine if the patient meets admission criteria, if their needs can be met, and if there is a discharge plan.
2. The potential for Swing Bed will be identified, if possible, at the time of the acute care admission as part of discussions with the provider and the care management team.
3. Care Management will review the potential admission with appropriate disciplines, including the physician, nursing, rehabilitation, pharmacy, and dietary as appropriate, to ensure that patient needs can be met.
4. The physician will discuss and inform the patient and/or the patient’s representative of the reason for Swing Bed admission, the expected length of stay, and goals for discharge. The conversation with the patient and/or the patient’s representative will be documented in the medical record by the physician.
5. Before being admitted to Swing Bed, and if the patient meets the criteria for Swing Bed admission, the patient will be given a choice of skilled nursing options, including Skilled Nursing Facilities (SNF). To assist the patient or their representative in selecting a Post-Acute Care (PAC) provider, data on quality measures and resource use measures will be shared for all facilities within a **50 mile radius** of Mayers Memorial Healthcare District that offer skilled care including other swing bed programs. The data provided must be relevant and applicable to the patient’s goals of care and treatment preferences. The information provided and the patient’s choice will be documented in the medical record.
6. If at all possible, before being admitted to Swing Bed, Care Management will determine the patient’s choice of an attending physician. (See Policy Choice of

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Physicians) If this does not occur prior to admission, and the patient ultimately chooses a physician other than the physician who admitted the patient to Swing Bed, care will be transferred as soon as possible to the new physician.

7. If the patient chooses to receive Swing Bed Care at MMHD, Care Management will discuss admission with the patient or legal representative to ensure that they are aware of expectations and agree to the Swing Bed admission.
8. If the patient chooses to receive Swing Bed Care at MMHD, Care Management will request payor authorization for any payor other than traditional Medicare or Medicaid.
9. If the patient chooses to receive Swing Bed Care at MMHD, the provider will write a discharge order from acute and admission order to Swing Bed.

D. Pre-Admission – Patients admitted from another facility

1. Care Management or designee will review all potential admissions to determine if the patient meets admission criteria if their needs can be met and if there is a discharge plan.
2. Care Management will review the potential admission with appropriate disciplines, including the physician, nursing, rehabilitation, pharmacy, and dietary as appropriate, to ensure that patient needs can be met and that there is a discharge plan
3. If the patient meets the criteria for swing bed care, Care Management will determine if a physician with privileges at MMHD will accept the patient. Care Management will discuss the potential admission with the physician, including admission goals, and expected length of stay if this has not already occurred. Note: The patient has a right to choose the attending physician (See Policy *Admission Policy, Acute*). If the patient ultimately chooses a physician other than the physician who initially accepted the patient, care will be transferred as soon as possible to the new physician.
4. Care Management will request payor authorization for any payor other than traditional Medicare or Medicaid.
5. If possible, Care Management will discuss admission with the patient or legal representative prior to admission to ensure that they are aware of expectations and agree to the Swing Bed admission.

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SUBJECT/TITLE: Swing Bed Criteria and Pre-Admission Processes	POLICY #SB008
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OWNER: M. Padilla	APPROVER: T. Overton

REFERENCES

Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs (Rev. 200, 02-21-20) §483.20(b), §483.21(b), §485.642(a)(8),

Medicare Benefit Policy Manual Chapter 8 - Coverage of Extended Care (SNF) Services Under Hospital Insurance Table of Contents (Rev. 10880; Issued: 08-06-21)

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: ABO/RH Confirmation of Patient	POLICY #LAB4003
DEPARTMENT/SCOPE: Laboratory – Blood Bank	Page 1 of 1
	EFFECTIVE: 12/18/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

POLICY

In order to ensure patient safety, a second ABO/Rh test will be performed on a separate venipuncture on all patients without history requiring transfusion.

PROCEDURE

Once it has been determined that the patient does not have blood bank history, the LIS system will reflex ABO/Rh recheck after resulting the type and screen. If possible, a different phlebotomist should redraw the patient. One PINK EDTA specimen should be drawn and centrifuged for processing.

Surgery patients without previous blood bank history will be drawn at the time of surgery. The surgery physician or surgery nurse will enter the order in CERNER and phlebotomist/nurse will draw the patient. Outpatient requiring blood transfusion will be drawn one day before the transfusion for type and screen and ABO/Rh retype.

A prenatal type and screen does not require an ABO/Rh recheck unless the patient has a transfusion order.

In the event that ABO/Rh recheck does not agree with the first ABO/Rh determination, the patient will be redrawn and all testing will be repeated. Issue group O products accordingly until testing is complete. If plasma is requested, thaw and issue type AB.

For emergent situations, please refer to Emergency Release Protocol.

REFERENCES:

Association for the Advancement of Blood and Biotherapies, Technical Manual, 20th Edition.
Website: https://www.aabb.org/docs/default-source/default-document-library/publications/technical-manual-20th-edition-methods-and-appendices.docx?sfvrsn=8c9876fe_2 | Retrieved on 12/18/2023

COMMITTEE APPROVALS:

P&P: 1/3/2024
MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Age Specific Guidelines	POLICY #3022
DEPARTMENT/SCOPE: Laboratory - General	Page 1 of 2
	EFFECTIVE: 12/04/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

POLICY:

To provide the Clinical Laboratory Department personnel with essential information about normal growth and development of individuals from birth through late adulthood and to enable them to adapt their approach and performance appropriate to the patient’s development.

PROCEDURE:

- A. Age specific competency will be included as part of the employee’s orientation. Each new lab employee will review the information and complete the competency.
 - 1. Introduction to Growth and Development throughout the life span
 - 2. Outline of Age Specific Care Considerations
 - 3. Neonate/Infant considerations
 - 4. Child/Ped Considerations
 - 5. Adolescent considerations
 - 6. Adult considerations
 - 7. Geriatric considerations
- B. The age specific information will be reviewed annually at a designated department meeting. Each employee will receive the information and any questions will be addressed.
- C. Age Specific criteria are included on the annual competency.

Each laboratory staff must demonstrate the required knowledge and skills necessary to provide care appropriate to the age of the patients served. The staff must demonstrate knowledge of the principles of growth and development over the life span and possess the ability to assess data reflective of the patient’s status and interpret the appropriate information needed to identify each patient’s requirement relative to his/her age-specific needs, and to provide the care needed by the following patient group:

<u>Patient Group/Competencies</u>	Validation Methods: Do- Direct Observation V- Verbal	<u>Competency</u>	
		Sat	Unsat
A. Pediatric Patient			
- Does not leave the pediatric patient unattended during procedures.			

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SUBJECT/TITLE: Age Specific Guidelines	POLICY #3022
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- Is able to develop rapport with the child to reduce his/her apprehension.			
- Considers privacy of pediatric patient; allows adolescent the freedom to speak and provide input.			
- Demonstrates effective phlebotomy or skin puncture techniques appropriate for the patient.			
B. Adult Patient			
- Able to address patient’s question/s and concern/s in an informative manner.			
- Demonstrates effective phlebotomy or skin puncture techniques appropriate for the patient.			
C. Geriatric Patient			
- Addresses patient questions and concerns in an informative manner.			
- Considers losses such as sight and hearing when providing care.			
- Demonstrates effective phlebotomy or skin puncture techniques appropriate for the patient.			
Conducted By: _____ Date: _____	Staff Signature: _____		

REFERENCES

Center for Medicare and Medicaid Services, *CLIA Interpretive Guidelines for Laboratories* | Website: [cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines/laboratories](https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines/laboratories) | Retrieved on 12/04/2023

Centers for Medicare and Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA)* | website: www.cms.gov/regulations-and-guidance/legislation/clia/downloads/brochure7.pdf | Retrieved on 12/04/2023

COMMITTEE APPROVALS:

P&P: 1/17/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Automated HDL Cholesterol	POLICY# LAB1001
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 11/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The AHDL method is an in vitro diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** Lipoproteins are categorized into four types based on the relative proportions of their lipid and protein content: chylomicrons, very low-density lipoprotein (VLDL), low-density lipoprotein (LDL) and high-density lipoprotein (HDL). The primary function of HDL is to transport cholesterol from peripheral tissues to the liver where it is metabolized. This process, known as reverse cholesterol transport, has been proposed to be a cardiovascular protective mechanism. Patients with low levels of HDL are generally considered to be increased risk for coronary artery disease.

The determination of serum HDL cholesterol level is a useful tool in identifying at risk patients. The Adult Treatment Panel of the National Cholesterol Education Program (NCEP) recommends that all adults 20 years of age and older should have their cholesterol levels checked at every 5 years to screen for risk of coronary artery disease.

The reference method for measuring HDL cholesterol utilizes ultracentrifugation and chemical precipitation to separate HDL from the other lipoproteins, followed by determination using the Abbell-Kendall method. Since this method is tedious and requires ultracentrifuge, most of the laboratories now use methods which selectively measures HDL-C by chemical means.

- 2. Principles of Procedure:** The AHDL assay measures HDL cholesterol levels directly without the need for sample pretreatment or specialized centrifugation steps, using a two reagent format. First reaction, chylomicrons, VLDL and LDL form water soluble complexes with dextran sulfate in the presence of magnesium sulfate. These complexes are resistant to the polyethylene glycol (PEG)-modified cholesterol esterase and cholesterol oxidase that react with HDL cholesterol. In the presence of oxygen, the HDL cholesterol is oxidized to Δ^4 -

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SUBJECT/TITLE: Automated HDL Cholesterol	POLICY OR REFERENCE #
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cholestenone and hydrogen peroxide. The generated hydrogen peroxide then reacts with 4-aminoantipyrine and sodium N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (HSDA) in the presence of peroxidase to form a colored dye that is measured using a bichromatic (600/700 nm) endpoint technique. The dye's color intensity is directly proportional to the serum HDL-C concentration.

- 3. Specimen Collection and Handling:** Serum and plasma (lithium or sodium heparin). Serum and plasma should be collected after a 12-hour period of fasting using recommended procedures for collection of diagnostic blood specimens by venipuncture. Separated samples are stable for 8 hours at room temperature, 7 days refrigerated at 2-8°C. For longer storage, specimens may be frozen for 3 months at -70 °C.

4. Procedure:

4.1. Materials

AHDL Flex® reagent cartridge, Cat. No. DF48B
 AHDL Calibrator, Cat. No. DC48B
 Quality Control Materials

4.2. Test Steps

- 4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator's Guide.
- 4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

4.3. Test Conditions

Sample Volume	3 µL
Reagent 1 Volume	300 µL
Reagent 2 Volume	100 µL
Temperature	37.0 °C ± 0.1 °C
Reaction time	8.6 minutes
Wavelength	600 and 700 nm
Type of Measurement	Bichromatic end point

4.4. Calibration

The general calibration procedure is described in your Dimension® Operator's Guide.

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AHDL requires lot-specific scalers which must be entered in the Calibration Set Up screen, prior to calibration. The scaler values are provided on the Flex® reagent cartridge carton. These scalers are applied to all QC and patient results to maintain accuracy. Failure to enter the lot-specific scalers will cause inaccurate results.

The following information should be considered when calibrating the AHDL method:

Measurement Range	3 – 150 mg/dL [0.08 – 3.89 mmol/L]
Calibration Material	AHDL Calibrator, Cat. No. DC48B
Calibration Scheme	3 levels, n = 3
Units	mg/dL [mmol/L] (mg/dL x 0.0259) = [mmol/L]
Typical Calibration Levels	0, 40, 165 mg/dL [0.00, 1.04, 4.27 mmol/L]
Calibration Frequency	Every 90 days for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	C ₀ 0.000 C ₁ 1.700

4.5. Quality Control

Bio-Rad Liquid Assayed Multiqual two-levels controls are run once daily.

4.6. Results: The instrument calculates the concentration of AHDL in mg/dL (mmol/L) using calculation scheme.

Reference ranges are established and maintained in the LIS.

Reference Range: 40 – 60 mg/dL

Repeat all critical values as needed.

Critical Value: Not applicable.

4.7. Analytical Measurement Range (AMR): 3 – 150 mg/dL [0.08 – 3.89 mmol/L]

Samples with results above 150 mg/dL [3.89 mmol/L] are reported as “Above Assay Range” and should be repeated with dilution.

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SUBJECT/TITLE:	Automated HDL Cholesterol	POLICY OR REFERENCE #
DEPARTMENT/SCOPE:	Laboratory - Chemistry	1001
		EFFECTIVE: 11/15/2023
OWNER: Sophia Lou Rosal, CLS		APPROVER: Kevin Davie

Autodilution (AD): The recommended autodilute sample volume is 2 µL. Refer to Operator’s Guide for details.

Manual Dilution: Dilute with Reagent Grade water to obtain results within reportable range. Recommended dilution is 1:2. Enter dilution factor on the instrument. Reassay. Resulting readout is corrected for dilution.

Samples with results less than 3 mg/dL [0.08 mmol/L] should be reported as “less than 3 mg/dL [0.08 mmol/L]”.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors.

Venipuncture should occur prior to Metamizole (Sulpyrine) administration due to the potential for falsely depressed results.

A system malfunction may exist if the following five-test precision is observed:

AHDL Concentration	SD
45 mg/dL [1.17 mmol/L]	>1.4 mg/dL [0.04 mmol/L]
60 mg/dL [1.55 mmol/L]	>2.0 mg/dL [0.05 mmol/L]

Interfering substances:

Abnormal liver function may affect lipid metabolism; therefore, HDL cholesterol and LDL cholesterol results are of limited diagnostic value. In some patients with abnormal liver function, the HDL-C result may significantly differ from the designated comparison method (DCM) result.

In very rare cases, gammopathy, in particular type IgM (Waldenstrom’s macroglobulinemia), may cause unreliable results.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Automated LDL Cholesterol	POLICY #LAB1003
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 11/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The ALDL method is an in vitro diagnostic test for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum and plasma.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** LDL is the main cholesterol-containing particle in plasma. When present in excessive amounts, LDL-C can be deposited in the arterial wall resulting in atherosclerosis. Clinical studies have shown that the different lipoprotein classes have very distinct and varied effects on coronary artery disease (CAD) risk. Additionally, numerous studies all point to LDL cholesterol as a key factor in the development of atherosclerosis and CAD. For this reason, the Third Report of the National Cholesterol Education Program (NCEP) Expert panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III- ATP III) identified elevated LDL-C as the primary target of cholesterol-lowering therapy. As a result, the cutpoints for initiating treatment are stated in terms of LDL-C concentration.

Methods for LDL-C measurement assume that total cholesterol is composed primarily of cholesterol in VLDL, IDL, LDL, HDL and Lp(a). LDL-C can be measured using both indirect and direct methods. The Friedewald equation is the most frequently used indirect method for estimating LDL-C concentration. Using this equation, LDL-C concentration is calculated as follows:

$$[LDL -C] = [Total Chol] - [HDL Chol] - [Triglyceride]/5$$

All concentrations are in mg/dL. The factor [Triglyceride]/5 is an estimate of VLDL cholesterol concentration and is based on the average ratio of triglyceride to cholesterol in VLDL. In practice, the Friedewald calculation works reasonably well. However, it should not be used with samples that have triglyceride concentrations above 400 mg/dL, when chylomicrons are present (i.e., non-fasting specimens) or in patients with dysbetalipoproteinemia (Type III hyperlipoproteineimia). At high triglyceride concentrations, LDL-C concentrations are underestimated. Until recently the only means of consistently

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OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

measuring LDL-C concentrations accurately was to perform beta-quantification; an expensive, time consuming and labor intensive approach that most clinical laboratories are unable to perform. The Automated Low Density Lipoprotein (ALDL) method is a direct assay not dependent on the Freidewald calculation and is referenced to the beta-quantification determination of LDL-C concentration

- 2. Principles of Procedure:** The ALDL Cholesterol assay is a homogeneous method for directly measuring LDL-C levels in human serum or plasma, without the need for any off-line pretreatment or centrifugation steps.

The method is in a two reagent format and depends on the properties of detergent 1 which solubilizes only non- LDL particles. Cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. Detergent 2 solubilizes the remaining LDL particles. The soluble LDL-C is then oxidized by the action of cholesterol esterase and cholesterol oxidase forming cholestenone and hydrogen peroxide (H₂O₂). The enzymatic action of peroxidase on H₂ O₂ produces color in the presence of N,N-bis(4-sulfobutyl)-m-toluidine, disodium salt (DSBmT) and 4-aminoantipyrine (4-AA) that is measured using a bichromatic (540, 700 nm) endpoint technique. The color produced is directly proportional to the amount of LDL-C present in the sample.

- 3. Specimen Collection and Handling:** Recommended specimen types are Serum, EDTA-treated or heparinized (lithium or sodium heparin) plasma.

Blood should be collected after a 12-hour fast by normal procedures. Separated samples are stable for 3 days refrigerated at 2-8°C within 24 hours. For longer storage, specimens may be frozen at -20 °C for several weeks or at -70 °C or lower for longer periods.

4. Procedure:

4.1. Materials

- ALDL Flex® reagent cartridge, Cat. No. DF131
- ALDL Calibrator, Cat. No. DC131
- Quality Control Materials

4.2. Test Steps

- 4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.
- 4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

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4.3. Test Conditions

Sample Size	3 µL
Reagent 1 Volume	300 µL
Reagent 2 Volume	100 µL
Temperature	37 °C
Wavelength	540 and 700 nm
Type of Measurement	Bichromatic Endpoint

4.4. Calibration

Assay range	5 – 300 mg/dL [0.13 – 7.8 mmol/L]
Calibration Material	ALDL Calibrator, Cat. No. DC131
Calibration Scheme	3 Levels, n = 3
Units	mg/dL [mmol/L] (mg/dL x 0.0259) = [mmol/L]
Typical Calibration Levels	0, 130, 315 mg/dL [0, 3.4, 8.1 mmol/L]
Calibration Frequency	Every 90 days for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	C ₀ 1.44 C ₁ 0.98

4.5. Quality Control

Bio-Rad Liquid Assayed Multiquel two-levels controls are run once daily.

4.6. Results: The instrument calculates the concentration of LDL-C in mg/dL [mmol/L] using calculation scheme.

Reference ranges are established and maintained in the LIS.

Reference Range: 0 – 12 mg/dL

Repeat all critical values as needed.

Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 5 – 300 mg/dL [0.13 – 7.8 mmol/L]

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Samples with results above 300 mg/dL [7.8 mmol/L] are reported as “Above Assay Range” and should be repeated with dilution.

Autodilution (AD): If using the auto-dilution feature, results above 300 mg/dL [7.8 mmol/L] will automatically be repeated. The autodilution volume is 2 µL.

Manual Dilution: Make appropriate dilution with Reagent grade water to obtain result within the assay range. Enter dilution factor. Reassay. Resulting readout is corrected for dilution.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors.

A system malfunction may exist if the following 5 test precision is observed:

Concentration	S.D.
130 mg/dL [3.4 mmol/L]	>2.0 mg/dL [0.05 mmol/L]
315 mg/dL [8.1 mmol/L]	>5.0 mg/dL [0.13 mmol/L]

Interfering substances:

Bilirubin (unconjugated) of 80 mg/dL [1368 µmol/L]e will decrease an ALDL result of 124 mg/dL [3.2 mmol/L] by 10%.

Lipemia (Intralipid®) of 3000 mg/dL [33.9 mmol/L] will decrease an ALDL result of 122 mg/dL [3.2 mmol/L] by 19%.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

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SUBJECT/TITLE: Cholesterol	POLICY #LAB1011
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 12/14/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The CHOL method is an in vitro diagnostic test for the quantitative determination of total cholesterol in human serum and plasma.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** The CHOL method is based on the principle first described by Stadtman and later an adaptation by other workers, including Rautela and Liedtke. Lipids and lipoproteins in circulation have been strongly associated with coronary heart disease (CHD), associated lipid metabolism disorders, and atherosclerosis, a cause of CHD.
- 2. Principles of Procedure:** Cholesterol esterase (CE) catalyzes the hydrolysis of cholesterol esters to produce free cholesterol which, along with preexisting free cholesterol, is oxidized in a reaction catalyzed by cholesterol oxidase (CO) to form cholest-4-ene-3-one and hydrogen peroxide. In the presence of horseradish peroxidase (HPO), the hydrogen peroxide thus formed is used to oxidize N,N diethylanilineHCl/4-aminoantipyrine (DEA-HCl/AAP) to produce a chromophore that absorbs at 540 nm. The absorbance due to oxidized DEA-HCl/AAP is directly proportional to the total cholesterol concentration and is measured using a polychromatic (452, 540, 700 nm) endpoint technique.
- 3. Specimen Collection and Handling:** Recommended samples are serum and plasma. Separated samples are stable for 8 hours at room temperature, 2 days refrigerated at 2-8°C. For longer storage, specimens may be frozen at -20 °C or colder. Repeated freezing and thawing should be avoided.
- 4. Procedure:**
 - 4.1. Materials**
 - CHOL Flex® reagent cartridge, Cat. No. DF27
 - CHOL Calibrator, Cat. No. DC16
 - Quality Control Materials

4.2. Test Steps

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4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.

4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

4.3. Test Conditions

Sample Size	3 µL
Reagent 1 Volume	8 µL
Reagent 2 Volume	26 µL
Diluent Volume	241 µL
Temperature	37 °C
Wavelength	452, 540 and 700 nm
Type of Measurement	Polychromatic endpoint

4.4. Calibration

Assay Range	50 – 600 mg/dL [1.3 – 15.5 mmol/L]
Calibration Material	CHOL Calibrator (Cat. No. DC16)
Calibration Scheme	3 levels, n = 3
Units	mg/dL [mmol/L] (mg/dL x 0.0259) = [mmol/L]
Typical Calibration Levels	50, 250, 450 mg/dL [1.3, 6.5, 11.6 mmol/L]
Calibration Frequency	Every 3 months for any one lot Every new reagent cartridge lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	C ₀ 0.3162 C ₁ 0.7886

4.5. Quality Control

Bio-Rad Liquid Assayed Multiqual two-levels controls are run once daily.

4.6. Results: The instrument calculates the concentration of cholesterol in mg/dL [mmol/L] using calculation scheme.

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Reference ranges are established and maintained in the LIS.
Reference Range: <200 mg/dL

Repeat all critical values as needed.
Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 50 – 600 mg/dL [1.3 – 15.5 mmol/L]

Samples with results above 600 mg/dL [15.5 mmol/L] are reported as “Above Assay Range” and should be repeated with dilution.

Autodilution (AD): Refer to Operator’s Guide for details.

Manual Dilution: Make appropriate dilutions with Reagent grade water to obtain result within the assay range Enter dilution factor. Reassay. Resulting readout is corrected for dilution.

Samples with results less than 50 mg/dL [1.3 mmol/L] should be reported as “less than 50 mg/dL [1.3 mmol/L]”.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
220 mg/dL [5.7 mmol/L]	>5 mg/dL [0.13 mmol/L]
400 mg/dL [10.3 mmol/L]	>7 mg/dL [0.18 mmol/L]

Interfering substances:

Use of oxalated blood collection tubes for cholesterol testing is not recommended.

Li Heparin can depress cholesterol results by an average of 4 mg/dL [0.1 mmol/L] at a level of 200 mg/dL [5.2 mmol/L].

Icterus – falsely decreases results

Hemolysis (1000 mg/dL) – falsely decreases results

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Lipemia – tripped a test report message; therefore, the magnitude of the interference could not be determined.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

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SUBJECT/TITLE: Collection and Arm Band Policy	POLICY #LAB4019
DEPARTMENT/SCOPE: Laboratory – Blood Bank	Page 1 of 3
	EFFECTIVE: 12/21/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

POLICY

Staff completes a type and screen or blood product request when noting the physician order for a blood product. A staff member who has demonstrated competency in venipuncture will collect the specimen for blood bank.

The collection of a properly labeled blood sample from the correct patient is critical to safe blood transfusion. Strict guidelines are necessary to ensure that sample integrity is assured for every specimen which is submitted to Blood Bank for testing. Any sample that does not meet these requirements will be rejected.

The laboratory Blood Bank provides blood products for the management of patient therapy. Blood Bank personnel perform procedures that yield information indicating whether or not blood products can be transfused safely to the patient. For this reason, it is essential that all patients for a type and screen or type and crossmatch have a blood bank identification bracelet attached to their extremity at the time of specimen collection.

The Blood Bank ID bracelet will be used at the time of transfusion as a double check of the patient’s identification. No transfusion will be started unless the blood bank number on the blood product component bag and compatibility slip correspond with the number on the patient’s bracelet.

PROCEDURE

- a) Obtain written consent from the patient.
- b) A nurse is able to witness consents.
- c) If the patient does not wish to sign a ‘Consent for Blood Transfusion’ form, the physician will be notified and notification documented in the multidisciplinary progress notes.
- d) The physician will provide the patient with more information and discuss the impact of blood transfusion refusal on any treatments that will be provided.
- e) If the patient still does not wish to consent for transfusion, they will sign a form stating that they ‘Refuse to Permit Blood Transfusion’. A multidisciplinary note will be made to document these actions and the type and screen will not be obtained. When such a patient present for treatment, they will be treated as all other patients, except in relation to blood / blood component administration.
- f) Should a patient come to the hospital unconscious and there is no reasonable means of the hospital knowing that the patient would refuse blood / blood components, then appropriate life-saving action would be taken. However, if an

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unconscious patient is brought to the hospital and a relative informs the staff the patient would refuse transfusion, then the refusal form must be completed.

- g) In the case of a minor brought in by a parent or legal guardian who claims that the patient refuses to consent to the administration of blood/blood components to that minor, nursing personnel must contact administration and risk management immediately.
1. If the patient is conscious, ask the patient, “What is your name?” DO NOT ask the patient, “Are you John Doe?” Patients often answer “Yes” to any question. Another check is to ask the patient their birth date.
 2. Check the patient’s hospital armband, and verify that the name and birthdate of the patient given matches the information on the hospital armband.
 3. If the patient’s hospital armband is absent, staff must place an armband on the patient before proceeding.
 4. Compare the laboratory requisition labels with the patient’s hospital armband. Verify that the patient’s name, M.R. #, age and sex match.
 5. If the above DO NOT match, staff must resolve the discrepancy. DO NOT collect the specimens until the discrepancy is resolved and the patient is properly identified.
 6. If the above match, then collect one 6 ml EDTA pink top tube.
 7. After collecting the specimen and **STILL AT THE PATIENT’S SIDE:**
 - a. Fill out a blood bank identification bracelet with the following 5 items:
 - patient’s name
 - M.R. #
 - date of collection
 - time of collection
 - employee number of the person who drew the blood.

The spelling of the patient’s name (middle initial is optional) on the blood bank specimen **MUST BE IDENTICAL** to the spelling on the laboratory requisition and hospital identification band for the specimen to be acceptable. The first and last name must be complete.
 - b. Peel the white label off the bracelet and place it on the pink top tube.
 - c. Place the bracelet around the patient’s wrist, and firmly close the clip. Tightness of band should allow you to put 2 fingers underneath for patient comfort. Re-verify the patient name spelling and MR # against the hospital ID band and make sure the information is legible.
 - d. Snap off the remaining portion of the bracelet (number tail) and place it along with the tube of blood. Place in a biohazard plastic bag and deliver it to the laboratory.

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- e. The bracelet must be placed on the patient and **NOT ON THE PATIENT’S BED**. If the bracelet cannot be placed on either arm, then it should be attached to the patient’s ankle.

If for any reason (need to start IV, etc) the blood bank identification armband needs to be moved to another extremity, the **PATIENT’S NURSE** can carefully cut the band, making sure all patient information is still legible, and slip this band into a new clear plastic hospital admission band and reattach this to the desired extremity.

- 8. Patient Identification in an Emergency Situation:
 - a. In an emergency situation, when the patient’s identity is unknown, and/or the hospital admission armband is absent, use a blood bank identification bracelet to identify the patient.
 - b. Follow step 8 above. Record as much patient information as known on the bracelet.

PROCEDURE NOTES

UNACCEPTABLE SPECIMENS INCLUDE:

- 1. Spelling of Patient’s name, first or last, is not **IDENTICAL** on Blood Bank Specimen and Laboratory Requisition.
- 2. Patient’s M.R. number is not **IDENTICAL** on blood bank specimen and laboratory requisition.
- 3. Wrong specimen container used (i.e., gel tube)
- 4. Specimen is unlabeled.
- 5. Specimen is diluted with IV solutions.
- 6. Sample hemolysis, the only exception is if the only test ordered is an ABO/Rh.
- 7. Current specimen blood group does not match historical group and type.

REFERENCES

American Association of Blood Banks, *Technical Manual*, 20th Edition, 2020
 American Association of Blood Banks, *Standards of Blood Bank and Transfusion Services*, 28th Edition, 2019

COMMITTEE APPROVALS

P&P: 1/3/2024
 MEC: 2/8/2024

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SUBJECT/TITLE: Critical Values with Read Back	POLICY # 3028
DEPARTMENT/SCOPE: Laboratory - General	Page 1 of 6
	EFFECTIVE: 12/04/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

PURPOSE:

To assure the accurate and quick turnaround of critical laboratory results. Further, to assure that potentially life-threatening laboratory results are immediately conveyed to the ordering physician, or the nurse in charge of the patient.

POLICY:

1. The lab values in this policy are potentially life threatening; therefore, the physician or licensed healthcare provider will be **IMMEDIATELY** notified by the laboratory should a result fall outside the indicated ranges. “Immediately” shall mean the next reasonable moment that communication can be made without compromising the integrity of other tests or specimens, but no later than 30 minutes from the time of verification of result(s).
2. Notification will be made by telephone or direct contact. Electronic transmission (e.g. FAX, computer), or broadcast printing of results is not acceptable for this type of notification.
3. **Read Back Policy:** It is required that all verbal delivery of results must be verified by “read back” of the test result by the receiving person. Read back must be documented by the laboratory personnel in the Laboratory Information System (LIS) or in writing (i.e., “Called to _____, at (Time), read back by “Name”).
4. If the responsible Laboratory Person is unable to contact a licensed healthcare provider within 30 minutes, then contact the ED doctor with the result. That contact must be documented by the laboratory personnel in the LIS.

Failure to reach a licensed practitioner for an outpatient should be noted in the Lab Communication Log so the next Tech coming on can attempt to reach a practitioner to relay the results. Upon still failing to reach the outpatient provider, turn the result over to the ED for evaluation.

5. These procedures apply regardless of the test’s ordering priority (Stat, Timed, Routine, etc.).
6. Repetitive "critical value" results on known patients that are consistent with their clinical history (e.g., Oncology patients) will still be called.
7. If the ordering physician chooses not to be notified of repetitive or anticipated critical values, the physician must indicate the order in writing on the patient chart, and ALSO send it to the lab.

PROCEDURE:

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Repeat/verify all critical values:

1. Verify ID (unique identifier/number and name) of the original sample container.
2. Examine sample for adequacy of volume, anticoagulant, and any interfering substances (i.e., clot/fibrin in an EDTA or coagulation tube, hemolysis, lipemic specimen, etc).
3. Review test procedures to assure proper test methods were followed.
4. Repeat analysis on the same sample (new aliquot if possible).
5. If the repeat must be done on the same instrument, move to a different location on the instrument (different cup position).
6. If a problem with the specimen is suspected, redraw to confirm original test result(s).
7. Enter in the result comment area “Critical Value verified by repeat analysis.”

Result Reporting

1. Inpatient Results:
 - a. Call the physician/nurse assigned to that patient (1st choice) on the Inpatient Unit, Clinic, or ED where the patient is located. If the physician/nurse is not available the charge nurse is the second choice, if both are unavailable give the results to a staff nurse (RN or LVN).
 - b. When communicating results, use the term “critical value” so they will understand the importance of the call.
 - c. The person you contact should write down and “read back” the critical test result to you for verification. If the person fails to do this, ask them to read back the result before you hang up.
 - d. In the event no one can be contacted by phone, carry inpatient critical results to the requesting location and deliver the result to the nurse or nursing supervisor. Obtain the name of the nurse and time, and then document in the information system-Comments.
 - e. Document all actions in the LIS (or manual report copy during computer down times) stating who was called, time, the person making the notification, and that the read back was performed.

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2. Outpatient Results

- a. Call the provider's office and ask to speak to the physician.
- b. If he/she is not available, give the results to the nurse. You must give the results to a clinician or nurse. If given to a nurse, then instruct them to communicate the results to the physician ASAP.
- c. If it is after normal office hours, call the physician. Give the result to the provider or other responsible person, not an answering service.
- d. When communicating results, use the term “critical values” so they will understand the importance of the call.
- e. Ask the person you contact to write down and “read back” the critical test result to you for verification.
- f. Document all actions including attempts to contact in the comment area of the LIS (or manual report copy during computer down times).
- g. Document who was called, time, the person making the notification, and that “read back” was performed.

Procedural Notes:

1. If the Laboratory Tech is unable to contact a licensed healthcare provider, then the Emergency Room physician must be notified of the critical value.

Critical Value Reference Listing:

CHEMISTRY	UNITS	LESS THAN or EQUAL TO:	GREATER THAN or EQUAL TO:
Alcohol, Ethyl	mg/dl	N/A	250
Bilirubin, Total	mg/dl	N/A	6.0
Calcium, Serum	mg/dl	6.6 & Alb \geq 3.7	13
Creatinine	mg/dl	N/A	4.0
Glucose, Adult	mg/dl	45	500
Glucose, Newborn	mg/dl	30	200

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Lactic Acid	mg/dl	N/A	2.0
Magnesium	mg/dl	1.0	4.2
Potassium, Blood	mEq/L	2.5	6.5
Sodium	mEq/L	120	160
Troponin I	Mg/dl	N/A	0.50
HS Troponin I	ng/mL	N/A	0.100
HEMATOLOGY/COAG			
	UNITS	LESS THAN or EQUAL TO:	GREATER THAN or EQUAL TO:
APTT	Seconds	N/A	70 ≥120 <u>if on heparin</u> ≥
D-Dimer		N/A	600
Prothrombin Time (PT) INR	INR	N/A	5.0
Hematocrit (HCT), Adult	Percent	20	60
Hemoglobin (HGB), Adult	Grams	7.0	20
Platelets, on first Testing only	Per CUMM	40,000	1,000,000
WBC	/cmm	2,000	25,000
THERAPEUTIC DRUGS			
	UNITS	LESS THAN or EQUAL TO:	GREATER THAN or EQUAL TO:
Salicylate	mg/dl	N/A	30
Carbamazepine	ug/ml	N/A	20
Digoxin	ng/ml	N/A	2.5

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Theophylline	mcg/ml	N/A	25
Dilantin	mcg/ml	N/A	35
Valproic Acid	ng/ml	N/A	200
Vancomycin	ug/ml	N/A	80
Phenobarb	ug/ml	N/A	50
Gentamycin	ug/ml	N/A	10.0
Acetaminophen	ug/ml	N/A	150

- CSF- Growth or antigen positive
- CSF Glucose and Protein – Any Positive Result
- CSF Gram Stain- Organisms present
- Positive RSV- Children under 5 years’ old
- C. Diff- Positive (in-house only)
- MRSA positive screen and cultures
- Blood Cultures- All confirmed positives
- AFB - Any positive
- Positive Rapid Covid-19 result
- Blood Bank:
 - All initial positive antibody screens

PRE-OPERATIVE LAB WORK:

The ordering physician will be notified immediately if any of the following tests are outside prescribed limits on pre-operative lab work:

WBC	<3.0 or >15/mm³
Hemoglobin	<8.0 gm/dL
Potassium	<3.3 meq/L or >5.2 meq/L
Glucose	<50 mg/dL or >150 mg/dL
Prothrombin Time	>13 sec or INR >1.3
PTT	>35 seconds
Platelets	<100,000/mm³

- Any pre-operative pregnancy test that is positive.

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Note* Computer System Downtime Procedure:

- a. Document Notification/Read Back of critical value(s) on the patient instrument printout, or downtime form.
- b. When the computer system is operational enter the critical value(s) and attach the appropriate Critical Value message.
- c. Edit the critical value notification fields (date, time, etc.) to match that recorded on the instrument print-out or downtime form.

REFERENCES:

Tietz – 2018, 12th Edition, Chemistry
Bailey and Scott – 14th Edition, 2018
NCCLS Guidelines – 2016

COMMITTEE APPROVALS:

P&P: 1/17/2024
MEC: 2/8/2024

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SUBJECT/TITLE: Emergency Release of Blood	POLICY #LAB4006
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OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITIONS

Emergency Release of Uncrossmatched Red Blood Cells or other blood products (typically 2 units but up to 4 units). An order to the transfusion service for emergency release of red blood cell when a crossmatch is not available, and the provider determines that blood is needed for a potentially life threatening emergency. There is a one-time order so additional products will require notification to the blood bank.

PURPOSE

A patient’s physician may determine that it is more life threatening to the patient to withhold blood while waiting for the completion of compatibility testing than to give uncrossmatched or partially crossmatched blood.

When there is an urgent requirement of blood, it may be released uncrossmatched or partially crossmatched (crossmatch incomplete) at the request of the patient’s physician.

POLICY

It is the policy of Mayers Memorial Hospital to follow the guidelines of the American Association of Blood Bank’s Standards for Blood Bank and Transfusion Services and Guidelines for Massive Blood Transfusion.

In an emergency, the requesting physician must sign the “Emergency Request for Blood Form” to obtain the uncrossmatched or partially crossmatched blood for patient. Compatibility testing will be completed promptly and any abnormalities must be reported to the requesting physician.

PROCEDURE

For Emergency Release of Blood Products (typically 2 units, but up to 4 units)

1. Emergency Release will only be activated when initiated by a provider. Qualified staff can initiate a verbal order for emergency release on provider’s behalf, by calling the transfusion service.
2. An Electronic Health Record for emergency release should be entered as soon as time permits. Blood products will be provided once the verbal order is received.
3. Blood and blood product administration may be carried out by a provider/MD, registered Nurse/RN and a licensed Independent Practitioner/LIP. A licensed vocational nurse (LVN) may verify blood products for administration but cannot administer blood products.

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Activation

1. The provider determines that a massive hemorrhage or active bleeding is occurring and the orders, or provides designee with a verbal order, to initiate the Emergency Release. The transfusion service will be notified by phone, and downtime procedures will be followed until an EHR order can be entered when time permits.
2. The following information will be required:
 - a. Name and Medical record number of patient
 - b. Location of the Event
 - c. Designated contact and call back extension for ongoing communication.
 - d. Ordering Provider’s full name
3. Verification of information is confirmed by Read Back to caller.
4. Immediately draw and deliver a PINK top patient specimen to the transfusion service, Label per the Blood Bank identification protocol, ideally before transfusion of any Blood product(s) commences.

Administration

1. DO NOT use previous records to determine patient’s ABORh. Issue 2 “O negative packed cells only.
2. If patient is male or female > 50 years of age switch patient to O positive after 2 units. Female <50 years old must continue to receive O negative units until type is obtained.
3. Preparation of Emergency Release Units:
 - a. The day shift Blood Bank CLS will keep 2 O negative and 4 O positive confirmed on the appropriate shelf at all times. Utilize these units first by pulling segments and fill out the emergency release form.
 - b. If additional units are needed the CLS will need to pull segments, perform confirmatory testing and fill out the emergency release form.
4. The blood must be issued (signed out) according to standard procedure. See SOP “Issuing Blood Components”
5. Obtain a specimen for pre-transfusion testing as soon as possible if not already available.
6. Determine patient ABORh and perform antibody screen.
7. Switch patient to group and type specific blood as soon as possible.
8. Perform an antibody screen and crossmatches on blood which release uncrossmatched. Use segments from units which were set aside.
9. If unexpected antibodies or incompatible crossmatches are detected, notify the patient’s physician and the pathologist immediately. Asked the nurse to stop the transfusion if the incompatible unit is ongoing transfusion.

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REFERENCES:

AABB *Standards for Blood Banks and Transfusion Services*; current edition

Association for the Advancement of Blood and Biotherapies, *Technical Manual*, 20th Edition.

Website: https://www.aabb.org/docs/default-source/default-document-library/publications/technical-manual-20th-edition-methods-and-appendices.docx?sfvrsn=8c9876fe_2 | Retrieved on 12/18/2023

The Joint Commission *CAMLAB Manual* QSA.05.11.01, current edition

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

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SUBJECT/TITLE: Handling and Processing Specimens	POLICY # LAB3031
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POLICY:

To assure the accurate and quick handling of specimens submitted to the laboratory. Further, to assure that laboratory personnel are functioning according to standards. The following procedure must be followed when handling and processing specimens for lab work.

PROCEDURE:

1. All specimens received must be labeled with the patient's name, hospital number (MR#) and/or account #, patient location, date and time sample was collected, requesting physician, and phlebotomist's/collectors' initials.
2. If submitting a manual requisition slip the date and time received and collected shall be handwritten in the appropriate space. If submitted electronically, then all required information must be documented.
3. The specimen shall be taken to the processing area for further processing and/or distribution.
4. If submitted from outside the hospital and associated Clinic, the specimen shall be accessioned into the Lab Information System (LIS), or in case of LIS downtime, documented on the laboratory backup form, or results printed from lab instruments.
5. The specimen test(s) will be performed, and results approved in the computer or handwritten on the appropriate result form and sent to the floor, clinic or office either according to prearranged times throughout the day, or as the results are verified. In case of LIS downtime, results will be recorded on the appropriate backup report form(s). Refer to the following for how to handle manually documented results.
 - a. The Tech shall initial the form.
 - b. The report form shall have the completion date/time documented on it.
 - c. A copy of the results will be kept in the laboratory so that the results can be entered into the LIS when it comes back up.
 - d. The report form is ready for distribution.

SPECIAL CONSIDERATION:

The lab will not process a blood sample transported by a patient.

COMMITTEE APPROVALS:

P&P: 2/7/2024

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PURPOSE:

To assure that lab environment is a safe, environmentally friendly environment for lab personnel to work in. Further, to ensure that laboratory personnel are functioning according to standards.

POLICY:

1. The laboratory environment is conducive to the optimal performance of personnel and equipment.
2. The ventilation system provides an adequate amount of fresh air and can remove toxic and noxious fumes.
3. There is adequate, conveniently located bench space for the efficient handling of specimens and for the housing of equipment and reagents.
4. Work areas are arranged to minimize problems in transportation and communication, and are adequately lighted to facilitate accuracy and precision.
5. There are a sufficient number of properly located utilities.
6. Musculoskeletal Disorders (MSDs): Employees are proctored, and systems reviewed in relation to risk factors, identification of physical work activities or conditions of the job commonly associated with work-related MSDs, and recommendations for eliminating MSDs. Proper ergonomics for all sections of the laboratory are reviewed and corrected as needed to assure a safe, ergonomically correct work environment.
7. Noise levels are kept to a minimum level to meet regulatory requirements.

Personal Practices

- To help prevent skin contact with corrosive, toxic, or hot liquids, laboratory protective clothing should cover your arms, main torso, legs, and feet. Do not wear tank tops, crop
- tops, shorts, ripped jeans, sandals, or open-toe shoes in the lab.
- Do not allow children or pets in laboratories.
- Never mouth pipette anything.
- Be aware of dangling jewelry, loose clothing, or long hair that might get caught in equipment.
- Designate and use non-lab areas for eating and drinking.
- Chemical/biological refrigerators and storage areas are not to be used to hold or consume food and drinks.
- Use lab coats, gloves, and other personal protective clothing safely in the lab.
- Never work alone in the lab if avoidable. If you must, make someone aware of your location so they can check on you periodically.

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- Wash your hands frequently for at least 15-30 seconds throughout the day and before leaving the lab.
- Caution is always advised when wearing contact lenses in a lab. Chemical liquids and vapors can get behind or penetrate the plastic lens where water cannot wash the eye, causing severe damage. It is recommended to wear eye protection when working with liquid chemicals and wearing contact lenses.

Housekeeping

- Clean your work area throughout the day and before you leave at the end of the day. It is necessary a minimum of 15-minute contact time of a disinfectant with the surface to properly decontaminate the working area.
- Clean (if necessary) equipment after use to avoid contaminating the next person who needs to use it. The use of an equipment log can help to monitor the proper cleaning and maintenance of equipment.
- Keep all aisles and walkways in the lab clear to provide a safe walking surface and an unobstructed exit.
- Any laboratory equipment that needs to be surplused or sent for calibration/maintenance, must be properly decontaminated, and have a decontamination form.

Laboratory Techniques and Procedures

Glasswares

1. Inspect all glassware before use. Repair or discard any broken, cracked, or chipped glassware in labeled-appropriate containers.
2. Tape or shield glass vacuum vessels to prevent flying glass in the case of an implosion. Also, tape or shield glass vacuum desiccators.
3. Do not use household Thermos bottles as a substitute for laboratory Dewar flasks; the walls are too thin.
4. Transport all glass chemical containers in secondary containers such as rubber or polyethylene bottle carriers.
5. Fire polish all cut glass tubing and rods before use.
6. Practice the following when inserting glass tubes or rods into stoppers:
 - a. the diameter of the tube must be compatible with the diameter of the stopper,
 - b. fire polish the end of the glass tube,
 - c. lubricate the glass with water or glycerol,
 - d. wear heavy gloves and hold the glass no more than two inches from the end to be inserted,
 - e. insert the glass carefully with a twisting motion, and
 - f. remove stuck tubes by slitting the stopper with a sharp knife.

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Assembling Apparatus

1. Keep work surfaces as uncluttered as possible.
2. Setup clean, dry apparatus, firmly clamped and away from the edge of the lab bench.
3. Use only equipment free from cracks, chips, or other defects.
4. Place a pan if possible, under a reaction vessel or other container to contain liquid if the glassware breaks.
5. Do not use burners or any other ignition sources nearby when working with flammable liquids.
6. Lubricate glass stopcocks.
7. Support and secure condensers and water hoses with clamps and wires. Be sure to direct the water hoses so that any drips from the hoses do not splash onto electrical wires or apparatus.
8. Position items that are attached to a ring stand so that the center of gravity is over the base and not to one side.
9. Assemble apparatus so burners or baths can be removed quickly.
10. Use a vapor trap and confine the setup to a fumehood if there is a possibility of hazardous vapors being released.
11. Put the setup inside a fumehood whenever conducting a reaction that could result in an implosion or explosion.
12. Always wear a lab coat, gloves, and proper eye and face protection.

Centrifuges

1. Anchor tabletop centrifuges and place them where the vibration will not cause bottles to fall off the bench.
2. Always close the centrifuge lid while operating and stay with the centrifuge until it is running safely without vibration.
3. If vibration occurs, stop the centrifuge, and check the load balances.
4. Regularly clean rotors and buckets with a non-corrosive cleaning solution.
5. Use sealed safety cups while centrifuging hazardous materials.

Electrical

1. Adequate electrical outlets should be provided in the lab to prevent circuit overloading. Examine all electrical cords periodically for signs of wear and damage. If damaged electrical cords are discovered, unplug the equipment, and send it off for repair.
2. All equipment must be properly grounded.
3. If sparks are noticed while connecting electric equipment or if the cord feels hot, do not use this equipment until it can be serviced by an electrician.
4. Do not run electrical cords along the floor where they will be a tripping hazard and be subject to wear. If a cord must be run along the floor, protect it with a cord cover.
5. Do not run electrical cords above the ceiling. The cord must be visible at all times to ensure it is in good condition.

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6. Do not plug too many items into a single outlet. Cords that enable you to plug more than one item in at a time should not be used. Multi-plug strips can be used if they are protected with a circuit breaker and if they are not over-used.
7. Do not use extension cords for permanent wiring. If you find that you must use extension cords all over the lab then it may be time to have additional outlets installed.

Food And Drinks In The Laboratory

To avoid ingestion of hazardous chemicals, follow these five guidelines to ensure your personal safety and that of the students as adopted from the National Research Council in Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards (6.C.2.3).

1. Eating, drinking, smoking, gum chewing, applying cosmetics, and taking medicine in laboratories where hazardous chemicals are used is NOT allowed.
2. Food, beverages, cups, and other drinking and eating utensils should not be stored in areas where hazardous chemicals are handled or stored. Also, cups, plates, and utensils for personal use should NOT be washed in sinks where chemical hazards can be found.
3. Glassware used for laboratory operations should never be used to prepare or consume food or beverages. Laboratory refrigerators, ice chests, cold rooms, incubator and so forth should not be used for food storage or preparation and should be labeled appropriately.
4. Laboratory water sources and deionized laboratory water should NOT be used as drinking water.
5. Never wear gloves or laboratory coats outside the laboratory or into areas where food is stored and consumed, and always wash laboratory apparel separately from personal clothing.

Personal Protective Clothing

The most important thing to remember about protective clothing is that it only protects you if you wear it. Safety Data Sheets (SDS) or EH&S should be consulted for information on the type of protective clothing that is best for the particular work you are performing. Tank tops, shorts, ripped jeans, sleeveless shirts, crop tops, flip flops, sandals, and open-toed shoes are not appropriate for the lab and are not allowed.

Protective Eyewear

1. Goggles provide the best all-around protection against chemical splashes, vapors, specks of dust, and mist.
2. Goggles that have indirect vents or are non-vented provide the most protection, but an anti-fog agent may be needed.
3. Standard safety glasses provide some protection against impact.

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Note: Prescription glasses do not provide adequate protection in a laboratory setting.

4. Prescription safety glasses can be purchased from most opticians, but again, solely protect against impact.
5. Contact lenses are not allowed for use in a lab because they can trap contaminants under them and reduce or eliminate the effectiveness of flushing with water from an eyewash.

Contact lenses may also increase the amount of chemicals trapped on the surface of the eye which otherwise might be removed by tears. If it is necessary to wear contact lenses in a lab, wear protective goggles at all times when using contact lenses.

Protective Gloves

1. Any glove can be permeated by chemicals. The rate at which this occurs depends on the composition of the glove, the chemicals present, their concentration, and the exposure time to the glove. This is why it is important to replace your gloves frequently throughout the day. Also, wash your hands regularly and remove gloves before answering the telephone or opening the door to prevent the spread of contamination.
2. Check gloves for cracks, tears, and holes before and during using them for lab work.
3. Butyl, neoprene, and nitrile gloves are resistant to most chemicals, e.g., alcohols, aldehydes, ketones, most inorganic acids, and most caustics.
4. Disposable latex and vinyl gloves protect against some chemicals, mostly aqueous solutions, and microorganisms as well as reduce the risk of product contamination.
5. Leather and other gloves will protect against cuts, abrasions, heat, and scratches, but do not protect against chemicals. These gloves are more appropriate for workshop use.
6. Temperature resistant gloves protect against cryogenic liquids, flames, and high temperatures.

Other Protective Clothing

1. There are many types of lab coats available. The primary purpose of a lab coat is to protect against splashes and spills. Lab coats should be nonflammable and be easily removed.
2. Lab coats must be worn in the laboratory when working with hazardous chemicals, infectious agents, radioactive materials, or other potentially hazardous materials.
3. Lab coats must not be worn in areas such as offices, lunch rooms, or other areas where potentially hazardous materials are not normally found.
4. Rubber coated aprons can be worn to protect against chemical splashes and may be worn over or under a lab coat for additional protection.
5. Face shields can protect against impact, dust, particulate, and chemical splashes on the face, eyes, and throat. However, always wear protective eyewear--such as goggles--

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underneath a face shield because a face shield only offers additional protection to the eyes. Chemical vapors and splashes can still travel under and around a face shield. If scratches or cracks are noticed in the face shield, replace the window.

Pregnancy And Other Health Risks

Laboratory personnel who are pregnant or have other health concerns may voluntarily contact HR for consultation and evaluation in reference to laboratory risks. Pregnant laboratory personnel should consult their physician for advice on whether or not to perform experiments in the laboratory. It is encouraged that treating physicians be provided with a list of the chemicals that might be a source of exposure while in the lab. One should also check the Safety Data Sheets to be aware of the hazards of the chemicals.

Evacuation Procedures

The following procedures and information are important in the event it is necessary to evacuate a laboratory.

1. Building evacuation may be necessary if there is a chemical release, explosion, natural disaster, or medical emergency.
2. Be aware of the marked exits in your area and building.
3. The evacuation alarm is a loud continuous siren or horn.
4. To activate the building alarm system, pull the handle on one of the red boxes located in the hallway. If there is a fire, call 1500 or 911. Remember to give your location and the location and size of the fire. The laboratory has an emergency exit door near Chemistry area. The doors can be pushed open to allow occupants to leave.
5. Whenever the building evacuation alarm is sounded or when you are told to leave emergency response personnel, walk quickly to the nearest marked exit and ask others to do the same.
6. Outside, proceed to a clear area that is at least 100 yards from the building. Keep walkways clear for emergency vehicles.
7. To the best of your ability and without re-entering the building, be available to assist emergency response personnel and police in their attempts to determine that everyone has been evacuated safely.
8. An Emergency Command Post may be set up near the emergency site by emergency responders. Keep clear of the Post unless you have important information to render.
9. Do not return to the building until you are told to do so by the police or by emergency response personnel.

Emergency Equipment

Know the location and how to use the emergency equipment in the laboratory (fire extinguisher, safety shower, etc.). In the event of an emergency asking someone to locate the emergency equipment or reading the instructions on how to use it may not be possible. Also, eye injuries may require finding emergency equipment without being able to see. To help

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locate and identify this equipment for emergencies, all emergency equipment should be marked with prominent signs. The following are recommendations on emergency equipment:

Emergency Showers

1. An emergency shower may be used to suppress a fire or more commonly to decontaminate a person who has been exposed to chemicals.
2. Remove all clothing, jewelry, and shoes while standing under the shower. If these items are not removed, they will hold the chemicals against the skin and increase the damage.
3. Remain under the shower for at least 15 minutes, then seek medical attention.
4. Always keep the area under an emergency shower unobstructed. You do not want to waste time moving boxes, tables, or other items. Electrical equipment in the area can also present an electrocution hazard.
5. Do not remove, tie, or secure the handle or ring of the shower if it interferes with the operation of the shower.
6. Safety Showers are tested annually by the maintenance facility department.

Eyewashes

1. To ensure a clean supply of water in the eyewash, it should be operated regularly (weekly) to flush any impurities that may accumulate. Flush the unit for 5 min every week and document it on the eyewash log for proper maintenance. If the unit has low pressure or hot water, please report it to Maintenance Department.
2. Never hesitate to flush your eyes immediately if chemicals are splashed in them. A delay of seconds could cause damage.
3. If chemicals are splashed into the eye, hold the eyelids open and flush with water continuously for at least 15 minutes or until medical assistance arrives if needed
4. Hold the eyelid open and move the eye up and down and sideways to wash thoroughly behind the eyeball where chemicals could be trapped.
5. Seek medical attention.
6. A continuous flow eyewash is preferred over a portable or self-contained eyewash. Portable and self-contained eyewashes have several disadvantages: limited supply of water, they readily become contaminated with microorganisms, and they require the use of your hands which prevents you from holding the eyelids open.

Fire Extinguisher

1. Almost all lab areas are equipped with a carbon dioxide or an ABC dry chemical powder fire extinguisher.
 - a. The ABC extinguishers work well on a paper, chemical, or electrical fire.
 - b. The carbon dioxide extinguishers are good for a chemical or electrical fire.
 - c. A carbon dioxide extinguisher is the one of choice for electrical equipment.
 - d. Never use a water extinguisher on an electrical fire.

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- e. Only a Class D combustible metal fire extinguisher can be used on a metal (magnesium, sodium, potassium, etc.) fire.
2. If you have been trained, only attempt to extinguish small fires and always fight a fire from a position that allows escape.
3. To use a fire extinguisher, follow these four steps,
 - a. Pull the pin.
 - b. Aim the extinguisher nozzle at the base of the fire.
 - c. Squeeze the handle to release the extinguishing media.
 - d. Sweep the nozzle from side to side at the base of the fire starting at the front and working forward until it is out.
4. Remember the word PASS when using a fire extinguisher: Pull, Aim, Squeeze, and Sweep.
5. If you cannot extinguish the fire in approximately 15-30 seconds, evacuate the area, close the door as you leave, and activate the fire alarm.
6. If you notice that a fire extinguisher has been used, found vandalized, or for any other reason needs service, call Maintenance department at 1171 for replacement. All fires
7. should be reported.
8. For training encompassing fire prevention, evacuation, responding, hands-on fire extinguisher use, or determining whether a fire extinguisher is needed in your work area, call the facility department at extension 1171.

Spill Equipment

1. Supplies for cleaning up a minor chemical or biological spill should be purchased and kept “on hand” in the laboratory.
2. Supplies to have for a chemical spill includes spill pillows, an inert absorbent such as vermiculite, a plastic (non-sparking) scoop, plastic bags to put the spilled material into, heavy gloves, goggles, and sodium bicarbonate or any other type of base to neutralize acids.
3. Supplies to have on hand for a biological spill includes paper towels or absorbent pads, plastic bags, glove, and a container of 1:10 bleach solution.

Laboratory Safety Equipment

Laboratory safety equipment includes fumehoods. This equipment is provided in laboratories to enable you to work safely with chemical, microorganisms and bioterrorism. In order to use this equipment properly, you should have a general understanding of how it works.

Fumehood Description

1. Chemical Fumehoods:
 - a. air is drawn through the front opening of the fumehood, across the work surface; through one or more baffles at the rear of the hood;
 - b. air flows up through the ductwork and into the blower located on the roof;

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- c. air flows out the exhaust stack and away from the building and any air intake.
- 2. Standard Fumehoods
 - a. Consist of a vertically sliding sash or horizontally sliding sash, rear baffle(s), a blower, and the ductwork which connects the hood to the blower.
 - b. The fan will draw air through the face of the hood at a certain rate, usually 80 -100 feet per minute (fpm) with the sash wide open. The velocity through the hood opening will vary depending on the position of the sash. As the sash is lowered, the velocity through the hood opening will increase.
 - c. The air velocity may be so high that it can knock over graduated cylinders or pull paper up into the blower.

Proper Use of Chemical Fumehoods

1. Equipment and other materials should be placed at least six inches behind the sash. This will prevent chemical vapors from escaping into the lab due to air turbulence.
2. When the hood is not in use, pull the sash all the way down. While personnel is working in the hood, pull down the sash as far as is practical. The sash is your protection against fire, explosions, chemical splashes, and projectiles.
3. Do not keep loose papers, paper towels, or tissue wipes in the hood. These materials can get drawn into the blower and affect the hood’s performance.
4. Do not use a fumehood as a storage cabinet for chemicals. Excessive storage of chemicals and other items will disrupt the airflow in the hood. In particular, do not store chemicals against the baffle at the back of the hood. This is where the majority of the air is exhausted.
5. If large equipment must be kept in a fumehood, set it on blocks about 1 ½ inches above the work surface to allow air to flow underneath. This reduces turbulence within the hood and increases its efficiency.
6. Do not place objects directly in front of a fumehood (such as refrigerators or lab coats hung on the controls). This will disrupt the air flow and draw contaminants out of the hood.
7. Keep in mind that modifications made to a fumehood system, e.g., adding on a snorkel, can render the entire system ineffective.
8. Minimize pedestrian traffic immediately in front of a hood. Walking past hoods causes turbulence which can draw contaminants out of the hood and into the room.
9. The Maintenance Department inspects chemical fumehoods annually to ensure they are working properly. If you suspect that your fumehood is not working properly or for any other questions regarding fumehoods, call Maintenance Department at 1711.

Chemical Waste

Containment and Storage

1. All containers are closed unless actively receiving waste.
2. No containers are leaking.

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3. All containers are compatible with their contents.
4. No waste is poured down the drain without prior approval by maintenance facility department.
5. The location of waste pick-up is in the immediate vicinity of the point of generation and under the supervision of the person who generated it.
6. Less than one quart of acutely hazardous waste is present.
7. Less than 55 gallons of possibly hazardous waste is present. (If more than 55 gallons is present, has a request for disposal form been submitted).

Labeling

1. All containers are labeled with the words “waste” or “spent” and their codes are identified.
2. No containers are labeled with the words “hazardous” or “non-hazardous.”

Disposal

1. Each waste container that is ready for disposal has a properly filled out waste pick-up request form attached to it, a waste sticker, and the proper information in the container as well.
2. For hazardous waste containers ready for disposal, you can submit an electronic request for pick-up on the IT Helpdesk icon and send the ticket to Maintenance facility Department.

Special Waste

Sharps

1. All sharps are deposited into red sharps containers which will be picked up Maintenance Facility department. Please do not autoclave sharp containers.
2. There is no evidence of bent, capped, or clipped needles.
3. Do not overfill the sharp containers.

Pathological Waste and Blood or Blood Products

- All pathological waste and blood or blood products are either treated [autoclaved] in the lab or picked up by a licensed disposal company. All waste picked up by a licensed disposal company must be manifested and a copy furnished to Maintenance Facility Department.

Microbiological Waste

- All microbiological waste is treated in the lab or autoclaved.

Disposal of Special Waste in the Lab

1. A log is kept of all special waste treated in the lab.

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SUBJECT/TITLE:	Laboratory Environment Health and Safety	POLICY #LAB3032
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OWNER:	Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

2. A lab that generates more than 50 lbs. of special waste per month has a written procedure or the operation and testing of equipment and for the preparation of any chemicals used if waste is treated in the lab.
3. The bags or containers of special waste are labeled “treated” and are placed into another bag of a different color that is also opaque. This is done before the bag is thrown into the regular trash.

REFERENCES

Center for Medicare and Medicaid Services, *CLIA Interpretive Guidelines for Laboratories* | Website: [cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines/laboratories](https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines/laboratories) | Retrieved on 12/10/2023

American Chemical Society. *Safety in Academic Chemistry Laboratories*, 7 th Edition, 2003.

Chemical Rubber Company, *CRC Handbook of Laboratory Safety*, 5th Edition, 2000.

National Research Council. *Prudent Practices in the Laboratory - Handling and Management of Chemical Hazards*, 2011.

COMMITTEE APPROVALS:

P&P: 2/7/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Loci Thyroid Stimulating Hormone	POLICY #LAB1037
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The TSHL method is an in vitro diagnostic test for the quantitative measurement of Thyroid Stimulating Hormone (TSH, thyrotropin) in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® Module. Measurements of TSH are used in the diagnosis and monitoring of thyroid disease.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** Thyroid stimulating hormone is a glycoprotein secreted by the anterior lobe of the pituitary gland. TSH stimulates the normal thyroid gland to synthesize and secrete thyroxine (T4) and triiodothyronine (T3). Although less sensitive measurements of TSH (or free T4) can be used to diagnose severe, clinically apparent hypo- or hyperthyroidism, only a highly sensitive TSH assay has sufficient clinical sensitivity to detect the minor degrees of thyroxine excess or deficiency associated with early, subclinical phases of hypo- or hyperthyroidism. The TSHL assay meets the criteria of a “third generation” assay, defined as a functional sensitivity of ≤ 0.02 mIU/L with a between-run coefficient of variation (CV) of $\leq 20\%$.
- 2. Principles of Procedure:** The TSHL method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-TSH monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-TSH monoclonal antibody and contains chemiluminescent dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead-TSH-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the TSH concentration in the sample.
- 3. Specimen Collection and Handling:** Recommended specimen types are serum, lithium and sodium heparin plasma, EDTA plasma. Separated samples are stable for 1 day at ambient

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temperature and 7 days at 2 – 8 °C. For longer storage, samples should be frozen at -20 °C for 1 month.

4. Procedure:

4.1. Materials

- TSHL Flex® reagent cartridge, Cat. No. RF612
- LOCI Thyroid Calibrator, Cat. No. RC610/RC610A
- MULTI 2 Sample Diluent, Cat. No. KD694
- TSH Sample Diluent, Cat. No. KD691
- HM reaction vessels, Cat. No. RXV1A
- Quality Control Materials

4.2. Test Steps

4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® EXL™ with LM System. For details of this processing, refer to the Dimension® EXL™ with LM Operator’s Guide.

4.3. Test Conditions

Sample Volume	12 µL
(delivered to the HM reaction vessel)	
Biotinylated Antibody Reagent Volume	20 µL
Chemibeads Reagent Volume	10 µL
Streptavidin Sensibeads Reagent Volume	12 µL
Temperature	37.0 °C
Reaction Time	16 minutes
Wavelength Illumination	680 nm, Emission 612 nm
Type of Measurement	Chemiluminescence

4.4. Calibration

Assay Range	0.007 – 100 µIU/mL [mIU/L]
Calibration Material	LOCI Thyroid Calibrator, Cat. No. RC610/RC610A
Calibration Scheme	5 levels, n = 3
Units	µIU/mL [mIU/L] (µIU/mL x 1)=[mIU/L]
Typical Calibration Levels	Level 2: 0.0 µIU/mL [mIU/L] Level 3: 4.0 µIU/mL [mIU/L] Level 4: 20 µIU/mL [mIU/L]

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Calibration Frequency Every
A new calibration is required

Level 5: 50 µIU/mL [mIU/L]
Level 6: 105 µIU/mL [mIU/L]
30 days for any one lot
*For each new lot of Flex® reagent cartridge
*After major maintenance or service as
Indicated by quality control results
*As indicated by laboratory quality control
Procedures or when required

4.5. Quality Control

Bio-Rad Liquichek Immunoassay Plus Control two-levels (level 1 and 3) are run once daily.

4.6. Results: The instrument calculates the concentration of TSH in µIU/mL [mIU/L] using the calculation scheme described in your Dimension® EXL™ with LM Operator’s Guide.

Reference ranges are established and maintained in the LIS.
Reference Range: 0.36 – 3.74 mIU/L

Repeat all critical values as needed.
Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 0.007 – 100 µIU/mL [mIU/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the analytical process and is equivalent to the assay range.

Samples with results in excess of 100 µIU/mL [mIU/L] should be repeated on dilution.

Manual Dilution: Dilute with TSH Sample Diluent, Cat. No. KD691 or MULTI 2 Sample Diluent, Cat. No. KD694, to obtain results within reportable range. The recommended dilution factor is 5.

Samples with results less than 0.007 µIU/mL [mIU/L] should be reported as “less than 0.007 µIU/mL [mIU/L]”.

5. Limitations

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Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. As with any immuno-recognition measurement of a peptide, extremely rare genetic variants may exhibit varying degrees of detection. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument's processing status and potential errors. Refer to your Dimension® Operator's Guide for the meaning of report flags and comments.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
4.0 µIU/mL [mIU/L]	0.5 µIU/mL [mIU/L]
20.0 µIU/mL [mIU/L]	2.3 µIU/mL [mIU/L]

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Loci Vitamin B12	POLICY #LAB1039
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 5
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The VB12 method is an in vitro diagnostic test for the quantitative measurement of vitamin B12 (B12) in human serum and plasma on the Dimension® EXL™ with LM integrated chemistry system.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** Vitamin B12, or cobalamin, is an essential vitamin with a molecular mass of 1355 Da that is found in a variety of foods such as fish, shellfish, meats and dairy products. Intrinsic factor (IF), transcobalamin II (TCII) and haptocorrin (HC) are binding proteins necessary for the assimilation, transport and delivery of B12 to the blood and body tissues.

Vitamin B12 is primarily stored in the liver and released on demand. The body uses B12 very efficiently, reabsorbing B12 from the small intestine and returning it to the liver so little is excreted and nutritional deficiency is extremely rare. Vitamin B12 is necessary for DNA synthesis, normal red blood cell maturation and myelin sheath formation and maintenance. It is a coenzyme in the conversion of methylmalonic acid to succinic acid and in the synthesis of methionine.

Vitamin B12 deficiency is one of the causes of megaloblastic anemia, a disease in which red blood cells are larger than normal and the ratio of nucleus size to cell cytoplasm is increased. Since folic acid deficiency can also cause megaloblastic anemia, measurement of serum B12 levels is an important part of the differential diagnosis. Vitamin B12 deficiency also causes macrocytic anemias which are characterized by abnormal red blood cell maturation and early release from the bone marrow. Pernicious anemia is a macrocytic anemia. In this disease, an absence of IF prevents normal absorption of B12. In both megaloblastic anemia caused by B12 deficiency and pernicious anemia, treatment with B12 is the therapeutic course.

Vitamin B12 deficiency can also lead to abnormal neurologic and psychiatric symptoms such as ataxia, muscle weakness, dementia, psychosis and mood disturbances. Many patients show neurological changes without developing macrocytic anemia. Populations at risk for B12 deficiency include strict vegetarians, the elderly and populations with increased B12 requirements associated with pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage,

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malignancy and liver or kidney disease. Early diagnosis of B12 deficiency is crucial because of the latent nature of this disorder and the risk of irreversible neurological damage. Recent studies suggest that in addition to serum B12 levels, folic acid, methylmalonic acid and homocysteine should be measured to improve the specificity of the diagnosis.

Elevated B12 levels are seen in hematological disorders (chronic myelogenous leukemia, promyelocytic leukemia, polycythemia vera) and in liver disorders (acute hepatitis, cirrhosis, hepatocellular carcinoma)

- Principles of Procedure:** The vitamin B12 method is a homogeneous, competitive chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and biotinylated intrinsic factor (IF).

The first bead reagent (Chemibead) is coated with a B12 derivative and contains a chemiluminescent dye. The second bead reagent (Sensibead) is coated with streptavidin and contains photosensitive dye. The patient sample is pretreated with sodium hydroxide (NaOH) and dithioerythritol (DTE) to release the serum B12 from its carrier proteins. Potassium cyanide (KCN) is added to convert all the forms of B12 into a single, cyanocobalamin form, and dicyanocobinamide is added to keep the B12 from rebinding with the carrier proteins. After the sample pretreatment, the biotinylated IF and chemibead reagents are added sequentially to the reaction vessel. Vitamin B12 from the sample competes with the B12 chemibead for a limited amount of biotinylated IF. Sensibead reagent is then added and binds to the biotin to form bead pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from the Sensibeads which diffuses to the Chemibeads triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the concentration of vitamin B12 in the sample.

- Specimen Collection and Handling:** Recommended specimen types are serum and plasma (lithium or sodium heparin, and EDTA). Separated samples are stable at room temperature for up to 24 hours. Samples may be stored refrigerated at 2 – 8 °C for up to 48 hours. If testing is delayed beyond 48 hours, samples should be frozen at -20 °C or colder.

4. Procedure:

4.1. Materials

- LOCI VB12 Flex® reagent cartridge, Cat. No. RF642
- LOCI ANEMIA Calibrator, Cat. No. RC640
- Reaction Vessels, Cat. No. RXV1

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Reagent Probe Cleaner, Cat. No. RD702
 Sample Probe Cleaner, Cat. No. RD703
 Quality Control Materials

4.2. Test Steps

4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® EXL™ System. For details of this processing, refer to the Dimension® EXL™ System Operator’s Guide.

4.3. Test Conditions

Sample Volume (delivered to the vessel)	12 µL
Extractant Reagent Volume	15 µL
DTE	12 µL
Biotinylated IF/Neutralizer Reagent Vol.	50 µL
Chemibead Reagent Volume	15 µL
Sensibead Reagent Volume	50 µL
Temperature	37 °C
Reaction time	32 minutes
Wavelength Illumination 680 nm, emission	612 nm
Type of measurement	Chemiluminescence

4.4. Calibration

Calibration Material	LOCI ANEMIA Calibrator, Cat. No. RC640
Calibration Scheme	Level 1, n = 5 Levels 2 – 5, n = 3
Units	pg/mL [pmol/L] (pg/mL x 0.7378) = [pmol/L]
Typical Calibration Levels	Level 1: 45 pg/mL [33 pmol/L] Level 2: 200 pg/mL [148 pmol/L] Level 3: 500 pg/mL [369 pmol/L] Level 4: 1000 pg/mL [738 pmol/L] Level 5: 2100 pg/mL [1549 pmol/L]
Calibration Frequency Every	Every 21 days for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required

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4.5. Quality Control

Bio-Rad Liquichek Immunoassay Plus Control two-levels (level 1 and 3) are run once daily.

4.6. Results: The instrument calculates the concentration of vitamin B12 in pg/mL [pmol/L] using the calculation scheme described in the Dimension® EXL™ Operator’s Guide.

Reference ranges are established and maintained in the LIS.

Reference Range: 193 – 986 pg/mL

Repeat all critical values as needed.

Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 80 – 2000 pg/mL [59 – 1476 pmol/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the analytical process and is equivalent to the assay range.

Samples with results in excess of 2000 pg/mL [1476 pmol/L] are reported as “Above Assay Range” and should be repeated on dilution.

Manual Dilution: Dilute with Reagent grade water to obtain results within the analytical measurement range. Recommended dilution factor = 3. Enter dilution factor on the instrument. Re-assay. Resulting readout is corrected for dilution.

Autodilution (AD): The autodilute sample volume is 4 µL (dilution factor = 3) for serum/plasma. Refer to your Dimension® system manual.

Samples with results less than 80 pg/mL [59 pmol/L] should be reported as “less than 80 pg/mL [59 pmol/L].”

5. Limitations

Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.

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Intrinsic Factor blocking antibodies are present in approximately half of pernicious anemia patients.¹⁴ There is a low frequency possibility that these antibodies may not be completely inactivated during the reaction pretreatment step. If test results are in conflict with the clinical diagnosis, the sample can be tested for intrinsic factor blocking antibodies.

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument's processing status and potential errors. Refer to your Dimension® Operator's Guide for the meaning of report flags and comments.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
200 pg/mL [148 pmol/L]	42 pg/mL [31 pmol/L]
1000 pg/mL [738 pmol/L]	104 pg/mL [77 pmol/L]

Interfering substances:

The VB12 method was evaluated for interference according to CLSI/NCCLS EP7-A2.15 Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference.

Dextran 40 at 6 g/dL [1500 µmol/L] decreases VB12 results by -14.9% at 200 pg/mL [148 pmol/L] and by -11.8% at 1000 pg/mL [738 pmol/L].

Hemoglobin at 500 mg/dL [0.31 mmol/L] increases VB12 results by 15.2% at 200 pg/mL [148 pmol/L] and less than 10% at 1000 pg/mL [738 pmol/L].

Specimens that contain biotin at a concentration of 100 ng/mL demonstrate a less than or equal to 10% change in results. Biotin concentrations greater than this may lead to falsely elevated results for patient samples.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

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SUBJECT/TITLE: Loci Vitamin D Total Assay	POLICY #LAB1040
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 5
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The LOCI Vitamin D Total assay is an in vitro diagnostic test for the quantitative measurement of total 25(OH)vitamin D in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® Module.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

1. Summary: Vitamin D is a steroid hormone involved in the intestinal absorption of calcium and the regulation of calcium homeostasis. Vitamin D is essential for the formation and maintenance of strong, healthy bones. Vitamin D deficiency can result from inadequate exposure to the sun, inadequate alimentary intake, decreased absorption, abnormal metabolism, or vitamin D resistance.

While there are many metabolites of vitamin D, the total 25(OH)vitamin D, that is, the sum of 25(OH)vitamin D2 and 25(OH)vitamin D3, is the most reliable indicator of vitamin D status. Vitamin D2 is derived from plant sources, whereas vitamin D3 is derived primarily from the conversion of 7-dehydrocholesterol in the skin by UV-B radiation from sunlight and secondarily from animal sources.

Whether consumed or produced, both forms of vitamin D (D2 and D3) are metabolized by the liver to 25(OH)vitamin D, and then converted in the liver or kidney into the active metabolites 1,25(OH)₂vitamin D2 and 1,25(OH)₂vitamin D3.

Vitamin D metabolites are bound to a carrier protein in the plasma and distributed throughout the body. The most reliable clinical indicator of vitamin D status is 25(OH)vitamin D because serum and plasma 25(OH)vitamin D levels reflect the body's storage levels of vitamin D, and 25(OH)vitamin D correlates with the clinical symptoms of vitamin D deficiency.

2. Principles of Procedure: The LOCI Vitamin D Total assay is a homogeneous competitive chemiluminescent immunoassay based on LOCI® technology. The assay measures the total 25(OH)vitamin D concentration [comprising both 25(OH)vitamin D2 and 25(OH)vitamin D3] in both serum and plasma. LOCI Vitamin D Total reagents include a releasing reagent, biotinylated monoclonal antibody, and two synthetic bead reagents. Patient sample is incubated

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with the releasing reagent to release 25(OH)vitamin D molecules from the vitamin D-binding proteins. The reaction mixture is then incubated with biotinylated antibody to form a 25(OH)vitamin D/biotinylated antibody complex. Chemibeads containing 25(OH)vitamin D3 analog and chemiluminescent dye are added to remove the excess free biotinylated antibody. Streptavidin-coated Sensibeads containing a photosensitive dye are added to bind the biotinylated antibody. Aggregates of the Chemibead analog/biotinylated antibody/ streptavidin Sensibeads are formed as a result. Illumination of the reaction mixture by light at 680 nm generates singlet oxygen from the Sensibeads, which diffuses into the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is inversely proportional to the concentration of total 25(OH)vitamin D in the sample.

3. **Specimen Collection and Handling:** Recommended specimen types are serum, lithium heparin plasma, and EDTA plasma. Separated samples are stable refrigerated at 2 – 8 °C for 7 days if not tested within 24 hours. For longer storage, samples may be frozen at -20 °C for three months.

4. **Procedure:**

4.1. **Materials**

- VITD Flex® reagent cartridge, Cat. No. RF634
- VITD CAL, Cat. No. RC634
- Reaction Vessels, Cat. No. RXV1A
- Quality Control Materials

4.2. **Test Steps**

- 4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® EXL™. For details of this processing, refer to the Dimension® EXL™ Operator’s Guide.

4.3. **Test Conditions**

Sample Volume (delivered to the reaction vessel)	8 µL
Reagent 4 Releasing Reagent Volume	18 µL
Reagent 1 Biotinylated Antibody Reagent Volume	24 µL
Reagent 2 Chemibeads Reagent Volume	24 µL
Reagent 3 Sensibeads Reagent Volume	84 µL
Temperature	37 °C
Reaction time	31.0 minutes

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Wavelength
 Type of Measurement

Illumination (680 nm),
 Emission (612 nm)
 Chemiluminescence

4.4. Calibration

Assay Range 5.0 – 150.0 ng/mL [12.5 – 375.0 nmol/L]
 Calibration Material VITD Calibrator, Cat. No. RC634
 Calibration Scheme 5 levels, n = 3
 Units ng/mL [nmol/L] (ng/mL x 2.5) = [nmol/L]
 Typical Calibration or Verification Levels
 Level 1: 0.0 ng/mL [0.0 nmol/L]
 Level 2: 12.0 ng/mL [30.0 nmol/L]
 Level 3: 30.0 ng/mL [75.0 nmol/L]
 Level 4: 75.0 ng/mL [187.5 nmol/L]
 Level 5: 165.0 ng/mL [412.5 nmol/L]
 Calibration Frequency Every
 A new calibration is required Every 7 days for any one lot
 *For each new lot of Flex® reagent cartridge
 *After major maintenance or service as
 Indicated by quality control results
 *As indicated by laboratory quality control
 Procedures or when required
 Assigned Coefficients
 C₀: 809.0
 C₁: -811.0
 C₂: -1.46
 C₃: 2.48
 C₄: 0.5

4.5. Quality Control

Bio-Rad Liquichek Immunoassay Plus Control two-levels (level 1 and 3) are run once daily.

4.6. Results: The instrument calculates the concentration of total vitamin D in ng/mL [nmol/L] using the calculation scheme described in your Dimension® EXL™ Operator’s Guide.

Reference ranges are established and maintained in the LIS.
 Reference Range: <20 = deficient
 20 - <30 = insufficient
 30 – 100 = sufficient
 100 – 150 = excess, but not toxic

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>150 = toxicity

Repeat all critical values as needed.

Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 5.0 – 150.0 ng/mL [12.5 – 375.0 nmol/L]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the analytical process and is equivalent to the assay range.

- Samples with results in excess of 150.0 ng/mL [375.0 nmol/L] are reported as “Above Assay Range”. Manual dilution is not required. There is no autodilute feature for VITD.
- Samples with results less than 5.0 ng/mL [12.5 nmol/L] should be reported as “less than 5.0 ng/mL [12.5 nmol/L]”.

5. Limitations

HAMA Anti-Mouse Antibodies (HAMA): Patient samples may contain heterophilic antibodies, of which human anti-mouse antibodies (HAMA) are the most commonly encountered. Heterophilic antibodies such as HAMA may cause falsely decreased or elevated results in immunoassay tests. A test result that is inconsistent with the patient’s clinical presentation and history should be interpreted with caution.

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors. Refer to your Dimension® EXL™ Operator’s Guide for the meaning of report flags and comments.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
12.0 ng/mL [30.0 nmol/L]	1.5 ng/mL [3.8 nmol/L]
30.0 ng/mL [75.0 nmol/L]	2.0 ng/mL [5.0 nmol/L]

Interfering substances:

Do not use hemolyzed samples. Hemoglobin at 500 mg/dL causes an increase in the vitamin D concentration by 11% at 15 ng/mL [37.5 nmol/L], 19% at 31.7 ng/mL [79.2 nmol/L] and 13% at 75.1 ng/mL [187.7 nmol/L].

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Do not use lipemic samples. Lipemia (Intralipid) at 500 mg/dL causes a decrease in vitamin D concentration by 10% at 14.9 ng/mL [37.2 nmol/L], 11% at 32.3 ng/mL [80.8 nmol/L] and 8% at 75.9 ng/mL [189.8 nmol/L].

Paricalcitol (Zemplar) at 24 ng/mL has shown a 93.8% cross-reactivity at 28.8 ng/mL [72.0 nmol/L] of vitamin D and 70.8% cross-reactivity at 54.7 ng/mL [136.8 nmol/L] of vitamin D.

Specimens that contain biotin at a concentration of 250 ng/mL demonstrate a less than or equal to 10% change in results. Biotin concentrations greater than this may lead to falsely elevated results for patient samples.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Millipore Water Culture	POLICY #LAB1050
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 2
	EFFECTIVE: 12/13/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

PURPOSE:

Laboratory grade water type 1 needs to be monitored for those contaminants which may be found in the water source. Ideally, reagent water should be bacteria free. Bacteria may affect the quality of reagent grade by:

1. Inactivating reagents or altering substances or metabolites by enzyme action.
2. Contributing to the total organic content of the water.
3. Altering the optical qualities of the water causing high background absorbance in the spectrophotometric analysis if bacterial clumps are present.
4. Producing pyrogens/endotoxins.
5. Organisms that frequently contaminate water are gram negative rods, including representatives the genera *Pseudomonas*, *Alcaligenes*, *Flavobacterium*, *Klebsiella*, *Enterobacter*, *Aeromonas*, and *Acinetobacter*.

Laboratory grade water is tested by means of a Millipore Sampler. Each sample is constructed to combine both an intimate contact of a 0.45 um Millipore membrane filter to a nutrient-pad (HPC medium) and the incorporation of an air-vent on the upper back portion of the paddle. This configuration allows for the draw-through of 1 mL of sample to affix microorganisms to the filter surface. Each sampler assembly is sterilized and packaged in a sealed plastic envelope.

POLICY:

50mL distilled water, collected aseptically (minimum 20 mL), The distilled water samples (type 1) will be collected weekly. The DI water is collected from the AFS 16D Millipore system that supplies water to the Dimension EXL with LM analyzer.

PROCEDURE

Materials

Sterile urine container

Water sample

Sample Procedure

Follow the steps below when culturing laboratory DI water:

Step	Action
1	Order the water environmental culture directly from CERNER using Laboratory Quality Account. Go to Order Result entry using account Laboratory Quality and specimen log in the Water Environmental culture in CP Micro.

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SUBJECT/TITLE: Millipore Water Culture	POLICY #LAB1050
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OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

2	Wipe the end and outer portion of the water Millipore outlet and Run the water at the outlet for several minutes before collection.
3	Collect minimum of 20 mL. Use sterile urine container for sampling.
4	Transport the sample to Microbiology and process the specimen for the next run.

INTERPRETATION

Acceptable results:

1. No Growth
2. If growth is present, but < 10%, then is also a pass

PROCEDURE NOTES

1. If unacceptable result are obtained, it will be the responsibility of the CLS to take corrective action. Notify the laboratory manager and biomedical engineer for positive culture results.
2. Bleach faucet and nozzle
3. Run water for several minutes prior to collecting repeat culture.
4. If warranted, Biomedical Engineer will replace the filters or pretreatment packs on the Millipore system. If cultures remain positive, Millipore corporation will be called to service the system.
5. Water filtration system is services at least annually by Millipore.

LIMITATIONS

Not all bacteria will produce visible colonies under these growth conditions.

REFERENCES:

Isenberg, Henry. *Clinical Microbiology Procedures Handbook*. Vol 2 1992 13.4.7

Millipore Corporation, *Millipore Samplers, Dilution Kits and Swab tests User Guide*. Millipore Package Insert p15325, REV.B, 1/95

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Total Prostate Specific Antigen	POLICY #LAB1035
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 5
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The TPSA method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an in vitro diagnostic test intended to quantitatively measure total prostate specific antigen (PSA) in human serum and plasma:

1. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostate biopsy is required for diagnosis of cancer.
2. As an aid in the management (monitoring) of prostate cancer patients.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

1. **Summary:** Prostate specific antigen (PSA) is a serine protease of approximately 30000 Daltons produced by the epithelial cells of the prostate gland. The level of PSA in serum and other tissues is normally very low. In malignant prostate disease (prostatic adenocarcinoma) and in non-malignant disorders such as benign prostate hypertrophy (BPH) and prostatitis, the serum level of PSA may become elevated.

In serum, PSA exists primarily as three forms: complexed with either α 1-antichymotrypsin (ACT) or α 2-macroglobulin and free. The PSA protein associated with α 2-macroglobulin is encapsulated and unavailable for measurement by current immunoassay systems. The Dimension® TPSA assay measures both the free and the ACT bound components of serum PSA.

The specificity of PSA to prostate tissue makes it a significant marker in the early detection and management of prostate diseases.

PSA testing is accepted as an adjunctive test in the management of prostate cancer. Serum levels of PSA are most useful when sequential values are obtained and monitored over time.

2. **Principles of Procedure:** The TPSA method is a one-step enzyme immunoassay based on the “sandwich” principle. Sample is incubated with chromium dioxide particles and β -galactosidase conjugate reagent; each coated with monoclonal antibodies recognizing different binding sites on PSA. A chrome particle/PSAa/conjugate sandwich forms during the

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incubation period. The incubation conditions are optimized to produce equivalent immunoreactions with both free PSA and PSA-ACT. Unbound conjugate is removed by magnetic separation and washing. The sandwich-bound β -galactosidase is combined with the chromogenic substrate chlorophenol red- β -d-galactopyranoside (CPRG). Hydrolysis of CPRG releases a chromophore, chlorophenol red (CPR). The color change measured at 577 nm due to formation of CPR is directly proportional to the concentration of PSA present in the patient sample.

3. **Specimen Collection and Handling:** Recommended specimen types are serum and lithium heparin plasma. Serum and plasma specimens should be separated from cells within 3 – 4 hours after venipuncture. 13 Samples should be kept at 4 °C and analyzed within 8 hours. For longer storage, samples may be frozen at -20 °C or colder. For extended storage samples are stable for at least four months if stored at -80 °C.

4. **Procedure:**

4.1. **Materials**

- TPSA Flex® reagent cartridge, Cat. No. RF451
- Reaction Vessels, Cat. No. RXV1A
- Chemistry Wash, Cat. No. RD701
- Sample Probe Cleaner, Cat. No RD703 T/F
- PSA Calibrator Cat. No. RC452
- Quality Control Materials

4.2. **Test Steps**

- 4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® system with the heterogeneous immunoassay module. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.
- 4.2.2. The sample container must contain sufficient quantity to accommodate the sample volume plus dead volume. Precise container filling is not required.

4.3. **Test Conditions**

Reaction Vessel

- Sample Size 40 μ L
- Antibody-CrO2 30 μ L
- Antibody- β -galactosidase 50 μ L
- Incubation Temperature 42 °C Dimension® RxL, Xpand®,

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RxL Max®, Xpand® Plus, EXL™
 37 °C Dimension® EXL™ with
 LM Dimension® EXL™ 200
 Incubation Period 9 minutes

Reaction Cuvette
 Transfer Volume 60 µL
 CPRG Reagent Volume 150 µL
 Temperature 37.0 °C
 Reaction Time 5 minutes
 Wavelength 577 and 700 nm
 Type of Measurement Bichromatic rate

4.4. Calibration

Assay Range 0.13 – 100.00 ng/mL [µg/L]
 Calibration Material T/F PSA Calibrator, Cat. No. RC452h
 Calibration Scheme Level 1, n = 5
 Level 2, n = 2
 Level 4, n = 3
 Level 5, n = 2
 Level 6, n = 3
 Units ng/mL [µg/L]
 Typical Calibration Levels 0.0, 4.0, 20.0, 50.0, 108.0 ng/mL [µg/L]
 Calibration Frequency Every 90 days for any one lot
 A new calibration is required *For each new lot of Flex® reagent cartridge
 *After major maintenance or service as
 Indicated by quality control results
 *As indicated by laboratory quality control
 Procedures or when required
 Assigned Coefficients C₀ -1000.0
 C₁ 3000.0
 C₂ -2.0
 C₃ 200.0
 C₄ 0.5

**The T/F PSA calibrator has 6 levels. To calibrate TPSA, use levels: 1, 2, 4, 5, 6. Do not use vial labeled 3.*

4.5. Quality Control

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Bio-Rad Liquichek Immunoassay Plus Control two-levels (level 1 and 3) are run once daily.

4.6. Results: The instrument calculates the concentration of total PSA in ng/mL [$\mu\text{g/L}$] using the calculation scheme described in your Dimension® Operator’s Guide.

Reference ranges are established and maintained in the LIS.
Reference Range: 0.0 – 4.0 ng/mL

Repeat all critical values as needed.
Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 0.13 – 100.00 ng/mL [$\mu\text{g/L}$]

This is the range of analyte values that can be measured directly from the specimen without any dilution or pretreatment that is not part of the analytical process and is equivalent to the assay range.

Samples with results in excess of 100.00 ng/mL [$\mu\text{g/L}$] should be repeated on dilution.

Autodilution (AD): Refer to your Dimension® Operator’s Guide. Recommended Auto Dilute volume is 2 μL .

Manual Dilution: Make appropriate dilution with Reagent grade water to obtain results within assay range. Enter dilution factor. Reassay. Resulting readout is corrected by dilution.

Results less than 0.13 ng/mL [$\mu\text{g/L}$] should be reported as “less than 0.13 ng/mL [$\mu\text{g/L}$]”.

5. Limitations

Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.

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PSA levels may be lower in patients who receive hormonal therapy and may not adequately reflect the presence of residual or recurrent disease.

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors. Refer to your Dimension® Operator’s Guide for the meaning of report flags and comments.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
4.0 ng/mL [µg/L]	>0.22 ng/mL [µg/L]
50.0 ng/mL [µg/L]	>2.63 ng/mL [µg/L]

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024
 MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Total Protein	POLICY # 1034
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 3
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The TP method used on the Dimension® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of total protein in human serum and heparinized plasma.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

1. Summary: The total protein method is a modification of the biuret reaction first introduced by Kingsley¹ and later modified by Henry² and presented as the method of choice for serum by Henry.³ This method incorporates tartrate as a complexing agent to prevent precipitation of Cu(OH)₂. Serum blanking increases method sensitivity and minimizes spectral interference from lipemia.

Measurements of total protein are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney or bone marrow as well as metabolic or nutritional disorders.

2. Principles of Procedure: Cupric ion (Cu⁺⁺) reacts with the peptide linkages (-C-NH-CH-C-NH-) of protein in a basic solution. The blue copper (II) protein complex thus

$$\begin{array}{c} \parallel \quad | \quad \parallel \\ \text{O} \quad \text{R} \quad \text{O} \end{array}$$

formed is proportional to the total protein concentration in the sample and is measured using a bichromatic (540, 700 nm) endpoint technique.

3. Specimen Collection and Handling: Recommended specimen types are serum, and plasma. Separated samples are stable for 8 hours at room temperature, 72 hours at 2 – 8 °C and 6 months when frozen at -20 °C or colder.

4. Procedure:

4.1. Materials

- TP Flex® reagent cartridge, Cat. No. DF73
- Total Protein/Albumin Calibrator, Cat. No. DC31
- Quality Control Materials

4.2. Test Steps

4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.

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SUBJECT/TITLE: Total Protein	POLICY # 1034
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4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

4.2.3. An alternate sample size (10 µL) can be programmed; refer to the Operator’s Guide for the use of alternate sample size.

4.3. Test Conditions

Sample Size	15 µL, (10 µL)
Reagent 1 Volume	85 µL
Reagent 2 Volume	85 µL
Diluent Volume	315 µL
Temperature	37 °C
Wavelength	540 and 700 nm
Type of Measurement	Bichromatic endpoint

4.4. Calibration

Assay Range	2.0 – 12.0 g/dL [20 – 120 g/L]
Calibration Material	Total Protein/Albumin Calibrator, Cat. No. DC31
Calibration Scheme	3 levels, n = 3
Units	g/dL [g/L] (g/dL x 10) = [g/L]
Typical Calibration Levels	2.0, 6.0, 10.0 g/dL [20, 60, 100 g/L]
Calibration Frequency	Every 90 days for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	Standard sample size = 15 µL C ₀ 3.700 C ₁ 0.0222 Alternate sample size = 10 µL C ₀ 5.357 C ₁ 0.031

4.5. Quality Control

Bio-Rad Liquid Assayed Multiqual two-levels controls are run once daily.

4.6. Results: The instrument calculates the concentration of total protein in g/dL [g/L] using calculation scheme.

Reference ranges are established and maintained in the LIS.

Reference Range: 6.4 – 8.2 g/dL

Repeat all critical values as needed.

Critical Value: Not Applicable

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4.7. Analytical Measurement Range (AMR): 2.0 – 12.0 g/dL [20 – 120 g/L]

Samples with results above excess of 12.0 g/dL [120 g/L] should be repeated with dilution.

Autodilution (AD): Refer to your Dimension® Operator’s Guide.

Manual Dilution: Make appropriate dilution with Reagent grade water to obtain result within the assay range. Enter dilution factor. Reassay. Resulting readout is corrected for dilution.

Samples with results less than 2.0 g/dL [20 g/L] should be reported as “less than 2.0 g/dL [20 g/L]”.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors. Refer to your Dimension® Operator’s Guide for the meaning of report flags and comments.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
6.8 g/dL [68 g/L]	>0.12 g/dL [1.2 g/L]

Interfering substances:

Dextran 40 of 1500 mg/dL [375 µmol/L] increases a TP result of 7.0 g/dL [70 g/L] by 17%.

Immunoglobulin G of 2.5 g/dL [25 g/L] increases a TP result of 7.0 g/dL [70 g/L] by 25%.

Hemolysis – increases Total Protein result

Icterus – can depress results

Lipemia (Intralipid®) – tripped an error flag on this method, so the magnitude of the interference is not available.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Triglycerides	POLICY #LAB1036
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The TGL method used on the Dimension® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of triglycerides in human serum and plasma.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** Triglycerides are water-insoluble lipids consisting of three fatty acids linked to one glycerol molecule. Triglycerides are transported in the blood as core constituents of all lipoproteins, but the greatest concentration of these molecules is carried in the triglyceride-rich chylomicrons and very low density lipoproteins (VLDL). Through the action of lipases and bile acids, triglycerides are hydrolyzed into glycerol and fatty acids which are absorbed by adipose tissue for storage or by other tissues requiring a source of energy. A peak concentration of chylomicron-associated triglycerides occurs within 3 – 6 hours after ingestion of a fat-rich meal; however, the rate of absorption of fats is highly variable, depending on the individual and dietary composition of the fat. After absorption, triglycerides are resynthesized in the epithelial cells and combined with cholesterol and a number of apolipoproteins to form chylomicrons.
- 2. Principles of Procedure:** The triglycerides method is based on an enzymatic procedure in which a combination of enzymes are employed for the measurement of serum or plasma triglycerides. The sample is incubated with lipoprotein lipase (LPL) enzyme reagent that converts triglycerides into free glycerol and fatty acids. Glycerol kinase (GK) catalyzes the phosphorylation of glycerol by adenosine-5-triphosphate (ATP) to glycerol-3-phosphate. Glycerol-3-phosphate-oxidase oxidizes glycerol-3-phosphate to dihydroxyacetone phosphate and hydrogen peroxide (H₂ O₂). The catalytic action of peroxidase (POD) forms quinoneimine from H₂ O₂ , aminoantipyrine and 4-chlorophenol. The change in absorbance due to the formation of quinoneimine is directly proportional to the total amount of glycerol and its precursors in the sample and is measured using a bichromatic (510, 700 nm) endpoint technique.
- 3. Specimen Collection and Handling:** Recommended specimen types are serum, and plasma. Separated samples are stable for 8 hours at room temperature, 2 days at 2 – 8 °C. For longer storage, specimens may be frozen at -20 °C or colder.

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OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

4. PROCEDURE:

4.1. Materials

TGL Flex® reagent cartridge, Cat. No. DF69A
 CHEM II Calibrator, Cat. No. DC20
 Quality Control Materials

4.2. Test Steps

- 4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.
- 4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

4.3. Test Conditions

Sample Size	4 µL
Reagent 1 Volume	133 µL
Temperature	37 °C ± 0.1 °C
Wavelengths	510 and 700 nm
Type of Measurement	Bichromatic endpoint

4.4. Calibration

Assay Range	15 – 1000 mg/dL [0.17 – 11.3 mmol/L]
Calibration Material	CHEM II Calibrator, Cat. No. DC20
Calibration Scheme	3 Levels, n = 3
Units	mg/dL [mmol/L] (mg/dL x 0.0113) = [mmol/L]
Typical Calibration Levels	120, 240, 485 mg/dL [1.37, 2.74, 5.54 mmol/L]
Calibration Frequency	Every 90 days for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	C ₀ -2.6 C ₁ 1.5

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OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

4.5. Quality Control

Bio-Rad Liquid Assayed Multiqual two-levels controls are run once daily.

4.6. Results: The instrument calculates the concentration of triglycerides in mg/dL [mmol/L] using calculation scheme.

Reference ranges are established and maintained in the LIS.

Reference Range: <150 mg/dL

Repeat all critical values as needed.

Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 15 – 1000 mg/dL [0.17 – 11.3 mmol/L]

Samples with results above excess of 1000 mg/dL [11.3 mmol/L] should be repeated on dilution.

Autodilution (AD): If using the auto-dilution feature, results above 1000 mg/dL [11.3 mmol/L] will automatically be repeated (for serum, plasma).

Manual Dilution: Make appropriate dilution with Reagent grade water to obtain a result within the assay range. Enter the dilution factor. Reassay. Resulting readout is corrected for dilution.

Samples with results less than 15 mg/dL [0.17 mmol/L] should be reported as “less than 15 mg/dL [0.17 mmol/L]”.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors. Refer to your Dimension® Operator’s Guide for the meaning of report flags and comments.

Venipuncture should occur prior to N-Acetyl Cysteine or Metamizole (Sulpyrine) administration due to the potential for falsely depressed results.

A system malfunction may exist if the following five-test precision is observed:

Concentration

SD

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100 mg/dL [1.13 mmol/L]

>5 mg/dL [0.06 mmol/L]

400 mg/dL [4.53 mmol/L]

>16 mg/dL [0.18 mmol/L]

Interfering substances:

Small amounts of free glycerol may be found in blood samples from healthy individuals due to natural lipolysis. The concentration of free glycerol may be increased by stress, disease states or administration of intravenous infusates. Free glycerol or other polyols may cause a positive interference.

Hemolysis – will increase triglycerides result

Icterus – will slightly increase results

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

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SUBJECT/TITLE: Uric Acid	POLICY #LAB1037
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The URCA method used on the Dimension® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of uric acid in human serum, plasma and urine.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** The uric acid method is a modification of the uricase method first reported by Bulger and Johns, later modified by Kalckar. Measurement of uric acid by monitoring the loss of absorbance at 293 nm following uricase treatment is generally recognized as being more specific and less subject to interference than other, indirect methods.
- 2. Principles of Procedure:** Uric acid, which absorbs light at 293 nm is converted by uricase to allantoin, which is nonabsorbing at 293 nm. The change in absorbance at 293 nm due to the disappearance of uric acid is directly proportional to the concentration of uric acid in the sample and is measured using a bichromatic (293,700 nm) endpoint technique.
- 3. Specimen Collection and Handling:** Recommended specimen types are serum, and plasma. Separated samples are stable for 1 day at room temperature, 3 – 5 days at 2 – 8 °C. For longer storage, specimens may be frozen at -20 °C or colder for up to 6 months. Alkaline urine samples are stable at ambient temperature for 3 – 4 days.

4. PROCEDURE:

4.1. Materials

URCA Flex® reagent cartridge, Cat. No. DF77
CHEM I Calibrator, Cat. No. DC18B or DC18C
Quality Control Materials

4.2. Test Steps

4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.

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4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

4.2.3. An alternate sample size of 10 µL can be programmed; refer to the Operator’s Guide for the use of alternate sample size.

4.3. Test Conditions

Sample Volume	17 µL, (10 µL)
Reagent 1 Volume	132 µL
Reagent 2 Volume	26 µL
Diluent Volume	231 µL
Temperature	37 °C
Wavelength	293 and 700 nm
Type of Measurement	Bichromatic endpoint

4.4. Calibration

Assay Range	0 – 20.0 mg/dL [0 – 1190 µmol/L]
Calibration Material	CHEM I Calibrator, Cat. No. DC18B or DC18C
Calibration Scheme	3 levels, n = 3
Units	mg/dL [µmol/L] (mg/dL x 59.48) = [µmol/L]
Typical Calibration Levels	0, 12, 23 mg/dL [0, 714, 1368 µmol/L]
Calibration Frequency	Every 90 days for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	Standard sample size = 17 µL C ₀ 0.146 C ₁ -0.070 Alternate sample size = 10 µL C ₀ 0.001 C ₁ -0.123

4.5. Quality Control

Bio-Rad Liquid Assayed Multiquel two-levels controls are run once daily.

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4.6. Results: The instrument calculates the concentration of uric acid in mg/dL [$\mu\text{mol/L}$] using calculation scheme.

Reference ranges are established and maintained in the LIS.

Reference Range: 2.6 – 7.2 mg/dL

Repeat all critical values as needed.

Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 0 – 20.0 mg/dL [0 – 1190 $\mu\text{mol/L}$]

Samples with results above excess of 20.0 mg/dL [1190 $\mu\text{mol/L}$] are reported as “Above Assay Range” and should be repeated with dilution.

Autodilution (AD) (for serum, plasma, urine): Refer to your Dimension® Operator’s Guide.

Automated Urine Dilution (AUD) (for Urine): Refer to your Dimension® Operator’s Guide.

Manual Dilution: Serum/Plasma: Make appropriate dilution with Reagent grade water to obtain result within the assay range. Enter dilution factor. Urine: Dilute 1 part urine: 9 parts Reagent grade water. Enter dilution factor of 10. Serum/Plasma/Urine: Reassay. Resulting readout is corrected for dilution.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors. Refer to your Dimension® Operator’s Guide for the meaning of report flags and comments.

Venipuncture should occur prior to Metamizole (Sulpyrine) administration due to the potential for falsely depressed results.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
4.9 mg/dL [291 $\mu\text{mol/L}$]	>0.2 mg/dL [12 $\mu\text{mol/L}$]
17.7 mg/dL [1053 $\mu\text{mol/L}$]	>0.4 mg/dL [24 $\mu\text{mol/L}$]

Interfering substances:

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Uric Acid	POLICY OR REFERENCE # 1037
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 4 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

Xanthine has been reported to decrease the URCA result by 40%.⁹
Formaldehyde (formalin) has been reported to give negative interference with the uricase methods.
Lipemia (Intralipid®) at 600 mg/dL [6.78 mmol/L] and above tripped a test report message; therefore the magnitude of the interference could not be determined.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Urinary/Cerebrospinal Fluid Protein	POLICY #LAB1038
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 1 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

DEFINITION:

The UCFP method used on the Dimension® clinical chemistry system is an in vitro diagnostic test intended for the quantitative determination of total protein in human urine and cerebrospinal fluid.

POLICY:

It is the policy of this department to ensure that all clinical laboratory scientists performing the test adheres to this policy to produce quality laboratory results at all times.

PROCEDURE:

- 1. Summary:** The UCFP method allows direct quantitation of proteins in urine and cerebrospinal fluid specimens. The UCFP method is an adaptation of pyrogallol red-molybdate method by Y. Fujita, I. Mori and S. Kitano.¹ Measurement of the protein content in urine is used in diagnosis and treatment of kidney diseases. Measurement of the protein content in cerebrospinal fluid is used in the diagnosis and treatment of central nervous system diseases.
- 2. Principles of Procedure:** In the reaction sequence, pyrogallol red combines with sodium molybdate to form a red complex with maximum absorbance at 470 nm. The protein in the sample reacts with this complex in acid solution to form a bluish-purple colored complex, which absorbs at 600 nm. The absorbance at 600 nm is directly proportional to the concentration of protein in the sample. The analyte concentration is determined by calculation using a logit curve fit on a previously stored calibration curve.
- 3. Specimen Collection and Handling:** Recommended specimen types are urine and cerebrospinal fluid. Specimens stored at 4 °C with no additives are stable for at least three days.

Random urine specimens may be used but timed 24-hr specimens are preferred. No preservative is required during 24-hr collection, but thereafter urine aliquots should be stored at 2 – 4 °C for <72 hours or frozen at -20 °C for up to 1 year. Urine specimens must be free of any particulate matter before analysis.

Cerebrospinal fluid specimens should be collected with care to avoid contamination with plasma proteins. Blood present in the cerebrospinal fluid invalidates the protein values since it reflects contamination with plasma proteins. Analyze fresh or store at 4 °C for <72 hours or frozen for up to 6 months.

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Urinary/Cerebrospinal Fluid Protein	POLICY OR REFERENCE # 1038
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 2 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

4. PROCEDURE:

4.1. Materials

UCFP Flex® reagent cartridge, Cat. No. DF26
 UCFP Calibrator, Cat. No. DC45
 Quality Control Materials

4.2. Test Steps

- 4.2.1. Sampling, reagent delivery, mixing, processing, and transmission of results to LIS are automatically performed by the Dimension® clinical chemistry system. For details of this processing, refer to the Dimension® clinical chemistry Operator’s Guide.
- 4.2.2. The primary tube or sample container must contain sufficient quantity to accommodate the sample volume plus dead volume.

4.3. Test Conditions

Sample Size	10 µL
Reagent Volume	350 µL
Diluent Volume	50 µL
Temperature	37 °C
Wavelength	600 and 700 nm
Type of Measurement	Bichromatic endpoint

4.4. Calibration

Assay Range	6 – 250 mg/dL [60 – 2500 mg/L]
Calibration Material	UCFP Calibrator, Cat. No. DC45
Calibration Scheme	5 levels, n = 2
Units	mg/dL [mg/L] (mg/dL x 10) = [mg/L]
Typical Calibration Levels	6.0, 30.0, 60.0, 135.0, 270.0 mg/dL [60, 300, 600, 1350, 2700 mg/L]
Calibration Frequency	Every 2 months for any one lot
A new calibration is required	*For each new lot of Flex® reagent cartridge *After major maintenance or service as Indicated by quality control results *As indicated by laboratory quality control Procedures or when required
Assigned Coefficients	C ₀ -193.89 C ₁ 1337.5

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Urinary/Cerebrospinal Fluid Protein	POLICY OR REFERENCE # 1038
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 3 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

C₂ -2.595
 C₃ 462.58
 C₄ 0.5

4.5. Quality Control

Bio-Rad Liquichek Urine Chemistry Control two-levels controls are run once daily.

4.6. Results: The instrument calculates the concentration of UCFP in mg/dL [mg/L] using calculation scheme.

Reference ranges are established and maintained in the LIS.
 Reference Range: 0 – 149 mg/24hr

Repeat all critical values as needed.
 Critical Value: Not Applicable

4.7. Analytical Measurement Range (AMR): 6 – 250 mg/dL [60 – 2500 mg/L]

Samples with results above excess of 250 mg/dL [2500 mg/L] should be repeated on dilution.

Autodilution (AD): For urine and CSF specimens: Refer to your Dimension® Operator’s Guide.

Manual Dilution: Make appropriate dilution with Reagent grade water to obtain result within the assay range. Enter dilution factor. Reassay. Resulting readout is corrected for dilution.

5. Limitations

The instrument reporting system contains flags and comments to provide the user with information regarding the instrument’s processing status and potential errors. Refer to your Dimension® Operator’s Guide for the meaning of report flags and comments.

A system malfunction may exist if the following five-test precision is observed:

Concentration	SD
32 mg/dL	1.2 mg/dL
142 mg/dL	2.0 mg/dL

MAYERS MEMORIAL HEALTHCARE DISTRICT

SUBJECT/TITLE: Urinary/Cerebrospinal Fluid Protein	POLICY OR REFERENCE # 1038
DEPARTMENT/SCOPE: Laboratory - Chemistry	Page 4 of 4
	EFFECTIVE: 12/15/2023
OWNER: Sophia Lou Rosal, CLS	APPROVER: Kevin Davie

Interfering substances:

Samples containing amikacin, gentamicin, kanamycin, and tobramycin should be avoided since these substances falsely increase UCFP results.

Neomycin sulfate at 15 µg/mL increases UCFP results by 11% and at 7.5 µg/mL the interference is less than 5%.

REFERENCES:

Siemens Dimension Clinical Chemistry System – Flex reagent cartridge kit insert

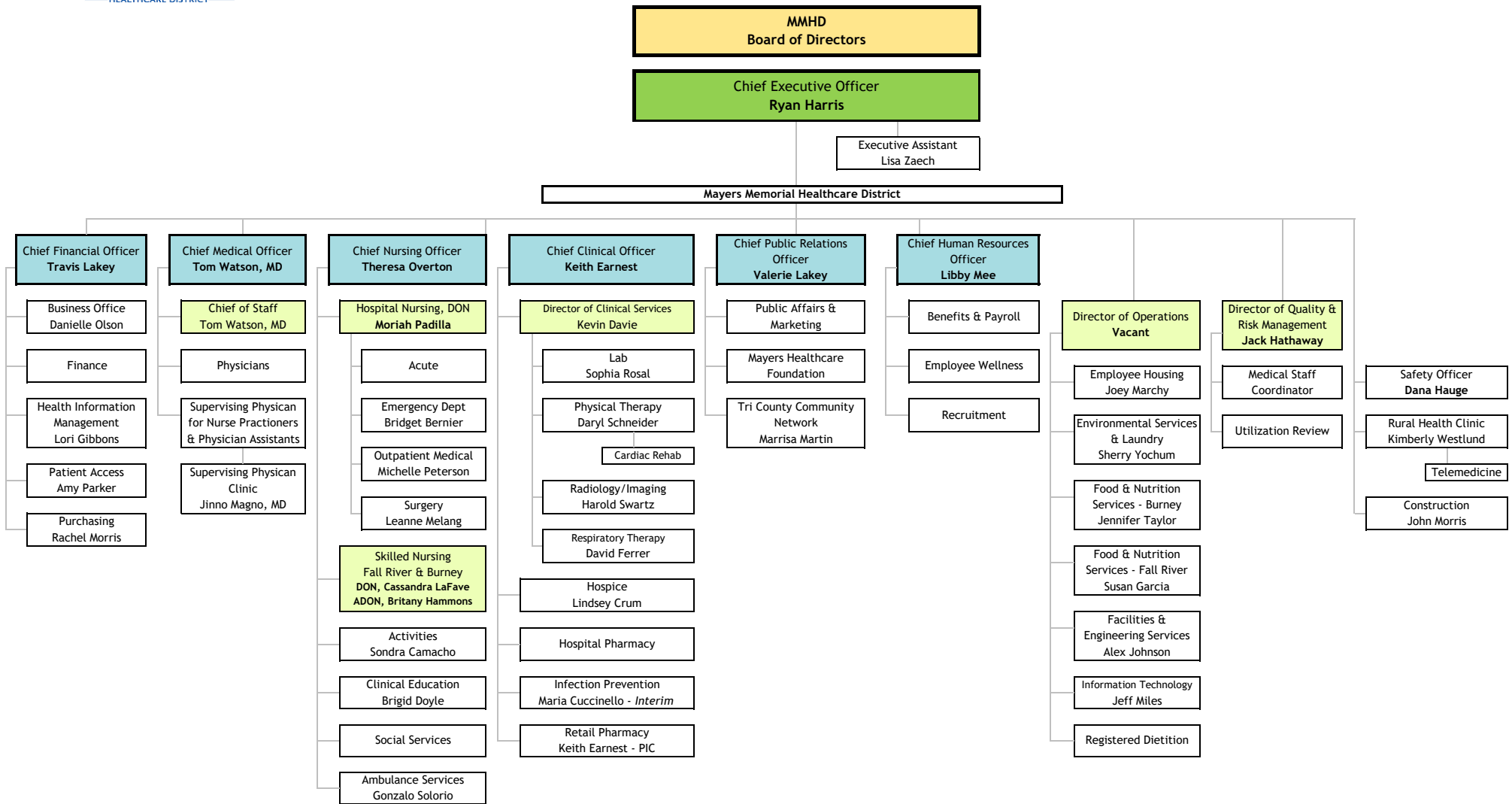
COMMITTEE APPROVALS:

P&P: 1/3/2024

MEC: 2/8/2024



Mayers Memorial Healthcare District Organization Chart





Operations Report February 2024

Statistics	January YTD FY24 <i>(current)</i>	January YTD FY23 <i>(prior)</i>	January Budget YTD FY24
Surgeries			
➤ Inpatient	0	0	TBD
➤ Outpatient	0	0	TBD
Procedures** (<i>surgery suite</i>)	0	0	TBD
Inpatient	1171	1160	984
Emergency Room	2450	2619	2525
Skilled Nursing Days	17079	16685	16125
OP Visits (OP/Lab/X-ray)	8579	9564	8003
Hospice Patient Days	282	758	835
PT	1117	1413	1472

*Note: numbers in RED denote a value that was less than the previous year.

**Procedures: include colonoscopies

Human Resources

February 2024

Submitting by Libby Mee – Chief Human Resource Officer

Staffing and Recruitment

We are currently in contract negotiations with a Provider in the Emergency Department and a CRNA for Surgery. In addition to our General Surgeon, the CRNA will be a shared provider with Modoc Medical Center.

As we are searching for permanent applicants, we are currently utilizing interim candidates for our Infection Prevention RN and SNF/Med Surge Acute Hospitalist positions.

Partnership Provider Recruitment Program

Mayers team members have a meeting on Tuesday February 27th to discuss new Provider Recruitment and Retention programs through Partnership that went into effect January of this year. Depending on the type of provider, the program would pay \$50,000 - \$120,000, payable over five years, to newly hired providers. The Retention Initiative would pay \$45,000 to MD/DO over three years and \$30,000 to NP/Pas over three years.

Fairs and Recruitment Events

Representatives from MMHD are scheduled to attend the below fairs and events in efforts to recruit employment applicants:

- Job Fair at Sacramento State – March 5th
- Smart Center Job Fair in Redding – March 26th
- Shasta College Nursing Division – March 28th
- American River College in Sacramento – April 17th
- Oregon Institute of Technology – April 24th

ACHC Accreditation

The HR team is excited to work with our new consultant. We have already identified the need to build an Employee Health Plan using previously existing policies related to employee health compliance, workman's comp and infection prevention standards.

Shay and I are also registered to attend a HR Accreditation Standards Training that was recommend by our consultant.

Employee Health, Wellness and Benefits

Insurance

We are settling into our new insurance options and establishing new procedures for processing documents and bills. Unfortunately, our previous carriers were not cancelled appropriately so some claims were billed to the wrong carrier, causing frustrations with staff. Fortunately, our

new broker is very engaged and has been available to help us get everything lined out going forward.

Work Related injury and Illness

Currently, for the year, we have had no reportable work related injury or illnesses. There has been one first aide injury, with no days away from work.

Paycom

On Wednesday February 21 we had our Client Relations Representative on site. This is the second time he has spent the day with us. It proves to be very productive to have a dedicated specialist looking at our system as we continue to make adjustments and increase the utilization of the system.

Training/Events/Conferences

Trusted Edge Leadership Institute Certification

I am currently working through the certification program to become a Trust Edge Certified Partner.

American Society of Healthcare Human Resource Administration

Members of the HR team will be attending the ASHHRA annual conference in April. The conference will provide trusted knowledge and critical education, specifically for healthcare HR professionals, dedicated to creating and maintaining healthier communities.

National Rural Hospital Association

I have submitted enrollment documents to achieve certification from the National Rural Hospital Association in HR. I will also be attending the annual conference in May with other team members.



EMPLOYEE STATISTICS

2024 Fiscal Year

295

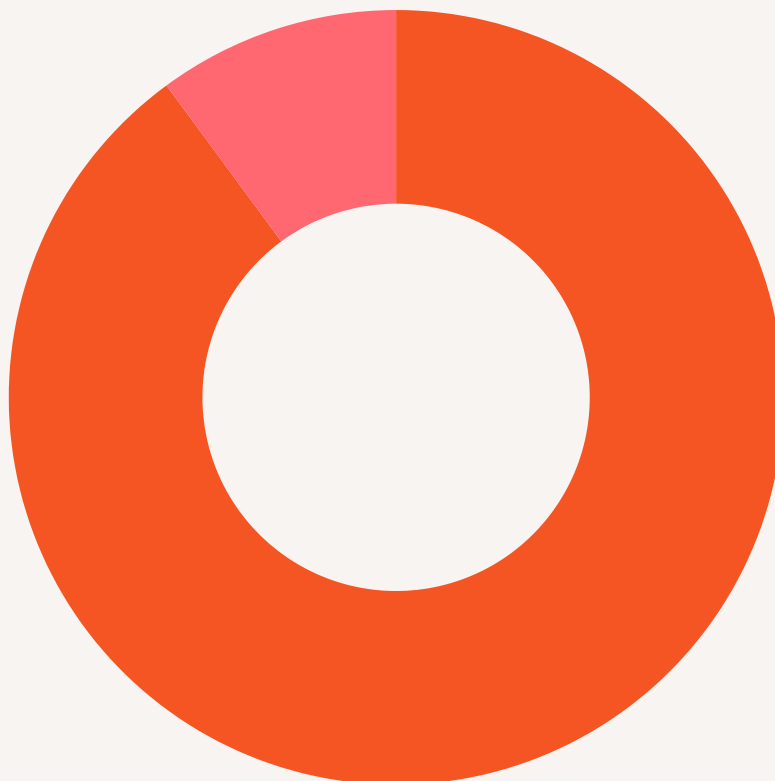
Total Employees

ADJUSTED TURNOVER STATS FOR 2024 FISCAL YEAR:

GOAL TURNOVER FOR
FY 24 IS 17.52%

Adjusted Turnover

10.09%





Bolded = Actively Recruiting

*= Top Priority

Positions:

available:

Director of Operations

1

***Emergency Dept Medical
Director**

1

***Emergency Dept Mid Level**

PT OR FT

***Emergency Dept Physician**

PT OR FT

Environmental Services Aide

1

Hospice Home Health Aide

PER DIEM

***Independent Retail
Pharmacist**

1

***Infection Prevention RN**

1

Lead Early Childhood
Educator

1

Med/Surg Acute RN

PER DIEM & FT



BOLDED= Actively Recruiting
 *= Top Priority

Positions: # available:

*Nurse Practitioner (SNF + ACUTE)	1
*Pharmacist	1
*Physical Therapy Assistant	1
*Radiology Tech	1
Retail Pharmacy Clerk	PT
*Skilled Nursing RN	3
*Skilled Nursing CNA	10: 2 PER DIEM, 1 PT, 7 FT
*Skilled Nursing LVN	9: 1 PER DIEM, 2 PT, 6 FT
Skilled Nursing Charge Nurse	1

Chief Public Relations Officer – Valerie Lakey
February 2024 Board Report

Legislation/Advocacy

The legislative season is in full swing. There are a few bills of note that specifically apply to rural healthcare.

AB 869 (Wood, D-Healdsburg)

AB 869 would prioritize certain smaller hospitals for the existing Small and Rural Hospital Relief Program, which is funded by the e-cigarette tax. This would allow them to get assessments for the cost of retrofitting their hospital and give certain smaller rural hospitals and certain district hospitals a five-year extension of the 2030 seismic deadline. It would also allow certain smaller rural and district hospitals, if they have experienced a financial hardship, an indefinite extension beyond 2035, until funds are appropriated by the state.

Status: In Senate Health Committee

SB 1432 is the spot bill for CHAs work on 2030 compliance. Senator Cabellero has agreed to lead joint authors Alvarado-Gil, Dodd, Eggman, and Newman, along with coauthors Grove and Becker to support this effort. The general framework includes:

- Additional time to comply with 2030 requirements for all hospitals
- Assess opportunities for financial support for rural and critical access hospitals, including support for AB 869 (Wood)
- Additional disaster planning requirements for hospitals
- Reports to the Legislature analyzing the cost impacts of seismic compliance, including the impact on meeting spending growth targets set by the Office of Health Care Affordability

We should have language in the next few weeks.

SB 1423 (Dahle) Cost based Medi-Cal Reimbursement for Critical Access Hospitals.

Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services, and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Under existing law, each hospital designated by the department as a critical access hospital and certified as such by the Secretary of the United States Department of Health and Human Services under the federal Medicare rural hospital flexibility program, is eligible for supplemental payments for Medi-Cal covered outpatient services rendered to Medi-Cal eligible persons. Existing law conditions those payments on receipt of federal financial participation and an appropriation in the annual Budget Act for the nonfederal share of those payments, with supplemental payments being apportioned among critical access hospitals based on their number of Medi-Cal outpatient visits. This bill would remove the provisions relating to supplemental payments and would instead require the reimbursement to a critical access hospital for Medi-Cal covered outpatient services at a rate equal to the actual cost to the hospital of providing the services or the amount charged by the hospital for the services, whichever is less. The bill would also

require reimbursement to those hospitals, under the same terms, for swing-bed services, relating to beds licensed for general acute care that may be used as skilled nursing beds. Existing law sets forth various Medi-Cal payment reductions by specified percentages for certain providers, including rural swing-bed facilities. This bill would make an exception to those payment reductions for rural-swing bed facilities in the case of critical access hospitals under the above-described reimbursement provisions.

I presented an ACHD webinar on Effective Advocacy this month and continue to work with ACHD and CHA on legislation efforts.

Public Relations/Marketing

Last month I mentioned a new system for tagging our various types of marketing so that we can determine which methods are the most beneficial. Below is a summary of social media activity for February so far.

Most Viewed Categories 	 
▼ Recruitment	472
▼ TCCN	422
▼ Pharmacy	295
▼ Departments	180
▼ Thrift Store	161
▼ Foundation	149
▼ District	147
▼ Announcements	99.1
▼ Thank You	96.7
▼ Hospice	84.0
▼ Events	79.0
▼ Observances	50.2
▼ Clinic	39.7

We are developing Marketing materials and a brochure for Respiratory Therapy and working with the Director of Clinical Services on a marketing plan for the other clinical departments.

We sent letters and education materials via mail to 475 female clinic patients between the ages of 21-65. January was Cervical Cancer Awareness Month. With February being Heart Month, we sent heart health information via email to our Rural Clinic patients. As a part of our monthly “community facing events” we set up a table at Ray’s Market and provided heart healthy snack, recipes, and education. We also provided blood pressure checks and information on our Cardiac Rehab and Maintenance

Department. The event was received very well. We will be doing the same thing at Safeway in Burney. Provided information is also available on our website. [CLICK HERE](#).



Our next planned Quarterly Event is scheduled for March 27th at the Community Center in Burney. The focus will be on the great things to come at TCCN and education for Nutrition Month.

Foundation

See Foundation Quarterly Report

Tri County Community Network

Things are moving along down at the Tri County Community Network. With the Executive Director in place a lot has been accomplished in the last two weeks. The painting, ceiling tiles and lights are nearing completion. We are waiting on outside companies to get the IT networking going. Once that is completed, we will be able to move some of the finance staff to the upstairs portion of the building and start getting the building put back together.

We have already “opened” the front doors for access to the public to provide job and rental listings and have other agencies scheduled to come in beginning in April. The list of programs and services is growing, and we are excited to get things going. We hope to have the building ready to start a children’s summer program in June.

TCCN will be joining MHF in efforts to host a new and invigorated Health Fair event.

The “Lunch with Community Helpers” event is scheduled at TCCN in April.

There are a lot of great programs and activities filling the calendar. We will be putting out an event calendar soon.

February Board Report
Clinical Division
2/19/2024

Laboratory

- Sophia Rosal, CLS, laboratory manager, next area of focus is the revision of Policies and Procedures surrounding microbiology. The blood bank policies and procedures are working through committee.
- I am pushing for a timeline from Cerner to complete implementation of the auto-verification process for normal results. Abnormal lab results will be reviewed by a CLS per the normal process.
- An open ticket has been submitted to Cerner regarding obtaining an antibiogram from our resistance data.
- Issues remain with Cerner regarding diagnosis codes (ICD-10 codes) not being correct when providers order labs. Correcting these codes results in a delay of billing and if incorrect codes are submitted, payment can be denied.

Imaging

- We are reviewing pricing from two PACS vendors. We are currently working with Fuji Synapse and Sectra.
- Harold Swartz and Amanda Benson are in the process of completing their CT certifications.
- Harold Swartz, Imaging Manager, has interviews scheduled with two permanent candidates.
- We selected GlassBeam to help us obtain the data from our radiation producing machines to obtain our quality metrics for radiation safety and ACHC compliance.

Physical Therapy

- Alex Winn is working as a PT Intern to obtain hours prior to starting PT school.
- Daryl Schneider, PT manager, is working with LTC Cerner team as the PT notes lack some required components. Training on Cerner SNF module started 1/29/2023.
- Physical Therapists assignments have been adjusted to accommodate a therapist with an orthopedic injury.

Cardiac Rehab

- Cardiac Rehab reached a new record of 48 monitored patient visits in January. The department has been very busy. Laura Sanders is assisting with maintenance patients while Zita Beihle works with the monitored patients.
- To commemorate American Heart Month, Mayers is doing outreaches at Rays Market, February 20th, and Safeway, February 27th, from 2-4 p.m. We are promoting heart related services at Mayers and performing free blood pressure checks. Staff is also providing heart healthy snacks and recipes, and smoking cessation education in English and Spanish.
- The new exercised bike purchased through an award from Mayers Healthcare Foundation was put in use February 21st.

Hospital Pharmacy

- The refrigerator in the central hospital pharmacy is repaired.
- The hospital now stocks Balfaxar in the Emergency Department for reversal of life-threatening bleeds in patients taking oral anticoagulants.
- Pharmacy is working with Infection Prevention and Skilled Nursing Leadership on how to better treat and prevent recurrence of c.diff infections.
- Time is spent everyday working through Cerner tickets to make the EHR work the best.

Retail Pharmacy

- The second Customer Service Survey is going out this week and will be open for the next month with a 20% off OTC items coupon when the survey is taken in store.
- We have completed our 340B audits that were due to the transition of our new TPA
- Kristi Shultz, Associate Manager, and Keith Earnest, PIC, are working with Mountain Valleys Health Centers on ways we can collaborate.

Visiting Nurse Service

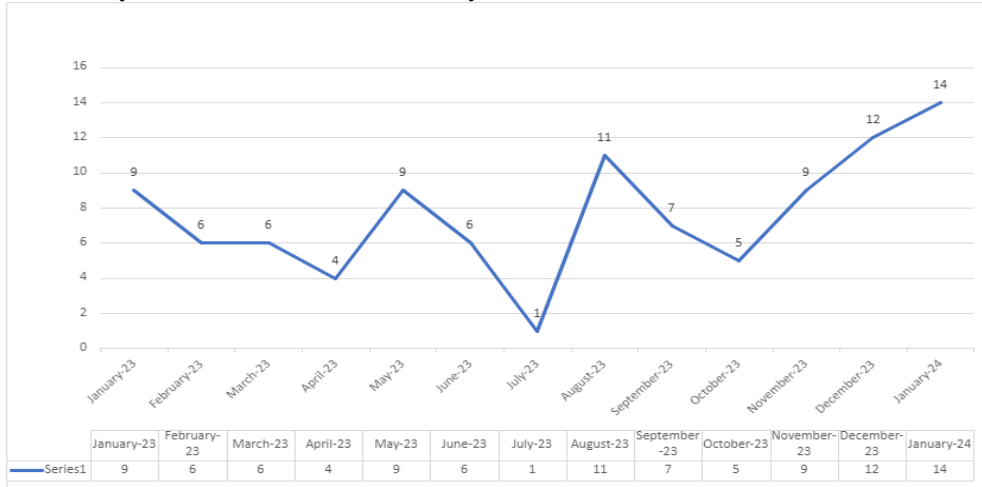
- We obtained some sample policies from Southern Humboldt Healthcare District.
- I have reviewed Cerner's Matrixcare Home Health software to see if it will be appropriate for a visiting nurse service. It would be an add on to the software hospice is already using. A quote has been requested.

Infection Prevention

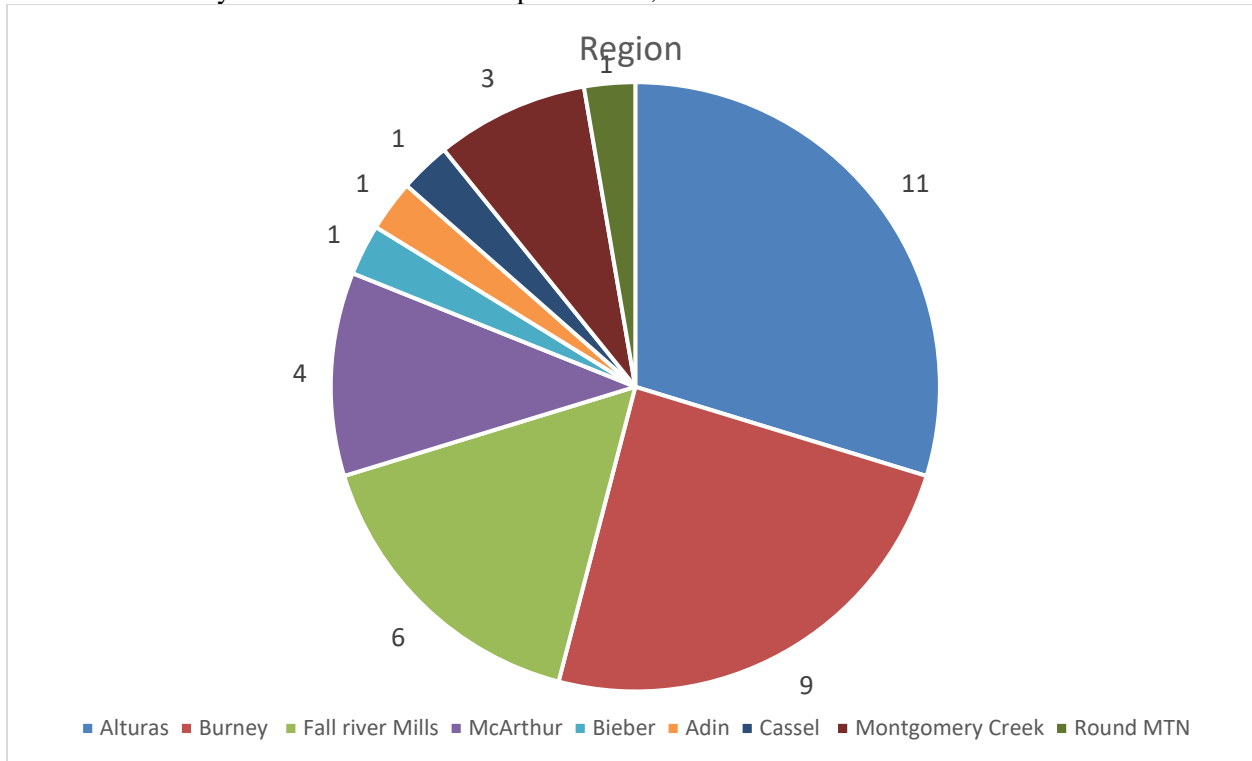
- We welcomed Maria Cuccinello, RN, as our interim Infection Preventionist. The goal with her time here is to streamline the processes and reporting so the IP is not tied to the computer and can be on the floor observing and educating staff.
- Maria is performing a Risk Assessment for the CAH and for SNF. Based on the findings each risk assessment, an Infection Prevention Plan will be created for the next year.
- As surgery/endoscopy will be restarting in March, Maria will be working with surgery staff on the areas of sanitation and sterilization.
- Another area of focus is the on boarding process for new staff and registry staff. Maria will be working hand in glove with nurse administration and the ACHC consultant.

Respiratory Therapy

- The new ABG machine from Nova-Biomedical is validated and is in use. The interface has been delayed as the assigned Cerner resource is also working on the Cerner skilled nursing build
- Three of the four Resmed ventilators are repaired and are back in service. The fourth ventilator required more repairs and is still being serviced.
- Pulmonary Function Tests Performed by month:



- Pulmonary Function Tests since September 18, 2023



NURSING SERVICES BOARD REPORT

February 2024

CNO Board Report

- CDPH returned to Burney Annex on Feb. 12 to reevaluate the Directed Plan of Corrections (DPOC) regarding the C.Diff violation. Upon exit, the state representative indicated good work had been done and that we needed to continue the course as directed in our DPOC.
- CDPH present at Burney Annex for complaint of low staffing related to sick staff. Surveyor exited with no deficiencies noted after review of staff schedule and sick log.
- Cerner build in progress for SNF with go live date Apr. 22nd
- ACHC regulations being reviewed with Quality and Acute Departments. Work in progress restructuring policies and procedures. Kickoff with ACHC consultant resulted in a burst of hope and still much work to be done.
- OPS process for opening March 11th with Dr. Syverson performing GI scopes. More detail under OPS.

SNF---See Quarterly SNF Board Report

Acute

- January 2024 Dashboard
 - Acute ADC 3.25, ALOS 4.20, Medicare ALOS 3.33
 - Swingbed ADC 2.41, ALOS 15
 - OBS Days
- January Staffing: Required 8 FTE RN/LVN's, 2 PTE RN's, 4 FTE CNA's & 2 FTE Ward Clerks
 - Utilizing 1 FTE Medifis, 1 FTE NPH RN, & 1 PTE NPH RN/LVN
 - Open positions: 2 FTE RN, Per Diem staff cover PTE
- Updates:
 - Tracking Cerner SR tickets and issues to complete follow up in streamline workflows.
 - Reviewing Statistical Data to identify gaps, and work with appropriate team members to rectify issues. Working with billing on deficient charts.
 - Working on Swing Bed Course, collaborating with team, and adjusting policies/workflows to better align with CMS guidelines and ACHC Standards.
 - Reviewing, updating, and reformatting policies to meet ACHC guidelines.

Emergency Services

- January 2024 Dashboard
 - Total treated patients: 355
 - Inpatient Admits: 24

- Transferred to higher level of care: 36
- Pediatric patients: 60
- AMA: 2
- LWBS: 4
- Present to ED vis EMS: 75
- January Staffing: Required 8 FTE RN, 2 PTE RN's, 2 FTE Tech's
 - Utilized 2 FTE contracted travelers
 - ED Manager continues with the temporary role of Project Manager for Cerner and key player in workflow changes, financial revenue review, and superuser, in addition to support the SNF Cerner launch.
 - Open positions: 1 FTE Noc RN
- Updates:
 - Reviewing, updating, and reformatting policies to meet ACHC guidelines.
 - Monitoring department workflows, identifying gaps, and working towards building skills fair and in-service courses to promote quality of care and meet ACHC guidelines.
 - 8-hour CEU for ED Techs on lethal arrhythmias, ventilation support management, and supporting the team during a code completed
 - 8-hour CEU course planned on the 25th for ED RN's was cancelled and to be rescheduled
 - TNCC Class to be held locally – dates pending
 - Monitoring patient charges, CPT codes, and documentation in Cerner system, identifying concerns, creating new workflows, and educating staff as needed.
 - Identifying quality reporting requirements and building streamlined process for obtaining accurate, efficient data

Outpatient Surgery

- Dr. Syverson, MMC, and MMHD have all agreed to proceed with the shared surgeon model. In this model, MMC will compensate Dr. Syverson for his time at MMHD using their existing contract, and MMHD will reimburse MMC for his services.
- Shannon Davidson, CRNA, MMC, and MMHD have all agreed to proceed with a shared anesthesia model. In this model, MMHD will compensate S. Davidson for her time at MMC. *Contract pending.*
- March 11th and 12th are scheduled as our official re-opening. Members from MMC will join us on site to streamline our opening and provide CERNER/educational support. *4 cases currently scheduled for March 11th* and looking at possibility of a ½ day for clinic.
- A staffing plan has been developed for March/ April with shared staff from Acute, OPM, and ED
- The surgical technician hired is continuing to work through her technician program. Currently sharing her time between pharmacy and OPS. She has begun traveling to MMC for on-site hands-on experience but due to obligations in pharmacy, this has been a slow process with minimal hours completed.
- Evaluating gaps in department and have been streamlining process for workflows.
 - Reviewing, updating, and reformatting policies to meet ACHC guidelines.

Ambulance Services

- Ambulance Runs-- 66 ambulance runs for the month of January. 24 of those were transfers.
- We have had an increase in calls and ground transfers to Reno, Sacramento, and Redding due to weather.
- We are still short 1 full time paramedic.

Outpatient Medical

- Census is 130 patients for January. This month OPM has high acuity patients.
- ACHC policy updates continued work.
- Continue to manually run statistics until we can find some good reports.
- Working toward following up on Cerner tickets/revenue issues/tracking open issues.
- Challenges are following cost capture and procedures. Continue to run reports and work with finance.
- Fully staffed.

CLINICAL EDUCATION

- **TRAINING CALENDAR**
 - Diabetes Webinar sponsored by American Heart Association was held in the Mayers Fall River Boardroom on 1/15/24 with 15 participants in attendance.
 - The calendar has been shared with CNA staff in in-services and includes 3 classes of 8-hour training for CNA staff to meet regulations for recertification. The staff will be scheduled by the manager and scheduling staff. The CNA staff continues to approve this process in recent classes with the DSD and Instructor.
 - Clinical Educator is working with 5 CNA staff needing to be scheduled for retesting with CDPH for recertification.
 - BLS training was held on January 16 and January 30. Audit of American Heart Association eCards assigned and HR/Evercheck records in progress.
 - PALS recertification training is scheduled on 2/22/24 and 3/5/24 for new employees and current staff requiring recertification.
 - Beta Safe Patient Handling Skills Fair will be scheduled for Spring TBD.
- **Nurse Assistant Training Program (NATP)**
 - The NATP resumed on 1/2/24 and was completed on 2/21/24. Three students (#3) will test for CDPH certification on 3/21 and orientated to work on the units when certification is received.
- **Special Project**
 - Clinical Educator is reaching out to like CAH in California for best practices in onboarding and assessing competencies for Registry Staff per CMS and CDPH regulations and of ACHC approval.

Respectfully Submitted by Theresa Overton, CNO

Chief Executive Officer Report

Prepared by: Ryan Harris, CEO

ACHC Accreditation

The ACHC consultant has already set week one milestones for the team and identified key gaps in our previous accreditation process. Collaborating with them has been exciting, and we are confident that with their help, we can successfully achieve our goal. While we are behind schedule for the fiscal year deadline, we are prioritizing the end result over the timeframe and are grateful for the consultant's clear roadmap for success.

Provider Search Update

I am pleased to announce that the contracted Physician Assistant has begun their role, and preparations are underway to interview a permanent Nurse Practitioner to take over once their contract expires. We are also finalizing arrangements for contracts with a new ER physician and CRNA. We also plan to post the position for the clinic physician and medical director by the end of February.

Skilled Nursing Update

I am pleased to report that the California Department of Public Health (CDPH) conducted a follow-up on our Immediate Jeopardy (IJ) tag. We received positive feedback from CDPH regarding our response and dedication to resolving root cause analysis issues. The team's outstanding efforts in crafting the response and conducting root cause analysis should be commended but ensuring accountability in the future needs to be ensured.

Chief Operations Officer Opening

I have received several applications for the Director of Operations position. The position will remain posted until 2/23, with interviews scheduled to take place between 2/26 and 3/8.

Solar Project

PG&E has furnished a cost estimate for a transformer upgrade from 300KVA to 750KVA, projecting a completion timeframe of 6-12 months with an estimated cost of \$173,334.04. Veregy is currently seeking clarification on the need for the upgrade and is in the process of arranging a call with PG&E to explore available options. The proposal was included in the latest board packet, but it is important to note that the estimate may be subject to adjustments based on the final scope of work.

Master Planning Criteria Documents

Progress is ongoing on the master planning adjustments that were deliberated upon at the previous month's meeting. A conceptual design is in the works for additional rooms at our new Rural Health Clinic (RHC) in Burney dedicated to specialty services. Furthermore, conversations have taken place with the leadership team about the potential establishment of Physical and Occupational Therapy services at the current RHC in Burney. This proposal, which involves repurposing existing space that is already OHSPD 3 compliant, aims to enhance PT accessibility

in the community and mitigate future wait times. Additionally, proposals are pending from the architect to renovate the RHC building in Fall River and an estimate for the associated costs.

Seismic Compliance Workgroup

At the seismic compliance workgroup meeting on 2/16/2024, I presented a proposal to separate seismic requirements from facility upgrades. The suggestion involves allocating State funding specifically for seismic elements of construction projects, while non-seismic upgrades would be the responsibility of the facility. Due to budget constraints, funding may face delays until 2030, with a 10-year extension for meeting compliance until 2040. This funding opportunity would be exclusively available to rural hospitals that are already compliant, and only until 2040. The objective is to align with the State's seismic and facility modernization objectives without placing the entire financial burden on the facility. This proposal, as well as others and recently introduced seismic bills will be explored at the Rural Healthcare symposium in early March.

QIP programs

We are currently in the process of identifying a secondary measure for PY6 (2023) that we can attain, with any anticipated funds arriving in 2025. Our measures for PY5 (2022) did not receive any funding, and it is probable that we may fall short of meeting the objectives for PY6 (2023). While the Quality team is dedicated to reaching our PY6 (2023) targets, there is a growing emphasis on preparing for PY7 measures and enhancing processes. Jack and I are collaborating on key areas for improvement, such as involving providers and staff in selecting PY7 measures, monitoring quality metrics regularly, addressing challenges in real-time, participating in QIP meetings and conferences, and exploring other initiatives. Furthermore, the possibility of implementing a quality coordinator position to oversee QIP and other quality programs throughout the year is under consideration.

Surgery

Surgeries are set to restart on March 11th, pending the finalization of an agreement with our CRNA.

Northern Sierra Section Meeting

I am scheduled to attend the Hospital Council Northern Sierra Section meeting with Partnership Leadership on Friday, February 25th in Chico. I am excited to participate in my first meeting with this group and will relay any relevant information to the board at our upcoming meeting.

Compliance Team Accreditation

The Rural Health Clinic and I have started our Compliance Team accreditation Renewal process. We are anticipating a reaccreditation survey in the next couple of months.

Masters Degree

I am excited to announce that I have successfully finished all required coursework for my Master's in Business Administration with a focus on Healthcare Management on Wednesday, February 14th. My graduation date is set for March 1st.

Telemedicine Program Update as of February 1st, 2024

Respectfully submitted by Samantha Weidner for Ryan Harris, CEO and Kimberly Westlund, Clinic Manager

We have completed a total of 2,764 live video consults since August 2017 (start of program).

Endocrinology:

- Dr. Bhaduri saw 25 patients in January. She continues to be our most productive, consistent provider.
- We've had 967 consults since the start of this specialty in August 2017.

Nutrition:

- Jessica saw three nutrition patients in January.
- We've had 200 consults so far since we started this specialty in November 2017.

Psychiatry:

- Dr. Granese saw six patients in January.
- We've had 691 consults since the beginning of the program in August 2017.

Infectious Disease:

- Dr. Siddiqui saw five patients in January.
- We've had 118 consults since the start of this specialty in September 2017.

Neurology:

- There were no neurology consults in the month of January. We now have a new Neurologist, Dr. Mandeville, on board. We have two blocks with him on 2/5 and 2/15. Currently, he is only able to see Partnership patients. We anticipate the CMS credentialing to be completed by the end of February.
- We've had 461 consults since the start of the program in November 2018.

Rheumatology:

- Dr. Tang saw eight patients in January.
- We've had 113 consults since the start of the program in May 2020.

Nephrology:

- Dr. Bassila saw three patients in January.
- We've had 24 consults since the start of the program in April 2023.

Talk Therapy:

- We began talk therapy services with Ryan McNeel, LCSW in mid-April 2023. We recently added 2 hours more to his block and have them filled as of now. Currently he sees five patients a week and this service has been going well.

Telemedicine Coordinator position:

- Amanda Harris will transition services over to Samantha Weidner permanently in February 2024.

