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SVHCD QUALITY COMMITTEE

AGENDA

WEDNESDAY, MAY 27, 2020
5:00 p.m. Regular Session

(Closed Session will be held upon adjournment of the Regular Session)

TO BE HELD VIA ZOOM VIDEOCONFERENCE

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AGENDA ITEM	RECOMMENDATION	
In compliance with the Americans with Disabilities Act, if you require special accommodations to attend a District meeting, please contact the District Clerk, Vivian Woodall, at vwoodall@sonomavalleyhospital.org or 707.935.5005 at least 48 hours prior to the meeting.		
MISSION STATEMENT *The mission of the SVHCD is to maintain, improve, and restore the health of everyone in our community.*		
1. CALL TO ORDER/ANNOUNCEMENTS	*Hirsch*	
2. PUBLIC COMMENT SECTION *At this time, members of the public may comment on any item not appearing on the agenda. It is recommended that you keep your comments to three minutes or less, Under State Law, matters presented under this item cannot be discussed or acted upon by the Committee at this time For items appearing on the agenda, the public will be invited to make comments at the time the item comes up for Committee consideration.*	*Hirsch*	
3. CONSENT CALENDAR • Minutes 02.26.20 (Revised) • Minutes 04.22.20	*Hirsch*	Action
4. SVH QUALITY INDICATOR PERFORMANCE AND PLAN	*Jones*	Inform
5. POLICIES AND PROCEDURES	*Jones*	Action
6. CLOSED SESSION: a. Calif. Health & Safety Code §32155: Medical Staff Credentialing & Peer Review Report b. Government Code §37624.3 and Calif. Health & Safety Code §§1461, 32155: Report of Medical Staff Bioethics Committee	*Hirsch* *Hirsch*	Action Inform
7. REPORT OF CLOSED SESSION	*Hirsch*	Inform/Action
8. ADJOURN	*Hirsch*	

SONOMA VALLEY HEALTH CARE DISTRICT
QUALITY COMMITTEE
February 26, 2020 5:00 PM
MINUTES
Schantz Conference Room

Members Present	Members Present cont.	Excused	Public/Staff
Jane Hirsch Susan Idell Ingrid Sheets Cathy Webber Carol Snyder	Howard Eisenstark, MD Michael Mainardi, MD		Sabrina Kidd, MD, CMO Danielle Jones, RN, Chief Quality Officer

AGENDA ITEM	DISCUSSION	ACTION
1. CALL TO ORDER/ANNOUNCEMENTS	*Hirsch*	
	5:03 pm	
2. PUBLIC COMMENT	*Hirsch*	
	None	
3. CONSENT CALENDAR		Action
• QC Minutes, 01.22.20		**MOTION:** by Mainardi to approve, 2nd by Eisenstark. All in favor.
7. SVH QUALITY INDICATOR PERFORMANCE AND PLAN	*Jones*	Inform
	Ms. Jones presented the quality indicator performance for January 2020. The Committee requested 1) national benchmarks be added; 2) report only cardiac deaths not present on admission that were strictly cardiac related, not due to some other primary cause; 3) include a definition of "total error reports" on good catches.	
8. PROPOSED QUALITY COMMITTEE CHARTER	*Jones*	Inform
	The sample charter was reviewed and changes suggested. Ms. Jones will send out a revised copy to the Committee.	

AGENDA ITEM	DISCUSSION	ACTION
9. POLICIES AND PROCEDURES	*Jones*	Action
	ORGANIZATIONAL **New:** Care of Unassigned Unaffiliated Metabolic Bariatric Surgery Patients PC810-190 **Revisions:** Code Grey – Aggressive Behavior Management CE8610-102 Code Pink – Infant Pediatric Security CE8610-148 Code Silver – Hostage-Active Shooter CE8610-147 Hospital Evacuation during Disaster EP8610-101 Patient's Rights to Visitation PR8610-166 Scope and Integration of Services GL8610-180 **DEPARTMENTAL** **New:** **Medical Records** Amendment of Protected Health Information 8700-185	**MOTION:** by Idell to approve, 2nd by Eisenstark. All in favor.
10. CLOSED SESSION	*Hirsch*	
a. Calif. Health & Safety Code § 32155 Medical Staff Credentialing & Peer Review Report	Called to order at 6:40 pm	
11. REPORT OF CLOSED SESSION	*Hirsch*	Inform/Action
	Medical Staff credentialing was reviewed.	**MOTION:** by Eisenstark to approve credentialing with correction, 2nd by Snyder. All in favor.
12. ADJOURN	*Hirsch*	
	6:42 pm	

SONOMA VALLEY HEALTH CARE DISTRICT
QUALITY COMMITTEE
April 22, 2020 5:00 PM
MINUTES
Schantz Conference Room

Members Present	Members Present cont.	Excused	Public/Staff
Jane Hirsch via Zoom Susan Idell via Zoom Ingrid Sheets via Zoom Cathy Webber via Zoom Carol Snyder via Zoom	Howard Eisenstark, MD via Zoom Michael Mainardi, MD via Zoom		Sabrina Kidd, MD, CMO via Zoom Danielle Jones, RN, Chief Quality Officer via Zoom Mark Kobe, CNO via Zoom

AGENDA ITEM	DISCUSSION	ACTION
1. CALL TO ORDER/ANNOUNCEMENTS	*Hirsch*	
	5:01 pm	
2. PUBLIC COMMENT	*Hirsch*	
	None	
3. CONSENT CALENDAR		Action
• QC Minutes, 02.26.20		**MOTION:** by Mainardi to approve, 2nd by Idell. All in favor.
4. SVH QUALITY INDICATOR PERFORMANCE AND PLAN	*Jones*	Inform
	Ms. Jones reviewed quality indicator performance for the month of March. CMS has allowed hospitals to delay publicly reporting data until June 2020 (including 2019 Q4 and 2020 Q1) due to COVID-19. Some of the reportable measures were in contradiction to recommended care for COVID-19.	
5. CENTER FOR IMPROVEMENT IN HEALTH-CARE QUALITY CORRECTIVE ACTION PLAN	*Jones*	
	Ms. Jones reviewed citations from the recent CIHQ survey. Those conditions will be relieved by the plan of correction which has been accepted. She indicated there were many	

AGENDA ITEM	DISCUSSION	ACTION
	small plant and facilities citations that were corrected prior to the surveyors leaving the site. Normally those are not cited, but this time they were so the report was lengthy. Ms. Jones will report quality improvement plans quarterly to this Committee.	
8. PROPOSED QUALITY COMMITTEE CHARTER	*Jones*	Inform
	Revisions to the charter were discussed. Further action was delayed until May.	
PATIENT CARE SERVICES DASHBOARD		
	Mr. Kobe reviewed the patient care services dashboard.	
9. POLICIES AND PROCEDURES	*Jones*	Action
	ORGANIZATIONAL **New:** Admits, Transfers, Readmissions PC8610-192 Management of Medical Emergencies in Off-Site Locations PC 8610-192 Pest Management Program CE8610-184 **Revisions:** Hazardous Materials and Waste Management Plan CE8610-140 Medical Waste Management Plan CE8610-158 Storage of Medications MM8610-123 Department Specific Performance Improvement (PI) Plan QA8610-104 Formalin Spill Cleanup LB8610-106 Pathology Specimen Handling LB8610-122 Reporting of Quality Monitoring and Performance QA8610-106 Sara Lite Lift PC8610-165 Reviewed/No Changes: Use of Medication Not Procured by the Facility MM8610-116 AccuChek Inform II Glucose Monitoring system LB8610-102 Patient Safety Evaluation System QA8610-101	**MOTION:** by Eisenstark to approve, 2nd by Sheets pending corrections on a few of the new policies. All in favor.

AGENDA ITEM	DISCUSSION	ACTION
	DEPARTMENTAL **New:** Metabolic and Bariatric Anesthesia Protocol 7430-109 Maggot Therapy 7740-109 Failure of HVAC Systems 8450-15 Failure of Sewer Services 8450-14 **Revisions:** EMTALA COBRA Transfers 7010-07 Cancellation No Show Wound Care 7740-102 Battery Powered Exit Lights 8450-100 Bulk Liquid Oxygen 8450-77 Electrical Failure 8450-63 Emergency Generator Testing 8450-65 Equipment Inventory 8450-48 Fire Alarm Testing 845091 Medical Gases Procurement and Contingency Plan 8450-76 Utilities Failure Phone List 8450-38 Vendor Contact List 8450-31 Linen Management Services 8440-43 Imaging Scope of services 7630-233 Medical Staff QAPI 8710-105 Diet Manual 8340-151 **Reviewed/No Changes:** AccuChek Certification and Recertification 7500-100 AccuChek Meter Replacement 7500-102 Individualized Quality Control Plan 7500-104 **Retire:** Emergency Battery Powered Lights 8450-90	
COVID-19 UPDATE		
	Dr. Kidd reported on the COVID-19 situation at SVH. The Incident Command Center has been open since early March. A core group of 20 staff have been meeting every day and have planned for a surge, increasing beds from 24 to 59, with room for 70+ if needed. SVH has been in close contact with affiliate UCSF to share supplies, protocols, and ask questions. UCSF will be part of the exit strategy as well. The hospital has stabilized from the first wave and is	

AGENDA ITEM	DISCUSSION	ACTION
	starting to focus on what comes next. It has been following County, State, and CDC guidelines throughout. There have been no surgeries other than emergencies since mid-March. The supply chain has not been restored at this point so SVH has to monitor personal protective equipment (PPE) carefully. Starting up surgeries would require a high volume of that equipment. The hospital has prepared an exit strategy with criteria to enact it. Precautions are with us to stay for the near future. Criteria include the need to have adequate PPE (30 days) and 14 days with no new cases. There will need to be a unified plan on opening back up, since many employees are from other counties.	
10. CLOSED SESSION	*Hirsch*	
a. Government Code §54956.9(d)(2): Discussion Regarding Significant Exposure to Litigation **b.** Calif. Health & Safety Code § 32155 Medical Staff Credentialing & Peer Review Report	Called to order at 6:36 pm.	
11. REPORT OF CLOSED SESSION	*Hirsch*	Inform/Action
	Medical Staff credentialing was not reviewed. The Committee had no credentialing report. An unusual occurrence with significant exposure to litigation was discussed.	No action was taken.
12. ADJOURN	*Hirsch*	
	6:45 pm	

Quality Indicator Performance & Plan

May 2020

Data for April 2020

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MORTALITY

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Scorecard Summary
Mortality

Status	Indicator	Current Value	Target	SPC Alert	Updated
Quality > Autopsies Mortalities					
▲	Acute Care Mortality Rate (M)	5.3%	n/a		Apr 2020
▲	DV Inpatients - Percent Transferred to Hospice (M)	7.7%	n/a		Apr 2020
Quality > Process of Care > Sepsis Care					
● ▲	Sepsis, Any Diagnosis - Mortality Rate (M)	16.7%	0.0%		Apr 2020
● ▲	Sepsis, Principal Diagnosis - Mortality Rate (M)	18.2%	0.0%		Apr 2020
● ▼	Sepsis, Secondary Diagnosis - Mortality Rate (M)	0.0%	0.0%		Apr 2020
● –	Sepsis, Severe - Mortality Rate (M)	0.0%	0.0%		Apr 2020
● ▲	Sepsis, Simple - Mortality Rate (M)	10.0%	0.0%		Apr 2020
● ▲	Septic Shock - Mortality Rate (M)	100.0%	0.0%		Apr 2020
● ▲	Severe Sepsis or Septic Shock - Mortality Rate (M)	50.0%	0.0%		Apr 2020

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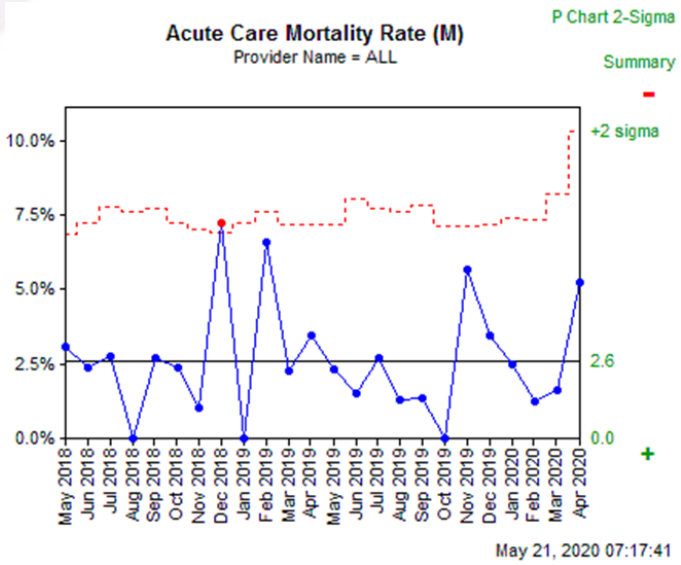
Sepsis Mortality Rate

Period	CDB009 - Acute Care - Mortality Rate (numerator)	CDB009 - Acute Care - Mortality Rate (denominator)	Percent
Apr 2020	2	38	5.3%
Mar 2020	1	61	1.6%
Feb 2020	1	81	1.2%
Jan 2020	2	80	2.5%
Dec 2019	3	86	3.5%
Nov 2019	5	88	5.7%
Oct 2019	0	89	0.0%
Sep 2019	1	72	1.4%
Aug 2019	1	76	1.3%
Jul 2019	2	74	2.7%
Jun 2019	1	66	1.5%
May 2019	2	85	2.4%



- Case Review
  - April 2020
  - Two mortalities
  - Hospice
    - Working with Information Systems and the Hospitalists group to create a process to discharge from inpatient status and admit to hospice status

Mortality rate among acute care inpatient encounters with a principal or secondary discharge diagnosis of severe sepsis or septic shock

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PREVENTABLE HARM EVENTS

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Scorecard Summary

AHRQ Patient Safety Indicators

Preventable Harm

Status	Indicator	Current Value	Target	SPC Alert	Updated
Quality > Patient Safety > AHRQ Patient Safety Indicators_PSI					
▼	AHRQ v6.0 PSI 03 Pressure Ulcer Rate |M|	0.0%	0.0%		Apr 2020
–	AHRQ v6.0 PSI 04 Death in Surgical IP with Serious Complications overall|M| per 1,000 py days	0.00	163.10		Mar 2020
–	AHRQ v6.0 PSI 06 Iatrogenic Pneumothorax Rate |M|	0.0%	0.0%		Apr 2020
–	AHRQ v6.0 PSI 08 In-Hospital Fall with Hip Fracture Rate |M|	0.0%	0.0%		Apr 2020
–	AHRQ v6.0 PSI 09 Perioperative Hemorrhage or Hematoma Rate |M|	0.0%	0.0%		Apr 2020
–	AHRQ v6.0 PSI 10 Post-Operative Acute Kidney Injury Requiring Dialysis Rate |M|	0.0%	0.0%		Mar 2020
–	AHRQ v6.0 PSI 11 Postoperative Respiratory Failure Rate |M|	0.0%	0.0%		Mar 2020
–	AHRQ v6.0 PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate |M|	0.0%	0.0%		Apr 2020
–	AHRQ v6.0 PSI 13 Postoperative Sepsis Rate |M|	0.0%	0.0%		Mar 2020
–	AHRQ v6.0 PSI 14 Postoperative Wound Dehiscence Rate|M|	0.0%	0.0%		Mar 2020
–	AHRQ v6.0 PSI 15 Accidental Puncture or Laceration Rate |M|	0.0%	0.0%		Mar 2020

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Scorecard Summary
Patient Falls
Preventable Harm

Status	Indicator	Current Value	Target	SPC Alert	Updated
Quality > Patient Safety > Falls					
▼	RM ACUTE FALL- NO INJURY (M) per 1000 patient days	0.00	0.00		Apr 2020
–	RM ACUTE FALL- WITH INJURY (M) per 1000 patient days	0.00	0.00		Apr 2020
–	RM ED FALL- NO INJURY (M) per 1000 patient days	0.00	0.00		Apr 2020
–	RM ED FALL- WITH INJURY (M) per 1000 patient days	0.00	0.00		Apr 2020

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Scorecard Summary
Coded Complications of Care
Preventable Harm

Quality > Patient Safety > Coded Complications of Care

Acute Postop Respiratory Insufficiency NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Acute Postop Respiratory Insufficiency, NPOA - Per 1000 ACA w/ Surgical Proc (M)	0.00	0.00		Apr 2020
Air Embolism NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Cardiac Arrest- per 1000 ACA (M)	26.32	n/a		Apr 2020
Cardiac Arrest-NPOA per 1000 ACA (M)	0.00	0.00		Apr 2020
Cardiac Complications NPOA per 1000 ACA (M)	0.00	0.00		Apr 2020
Cardiogenic Shock NPOA per 1000 ACA (M)	0.00	0.00		Apr 2020
Deaths per 1000 ACA Elective Admission (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Cardiac Incl. Valve, NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Genitourinary/Urologic NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Nervous System NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Orthopedic Device NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Other/NEC Device NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Vascular Device NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Complications, Vascular NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Functional Complications NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant Other Complications NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Device/Implant, Inflammatory Reaction NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Digestive System Complications NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Disruptions of Operative Wound, NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020

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Scorecard Summary
Coded Complications of Care
Preventable Harm

DVT/PE, Orthopedic, NPOA - Per 1000 Inpatients w/ Total Knee/Hip Replacement (M)	0.00	0.00		Apr 2020
Iatrogenic Pneumothorax NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Iatrogenic Pulmonary Embolus NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Infection from Central Venous Cath, NPOA - Per 1000 Inpatients w/ CV Cath (M)	0.00	0.00		Apr 2020
Intraoperative Injuries NPOA- Per 1000 ACA with a Surgical Procedure (M)	0.00	0.00		Apr 2020
Nervous System Complications NPOA- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Other Complications NPOA- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Peripheral Vascular Complications NPOA - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Postoperative Hemorrhage_Hematoma NPOA - Per 1000 ACA with surgical procedure (M)	0.00	0.00		Apr 2020
Postoperative Infection - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Postoperative Pulmonary Edema - Per 1000 ACA (M)	0.00	0.00		Apr 2020
Postoperative Pulmonary Edema NPOA with Surgical Procedure- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Postoperative Shock NPOA with Surgical Procedure- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Respiratory Complications NPOA- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Retained Foreign Body NPOA- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Transfusion Reaction, all types NPOA- Per 1000 ACA (M)	0.00	0.00		Apr 2020
Urinary Complication NPOA- Per 1000 ACA (M)	0.00	0.00		Apr 2020

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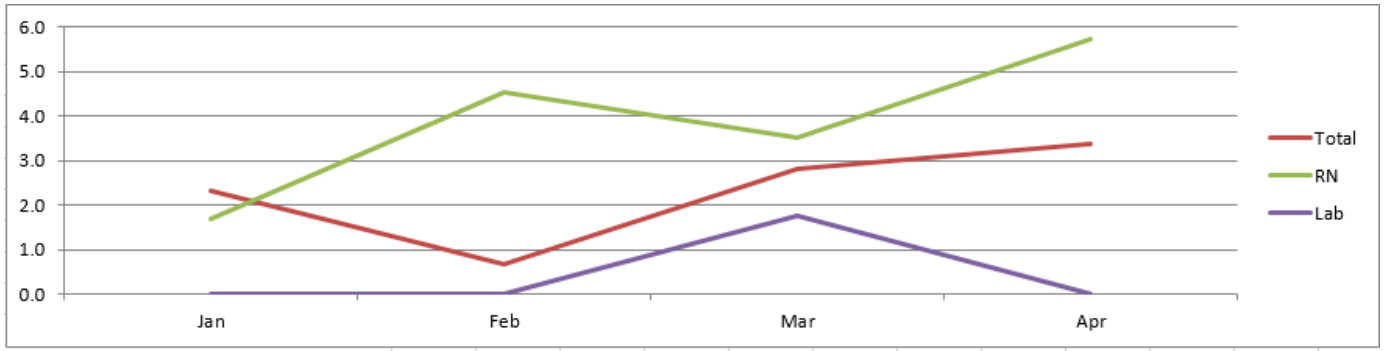
Scorecard Summary

Blood Utilization

Blood Culture Report - Monthly for 2020				
	Jan	Feb	Mar	Apr
Total Blood Cultures Processed	130	147	142	118
True Postive Cultures	6	11	7	11
True Postive Culture Rate (percent)	4.6	7.5	4.9	9.3
Total Contamination Cultures	3	1	4	4
Total Contamination Rate (percent)	**2.3**	**0.7**	**2.8**	**3.4**
Acceptable Contamination Rate ≤3.0%	Yes	Yes	Yes	No
Blood Cultures Drawn by RN Staff	59	66	85	70
Contaminated Culture Reported	1	3	3	4
RN Contamination Rate (percent)	*1.7*	*4.5*	*3.5*	*5.7*
Acceptable Contamination Rate ≤5.0%	Yes	Yes	Yes	No
Blood Culture Drawn by Lab Staff	88	64	57	48
Contaminated Culture Reported	0	0	1	0
Lab Contamination Rate (percent)	*0*	*0*	*1.8*	*0.0*
Acceptable Contamination Rate ≤3.0%	Yes	Yes	Yes	Yes



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HEALTHCARE ACQUIRED INFECTION

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Infection Prevention Report: 4th Quarter 2019

Indicator	Comparison Rates: 2013-2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019
Quarterly reporting of National Healthcare Safety Network (NHSN) indicator data is required by CDPH. NHSN provides the predicted number of HAIs based on standardized infection rations (SIRS). ** indicates public reporting on CDPH website. Green indicates no action indicated, yellow indicates					
***CLABSI (NHSN) (CMS Never Event)** *# Central Line Associated Bloodstream infections (CLABSI)/1000 central line days*	**0 since 2011**	**0** 0/108	**0** 0/89	**0** 0/51	**0** 0/77
***CDI (NHSN)** *#Inpatient Hospital Acquired infections due to C. difficile per 10,000 patient days*	**2.1 /7.2 /12 15/21.7/7.5**	**0** 0/872	**0** 0/901	0 **0/821**	**9.9** 1/1006
***MRSA Bloodstream Infections (NHSN)** *#bloodstream infections due to MRSA per 1000 pt. days*	**1.3 /0 /0 0/ 0/0**	**0** 0/872	**0** 0/901	**0** 0/821	**0** 0/1006
***VRE Bloodstream Infections (NHSN)** *#Hospital Acquired bloodstream infections due to VRE per 1000 pt. days*	**0 x 6 yrs**	**0** 0/872	**0** 0/901	**0** 0/821	**0** 0/1006
***Hip: Deep or Organ Space Surgical Site Infections (NHSN)** *# infections/ # Total Hip Cases x 100*	**0 / 1.8% / 0 1.6% / 0**	**0** 0/11	**0**	**0** 0/12	**0** 0/15
***Knee: Deep or Organ/Space Surgical Site Infections (NHSN)** *# infections/ # Total Knee Cases x 100*	**0 / 1.7% / 2 1.4% / 1.3%/3.5**	**0** 0/17	**0**	**0** 0/14	**0** 0/19
***Overall Surgical Site Infections (SSI)** *Total # SSI/Total # surgeries x 100*	**0.2%/0.7% (12)/ 0.4% (6)/ 0.5% (8)/ 0.4% (8)**	0.4% 2/473	**0.8%** **5/586**	**0** 0/462	**0.4%** 2/532
Class I SSI rate	**<1% x 5 yrs**	0.2% 1/409	**0.9%** **4/420**	0 0/373	0.2% 1/470
Class II SSI rate	**< 1.3% x 5 yrs**	0 0/56	**0 0/54**	0 0/61	0 0/44
Total Joint SSI rate	**0 / 0.8%/1.9%/1.4%/1.4%**	**0**	**0**	0 0/23	0 0/39
Post discharge surveillance surgeon compliance	**57%, 64%, 84%, 96.5%, 95.3%**	92% Jan sample	**90.5% Apr/May**	90% Jul/Aug	90% Oct/Nov
Hand Hygiene Compliance *hand hygiene observations: # opportunities/# hand hygiene procedure observed*	**2017 98.7%** **2018 92.7%**	**95%** **19/20**	**100&** **19/19**	**100%** 23/23	

****Ventilator Associated Event (VAE)** *# Ventilator Associated Pneumonias or events/ # vent days x 1000*	**0 x 4 yrs.**	**0** 0/7	**0 0/23**	**0/0**	**41.6 1/24**
****Hospital Acquired Pneumonia (HAP)** *# hospital acquired pneumonia/# pt days x 1000 pt days*	**0.2/0.5/0.9/1.6/ 0.7**	acute 0/872 SNF 0/988	1.1 1/901	0 0/821	0.1 1/1006
****Inpatient Hospital Acquired Catheter Associated Urinary Tract Infections (CA-UTI) (CMS Never Event)** *# inpatient CAUTI/# catheter days x 1000*	**0.7 /0 / 1.7 1.4/1.6/0.85**	**0** 0/197	**4.6** 1/217	**0** **0/221**	**0** **0/274**
Communicable Disease Exposures		1	1	**0**	**0**
MRSA Active Surveillance Cultures (nares cultures only) *# positives/total screened x 100*	**14%, 20%, 26%** **9.2%/5.8%**	**9.5%** 10/105	**11%** 11/100	**6.3%%** 5/80	**9.7%** 9/93
% ESBL (E. coli;K. pneumoniae, K. oxytoca, P. mirabilis)	**2% /3%/4.2%/4.1%**	7%	15.5%	7.7%	7.6%
# CRE cases	**0/0/0/1**	1 (0.34%)	0	0	1(.34%)
Legionella Monitoring: water samples and patients with HA pneumonia		0	0	0	0
Environmental Cleanliness Monitoring	95%	97%	96%	100%	100%
Total Influenza Vaccination All HCP	80%, (2018)				
Physicians, LIP, PAs		81%			pending
Employees		87%			89%
Volunteers	100%	pending			
Students		100%			100%
Patients		64 flu shots			50 flu

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MEDICATION EVENTS

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Scorecard Summary
Adverse Drug Events

Quality > Pharmacy > Adverse Drug Events					
▼	Rx-ADEs-Administration Errors Per 10,000 Doses	0.62	1.00		Apr 2020
▲	Rx-ADEs-High Risk Med Errors Per 10,000 Doses	0.62	1.13		Apr 2020
—	Rx-Adverse Drug Reactions	4	n/a		Q1-2020
—	Rx-Adverse Drug Reactions-Antibiotics	25%	n/a		Q1-2020
▲	Rx-Adverse Drug Reactions-Anticoagulants	25%	n/a		Q1-2020

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CORE MEASURES

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Scorecard Summary
Core Measures

Quality > Core Measures					
▼	Core OP-18b - Median Time ED Arrival to ED Departure - Reporting Measure (M)	128.50	140.00		Apr 2020
—	Core OP-23 - Head CT/MRI Results for STK Pts w/in 45 Min of Arrival (M)	100.0%	72.0%		Apr 2020
Quality > Core Measures > HOP Measures > HOP Colonoscpy					
▲	Core OP29/ASC9 - Colonoscopy:F/U for Avg Risk Pts (M)	75.0%	89.0%		Mar 2020

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READMISSION

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Scorecard Summary
Readmissions
Sepsis

Quality > Process of Care > Sepsis Care					
Sepsis, Severe - % Readmit within 30 Days (M)	0.00%	0.00%		Apr 2020
Sepsis, Simple - % Readmit within 30 Days (M)	0.00%	0.00%		Apr 2020
Septic Shock - % Readmit within 30 Days (M)	0.00%	0.00%		Mar 2020

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Scorecard Summary
Readmissions

Quality > Readmissions					
07-DV Inpatients - % Readmit to Acute Care within 07 Days (M)	0.0%	8.0%		Apr 2020
14-DV Inpatients - % Readmit to Acute Care within 14 Days (M)	0.0%	8.0%		Apr 2020
30-DV Inpatients - % Readmit to Acute Care within 30 Days (M)	0.0%	8.0%		Apr 2020
AMI, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)	0%	16%		Nov 2019
COPD, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)	0%	20%		Apr 2020
HF, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)	0%	22%		Apr 2020
Hip/Knee, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)	0.00%	4.00%		Mar 2020
Medicine, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)	0%	0%		Apr 2020
PNA, CMS Readm Rdctn - % Readmit within 30 Days, ACA (M)	0%	17%		Apr 2020
Sepsis, Any Diagnosis - % Readmit within 30 Days (M)	0%	0%		Apr 2020
Surgery, CMS Readm Rdctn -% Readmit within 30 Days_ ACA |M|	0.00%	8.00%		Apr 2020

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PDSA QUALITY IMPROVEMENT PROJECTS Q2 2020

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100 Day Work Outs

- Laboratory reorganization and restructure
- Point of service collections
- Reference lab send outs for complex/molecular orders
- Contaminated blood cultures
- Bad debit
- Physician discharge documentation
- Total joint patient status
- ICIMS applicant tracking
- Medication Reconciliation
- One Call Now

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CIHQ ACUTE STROKE READY SURVEY

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SRH-4 Care of the Stroke Patient in the Emergency Department

- Finding
  - Physician summary of care contained missing required elements
- Action Plan
  - A standardized template for stroke documentation by emergency department physicians has been developed that includes documentation criteria to support the recognition, assessment and management of stroke

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SRH-4 Care of the Stroke Patient in the Emergency Department

- Finding
  - The initial assessment using the NIH stroke scale and the repeated assessment after 2 hours were not timed
- Action Plan
  - Staff will sign attestation concerning the important requirement to document initial and 2 hour NIH scale Date and Time. NIH Stroke Scale will be completed initially on arrival and repeated in two hours. The entries will be dated, timed and signed

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SRH-6: Admission & Transfer

- Finding
  - The record contained conflicting information concerning the disposition of the patient
- Action Plan
  - Staff will sign attestation indicating understanding of importance of documentation of correct patient disposition and review Stroke transfer policy and procedure. Patient disposition has been added to the internal code stroke sheet for data collection and monitoring

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CDPH INFECTION PREVENTION COVID SURVEY

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Focus

- Standard precautions
- Transmission precautions
- PPE
- Environmental cleaning protocols
- Infection surveillance
- Visitor, Staff and patient screening
- Emergency preparedness plan
- Competencies for dawning and doffing PPE

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Findings

- The CDPH surveyors were impressed with SVH preparedness related to COVID-19 and the front line staff knowledge of personal protective equipment guidelines
- We are working to update the N95 reuse protocol

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HUMAN EXPERIENCE

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Human Experience vs. Patient Experience

- Improving Human Experience = Creating respectful, empathetic interactions that deliver joy and ease suffering for all people involved in healthcare, patients, families, and care team members
  - Leadership meeting in early June to develop a plan to take our culture to the next level

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Policy and Procedures – Summary of Changes
Board Quality , May 27, 2020

Review and Approval Requirements

The SVH departmental/organizational policies and/or procedures on the attached list have been reviewed and approved by the P&P Team and organizational leaders for meeting all of the following criteria. All of these policies and procedures are:

- Consistent with the Mission, Vision and Values of the Sonoma Valley Health Care District
- Consistent with all Board Policy, Hospital Policy and Hospital Procedures
- Meet all applicable law, regulation, and related accreditation standards
- Consistent with prevailing standards of care
- Consistent with evidence-based practice

We recommend their acceptance by the Medicine Committee.

ORGANIZATIONAL

NEW: None to report

REVISIONS:

Assessment and Disposition for Psychiatric Patients In the ED
Added psychiatric assessment, screening for potential suicide/self harm risk to be completed by RN. Added environmental risk assessment. Added Consult with SVH Social Worker and consult with Psychiatrist on call.

Clinical Nursing Procedures PC8610-124
Included Respiratory Therapy clinical practices, and update to Dynamic Health from Lippincott. Several Respiratory Therapy policies have been retired as a result of update to Dynamic Health.

REVIEWED/NO CHANGES:

Informed Consent PR8610-134
Advanced Directives PR8610-100

DEPARTMENTAL

NEW:

Physical Therapy

Medical Emergencies in SVH Hand and Physical Therapy Clinic 7770-141
Hazardous Material Handling in the Outpatient rehabilitation Clinic 7770-143

Laboratory

C. Difficile By PCR 7500-100

REVISIONS:

Wound Care

Conservative Sharp Debridement 7740-103
Changes include approved by to Chief Ancillary Officer. Removed brand names of antiseptic, reference to resident and hand sanitizer, added use of 2 patient identifiers

Pulse Lavage 7740-140
Changes include approved by to Chief Ancillary Officer. Expanded PPE to Personal Protective Equipment, moved reference to hand sanitizer and resident.

Silver Nitrate, Use of 7740-105
Changes include approved by to Chief Ancillary Officer. Reference to MSDS instructions, removal of brand name calmoseptine. Removal hand santizer (redundant), replace doff with remove and added reason for skin barrier.

Physical Therapy
Cold Pack Usage 7770-103
Update to procedure for additional safety and precautions. Reference added. Triennial review.

Department Staffing Plan 7770-109
Changes made to coincide with changes in Rehab care delivery at SVH. Triannual Review.

Discharge Criteria of Rehabilitation Patients 7770-111
Change made to reflect CIHQ standard to notify patients in writing prior to discharge.

Gaits Belts, Use and Cleaning of 7770-117
Change to allow therapist to use Clorox wipe on plastic belt after use.

Iontophoresis 7770-127
Change to use single vials and add reference.

Respiratory Therapy
PB 840 Ventilator 7721-57
Included Dynamic Health as the trusted clinical resource for SVH. Formatting changes.

Phillips V60 BiPap 7721-12
Updated equipment added Patients with Obstructive Sleep Apnea or Central Sleep Apnea.

Scope of Service 7721-66
Updated this scope to reflect Respiratory Therapy services, separate from Cardiopulmonary.

Vapotherm High Flow System 7721-71
Added definitions for Fi02 and liters per minute.

Laboratory
Quarantined Blood Products 7500-102
Updated policy in response to CIHQ survey. Policy Name Change to Compromised Blood Products.

REVIEWED/NO CHANGES:
Physical Therapy
Cancellation Policy 7710-100
Clinical Competency 7770-101
Contested Decision to Discontinue Skilled Rehab Services 7770-105
Collection of Co-Payment 7770-107
Downtime Scheduling Procedure 7770-112
Fluidotherapy Usage 7770-113
Frequently Used Terminology and Abbreviations 7770-115
Hot Pack/Heating Pad Usage 7770-119
Hoyer Lift 7770-121

Ice Massage 7770-123
Initial Evaluation 7770-125
MD Notification 7770-129
Paraffin Use 7770-131
Patient Education 7770-133
Phonophoresis 7770-135
Transcutaneous Electrical Nerve Stimulation 7770-137
Ultrasound 7770-139

Retire
Respiratory Therapy
Aerosol Therapy T Piece or Tracheostomy Mist
Alert Patient Protocol for Continuous CPAP
Arterial Blood Gas Sampling Recommended Parameter
Arterial Puncture for Blood Gas Analysis, Technique for Performing
Auto Vent 3000
CPAP Treatment Procedure Alert Patient Protocol, CPAP Mask Procedure
Cuff Leak Assessment
Cuff Pressure Indicator
Education Home Care Use of Compressor and Nebulizer Therapy
Extubation Procedure
Gas Cylinders Protocol
Incentive Spirometry Indications
Incentive Spirometry
Infant Oxyhood
Infection Control
Metered Dose Inhaler Therapy
Nasotracheal Suctioning-Recommended Parameters
Oral Care for the Mechanically Ventilated Patient
Oxygen Administration Per Nasal Cannula
Oxygen Administration Per Venturi Mask Procedure
Oxygen Delivered by Disposable Face Mask
Oxygen Delivery by High Concentration Mask, Non-rebreather Mask
Pulse Oximetry

SUBJECT: Medical Emergencies in SVH Hand and Physical Therapy Clinic	POLICY: 7770-141
	PAGE 1
DEPARTMENT: Rehab	EFFECTIVE:
REVISED:	

NEW POLICY
To assure that adequate provisions are made for the availability of emergency services at non-emergency department locations, specifically the SVH Hand and Physical Therapy Clinic.

WHY: To assure that there are trained and qualified personnel immediately available to determine if a patient has an emergency medical condition. Provide necessary stabilizing medical treatment within the capabilities of the location. Refer or transfer the patient to a facility with the appropriate capabilities to manage the patient's conditions. Meet all requirements noted under 42 CFR 482.12(f).

OWNER: Manager Rehab Services

AUTHORS/REVIEWERS: Christopher Gallo

APPROVALS:
Policy & Procedure Team:
Medicine Committee:
Medical Executive Committee:
Board Quality Committee:
The Board of Directors:

SUBJECT: Medical Emergencies in SVH Hand and Physical Therapy Clinic	POLICY: 7770-141 PAGE 1
DEPARTMENT: Rehab	EFFECTIVE:
REVISED:	

PURPOSE:
To ensure that there is an immediate and effective response to a medical emergency in the practice.

POLICY: It is the policy of the practice to prepare and respond to all medical emergencies. A medical emergency is defined as a medical condition that manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in 1) placing the health of the individual in serious jeopardy, 2) serious impairment to bodily functions, 3) serious dysfunction of any bodily organ or part.

1. **PROCEDURE:** The practice maintains clinical staff qualified in basic life support (BLS) because effective and efficient performance of BLS depends on adequate training and practice.

2. The clinical staff routinely reviews “code blue” procedures and conducts drills no less than every twelve months.

3. The practice maintains an AED. This is checked on a monthly basis.

4. Any clinician or employee who discovers a patient, visitor, or employee needing emergent care is responsible for activating the emergency medical system. This involves:

    a. Getting appropriate assistance including notifying an employee who is currently trained in cardiopulmonary resuscitation (CPR).

    b. Calling 911 to notify them of the emergency and exact location.

5. The first staff on scene shall evaluate the situation and initiate appropriate First Aid and/or BLS measures.

6. The first clinician on the scene is responsible for managing the emergency situation until paramedics arrive. He or she should then assist as necessary. If the patient requires CPR, the clinician can delegate roles as he or she sees fit for the effective performance of resuscitation. At a minimum, this includes at least three personnel:

SUBJECT: Medical Emergencies in SVH Hand and Physical Therapy Clinic	POLICY: 7770-141
	PAGE 1
DEPARTMENT: Rehab	EFFECTIVE:
REVISED:	

a. One person responsible for airway management;
b. One person responsible for chest compressions; and
c. One person to record the events.

7. CPR is continued until paramedics take over.

8. An employee is assigned to Sonoma Highway and the front door to the clinic to direct paramedics to the emergency location.

9. Patients are then transported by ambulance to the hospital emergency department.

10. The first clinician on the scene shall make an entry into **Midas+™ Remote Data Entry portal** to create a record and document the situation. The clinician will work with any eye witnesses and the person assigned to document the situation. Following a "code blue" event, the clinician will review the record for accuracy and completeness. He or she completes and submits an incident report to **Midas+™ Remote Data Entry.**

11. Every actual "code blue" event is followed within two working days by a meeting of all involved providers and employees at which time performance is reviewed and suggestions for improvement are noted.

12. Equipment needs are reviewed annually based on the needs of patients.

13. Emergency response drills will be performed annually.

REFERENCES:

The MGMA Operating Policies and Procedures Manuel. Woodcock, Elizabeth. 5th edition. 2016.
Medical Emergencies in the Physician Practice, POLICY #PC7073-102

42 CFR 482.12(f).

SUBJECT: Hazardous Material Handling in the Outpatient rehabilitation Clinic	POLICY: 7770-143
	PAGE 1
DEPARTMENT: Rehab	EFFECTIVE:
REVISED:	

NEW POLICY

This policy was created to direct staff in the safe handling of hazardous materials in the Outpatient Rehabilitation Clinic.

WHY: In response to CIHQ deficiency: An unlabeled bottle of rubbing alcohol was found during the Triannual CIHQ survey.

OWNER: Christopher Gallo

AUTHORS/REVIEWERS: Christopher Gallo

APPROVALS:
Policy & Procedure Team:
Medicine Committee:
Medical Executive Committee:
Board Quality Committee:
The Board of Directors:

SUBJECT: Hazardous Material Handling in the Outpatient rehabilitation Clinic	POLICY: 7770-143
	PAGE 1
DEPARTMENT: Rehab	EFFECTIVE:
REVISED:	

PURPOSE: To establish and maintain a safe environment for the staff, patients and visitors to the Outpatient Rehabilitation Clinic.

POLICY: It is the policy of the Rehabilitation department that all hazardous materials will be maintained and handled in a safe and appropriate manner.

PROCEDURE:

1. Hazardous materials will be dated and initialed by person receiving such materials.

2. When opened, hazardous materials will be dated and initialed by the person opening it.

3. If hazardous material is transferred from its original container to a more user appropriate container, that user appropriate container will be labeled with the correct identity of the hazardous material, the opening date from the original bottle and will initialed by the person transferring the hazardous material.

REFERENCES:

SUBJECT: CLOSTRIDIUM DIFFICILE (C.DIFF) BY PCR USING VERIGENE MULTIPLEX MOLECULAR SYSTEM	POLICY: 7500-100
	PAGE 1
DEPARTMENT: Laboratory	EFFECTIVE:
REVISED:	

NEW POLICY
Briefly state the reasons for creating a new policy.

WHY:

OWNER:
Lab Manager

AUTHORS/REVIEWERS:
Shukurat Baruwa MLS(ASCP), Lab Supervisor
Nicolaos Hadjiyianni MT(ASCP) , Lab Manager
Frederick Kretzschmar, MD, Lab Director

APPROVALS:
Policy & Procedure Team: 3/4/20
Medicine Committee:
Medical Executive Committee:
Board Quality Committee:
The Board of Directors:

SUBJECT: CLOSTRIDIUM DIFFICILE (C.DIFF) BY PCR USING VERIGENE MULTIPLEX MOLECULAR SYSTEM	POLICY: 7500-100 PAGE 1
DEPARTMENT: Laboratory	EFFECTIVE:
REVISED:	

PURPOSE:

The VERIGENE® System utilizes advanced automation and proprietary chemistry to enable rapid, sample to result detection of nucleic acid and protein targets. Targeted assays such as *C. difficile* and *Enteric Pathogen Assays panels* enables clinical laboratory the flexibility and scalability in their GI assays to deliver optimal results to physicians for patient care, antimicrobial stewardship, and infection control.

Clostridium difficile infections (CDI) are potentially life-threatening health risks that tend to occur in people who have taken antibiotics or been admitted to hospitals. CDI accounts for 15-25% of all antibiotic associated diarrhea and is the most common cause of infectious diarrhea in a healthcare setting.

POLICY:

It is the policy of Sonoma Valley Hospital Laboratory to perform *C-Difficile* testing on patient who may exhibit the symptoms of C-diff due to diarrhea or antibiotic related diarrhea to order molecular test **CDIFFDN** when requesting for a CDIFF test. A positive result will then reflex to an **EIA** test which can determine if positive result from the PCR is a Toxin and/or an Antigen.

REAGENT:

Verigene C.Difficile Kit.

- **Verigene C.Diff Test Cartridges**
  Each Cartridges consist of preloaded reaction reagents needed to generate an accurate test result. Reagents Kit include wash solutions, oligonucleotide probe solution and signal amplification solutions
- **Verigene C.Diff Extraction Tray**
  Extraction stray also consist of preloaded reagents needed for nucleic acid extraction such as lysis/binding buffer, wash solutions and buffer solution.
- **Verigene C.Diff Stool Preparation Sample Kit**
  Consist of 20 tubes /Swabs containing stool preparation buffer packaged in a resealable bag.
- **Verigene C.Diff Amplification Trays**
  Amplification trays consist of preloaded required reagents such as enzymes, buffer and amplification tubes necessary for nucleic acid amplification.

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SUBJECT: CLOSTRIDIUM DIFFICILE (C.DIFF) BY PCR USING VERIGENE MULTIPLEX MOLECULAR SYSTEM	POLICY: 7500-100
	PAGE 1
DEPARTMENT: Laboratory	EFFECTIVE:
REVISED:	

MATERIAL:

- Micro-Pipettor
- Vortex
- Table-top quick spin Mini centrifuge
- Decontamination wipes/spray
- Biological Safety Cabinet (BSC)

REAGENT STORAGE AND STABILITY:

Verigene C. Diff Test Component	Storage Conditions	Comments
Stool Prep Buffer (SPB) Tubes & Swabs	2°C to 30°C	Do not Freeze
Tip Holder Assemblies	2°C to 30°C	Do not Freeze
Extraction Trays	2°C to 8°C	Do not Freeze
Test Cartridges		
Amplification Trays	≤ 20°C	Shipped Frozen. Upon receipt, store frozen. Do not re-freeze after thawing.

SPECIMEN REQUIREMENTS FOR IN VITRO USE:

The following sample requirements are critical for accurate results:

- Collect an unformed ***(liquid or soft)*** stool specimen in a sterile container from the patient suspected of having *C. difficile* infection.
- Store the stool specimen at 2 – 8°C. Specimens must be tested within 48 hours of collection.

SPECIMEN PREPARATION:

1. Remove one Stool Prep Buffer Tube (green top with clear preloaded liquid buffer) from the CDF Stool Preparation Sample Kit, immediately apply the Sample ID, and place into the hood with a sterile flocked swab and sterile paddle.
2. Observe the consistency of the specimen. If specimen is liquid proceed to subsection ***(a)*****.** If specimen is a soft solid proceed to subsection ***(b)*****.**

a. Liquid Stool:

- Thoroughly mix the stool in the original container with a sterile paddle for 5 seconds.
- Transfer 150 µL of specimen into the Stool Prep Buffer tube.

- Screw the cap finger tight on to the Stool Prep Buffer tube and set aside.

b. Soft Stool:

- Thoroughly mix the stool in the original container with a sterile paddle for 5 seconds.
- Dip the flocked swab into the specimen until flocked tip is fully immersed in specimen.
- Once evenly coated transfer swab to the Stool Prep Buffer tube and break swab at the pre-formed scored breakpoint.
- Leave scored swab in the Stool Prep Buffer tube and screw the cap finger tight on to Stool Prep Buffer tube.

3. Vortex the Stool Prep Buffer tube for a minimum of 15 seconds.
4. Microfuge the specimens for a minimum of 30 seconds.
5. Put on fresh gloves before starting the CDF Test Procedure.

NOTE:

A. If not running the VERIGENE CDF procedure immediately after preparation of the Stool Prep Buffer (SPB) specimen, store the inoculated SPB specimen at 2 - 8°C and test within 24 hours, including any necessary repeat testing.

PROCEDURE:

Test set up

1. Remove an Extraction Tray, Tip Holder Assembly, and Test Cartridge from the refrigerator. Remove the Amplification Tray from the freezer and thaw at room temperature for 10 minutes.
2. Begin test run within 30 minutes or store thawed Amplification Tray at 2 – 8°C until ready to initiate testing. Avoid subjecting Amplification Tray to multiple freeze-thaw conditions.
3. Open the Drawer Assembly by pressing the black OPEN/CLOSE button located on the front of the VERIGENE Processor *SP*.
4. Open the Drawer Clamp by pressing in the silver latch and lifting the Clamp prior to loading the consumables.

Loading the Extraction Tray

1. Prior to loading the Extraction Tray, thoroughly shake the Tray to resuspend the magnetic beads which have settled during storage. Check for complete resuspension by visually inspecting the well containing the black magnetic beads. Following adequate resuspension, gently tap the tray on the bench to ensure that the reagents settle to the bottom of each well.

2. The Extraction Tray can only be loaded in one location and orientation in the Drawer Assembly. When loaded correctly, the Sample Loading Well is located in the front right hand corner of the Drawer Assembly.
3. Place the Extraction Tray in the Drawer Assembly and press down on the corners of the tray to ensure it is level.

Loading the Tip Holder Assembly:

1. The Tip Holder Assembly is a plastic holder that contains two Pipette Tips and a rubber Tip Seal. Each Pipette Tip contains an O-ring on top.
2. Insert the Tip Holder Assembly into the Drawer Assembly. The Tip Assembly can only be loaded in one location and orientation in the Drawer Assembly. For orientation, there are two holes on the deck of the Drawer Assembly that fit each Pipette Tip and the opening to the Tip Seal should face away from Processor *SP*.

Loading the Amplification Tray

1. After thawing, gently vortex (< 5 seconds) the Amplification Tray and gently tap the tray on the bench to settle the reagents.
2. Remove the cap from the Amplification Tube and save the cap to re-cap the tube when processing is complete
3. Insert the Amplification Tray into the Drawer Assembly. The Amplification Tray can only be loaded in one location and orientation in the Drawer Assembly. When loaded properly, the tray sits flat.
4. Lower and latch the Drawer Clamp over the Trays while supporting the Drawer with the opposite hand. The Drawer Clamp will latch onto the Drawer Assembly when closed properly, and the user will be unable to lift the Drawer Clamp without pressing in the silver latch.

Ordering a Test

1. All tests must be ordered through the VERIGENE Reader. No tests can be processed on the VERIGENE Processor *SP* without the user entering the Test Cartridge ID and Sample ID to the VERIGENE Reader.
2. Log in to the VERIGENE Reader.
3. If the user would like to start a new Session, proceed to the next step **(iii).** If the user would like to order a test in a previously created session, they can select the desired Session from the drop down 'SESSION' menu then proceed to step **(iv).** Up to 60 cartridges can be entered into a single session.

iii. From the Menu Bar, SESSION tab, select Start New Session where the Session Setup window will appear.

a. Touch Session ID button and enter information by using the data entry keyboard. The Session ID can be any unique identifier in a format defined by the laboratory. The operator ID is automatically entered as the currently logged in 'user'.

iv. Touch the Processing option on the Navigation Bar at the bottom of the screen.
   a. Enter the Test Cartridge ID by scanning the barcode using the barcode scanner attached to the Reader.
   b. The user may manually enter in the Test Cartridge ID by selecting MENU and 'Enter Barcode' and then keying in the Test Cartridge ID number with the Reader's keyboard.
   c. Scan the Test Cartridge Cover's 2D barcode using a barcode gun-style scanner to display the Test Cartridge's Reference Number, Expiration Date, and Lot Number on reports.

Loading a Test Cartridge

1. Hold the Test Cartridge by the handle with one hand, using the other hand apply pressure with the palm of the hand and remove the cartridge cover by bending the cover away and over the Reagent Pack edge. Ensure that the valve plate is not moved during cover removal.
   NOTE: Do not remove the Test Cartridge cover until immediately prior to inserting the Test Cartridge into the Processor *SP*.
2. Insert the Test Cartridge into the Hybridization Module of the Processor *SP* until it reaches a stopping point.
   NOTE: If the Test Cartridge is not inserted properly, the Processor *SP* will display a message on the information screen when the user attempts to close the Drawer Assembly.

Loading the Sample

1. At the Reader, enter the Sample ID by scanning or manually enter the Sample ID using the Reader's touch-screen keyboard. Press Yes to confirm the Sample ID. Ensure Hybridization, Amplification, and Extraction options are selected.
2. In the subsequent dialogue box, select or de-select **"Toxigenic C. diff" and/or "Ribotype 027"** from the list to activate or de-activate results reporting for those targets. Press Yes to confirm. The VERIGENE.
3. Reader will automatically default to the selected targets for the next test run.
4. Pipette 150 µL from the SPB tube avoiding any solids at the bottom of the tube into the bottom of the Sample Loading Well in the Extraction Tray
   NOTE: If pipette tip clogs when loading re-centrifuge the SPB tube for an additional 30 seconds.

5. Close the Drawer Assembly by pressing the OPEN/CLOSE button on the Processor *SP*. The Processor *SP* will automatically verify that each consumable is properly loaded and begin sample processing.
6. Confirm countdown has started on the Processor *SP* display screen before leaving the area.
7. In order to set up additional tests on other Processor *SP* instruments follow the same procedure to avoid contamination and sample mix-ups, set up one test at a time, change gloves after handling a sample, and decontaminate pipettes and sample tubes between tests.

Upon Completion of a Test Run

1. The VERIGENE Reader will generate a ring to notify the user when the test is completed and the Processor *SP* will display a message indicating "Procedure Complete. Ready to Open Drawer." The Test Cartridge should be removed from the Processor *SP* upon completion of the test or within 12 hours of completion.
2. Open the Drawer Assembly by pressing the OPEN/CLOSE button. Cap the Amplification tube for disposal.
3. Remove the Test Cartridge and immediately orient to its side. While keeping the Test Cartridge on its side, separate the Reagent Pack.

Analyzing Results

1. Remove the protective tape from the back of the slide in the Substrate Holder.
2. Use the Reader's barcode scanner to read the barcode on the Substrate. When the barcode is accepted, a prompt to load the Substrate Holder into the Reader will be displayed. Immediately insert the Substrate Holder into the Reader.
3. When the load substrate prompt occurs, it will only display for 20 seconds. The analysis will only start if the Substrate is loaded during the animated prompt.
4. To properly insert the Substrate into the Reader hold the Substrate by the handle with the barcode facing away from you. Next, insert the Substrate Holder into the Reader substrate compartment. **The compartment is designed to place the Holder in the correct position**.
5. Insert it into the compartment as far as it will go comfortably. Close the door of the substrate compartment.
6. The analysis will automatically begin. A small camera icon will appear on the Reader to indicate that analysis has begun.
7. Once the analysis is completed by the Reader, the camera icon is replaced with an upward facing arrow and the Reader rings.
8. Confirm that a result other than "No Call – No GRID" has been generated by touching the substrate icon for the test. A Substrate producing a "No Call – No GRID" result

should be rescanned and reanalyzed. Once the scan is complete, dispose of used Test Substrate.

Printing Results

1. Touch the substrate icon in the Session's Processing screen. A window displaying the results will open; touch the "Print" option on this screen to print a Detail Report.
2. A Summary Report is available by moving to the Results screen of the Session on the bottom Navigation Bar; go to MENU then select "Print Summary". The Summary Report will provide the results for all tests processed within the current Session.

RESULT INTERPRETATION:

1. CDF provides a qualitative result for the ***presence (Detected) or absence (Not Detected)*** of the CDF target genes.
2. The presence or detection of ***toxin gene*** will then be reflex to an EIA method for toxin detection.
3. Error calls such as No Call, No Grid, and INT CTL; repeat C-diff. Please see operator's manual for instructions on error codes.

Below are the interpretation of *C.Difficile* results on Verigene

tcdA	tcdB	Binary	tcdC Result	Result
Not Detected	Not Detected	N/A	N/A	Toxigenic C.Diff Not Detected
Detected	Detected	Detected	Wild type	Toxigenic C.Diff Detected
Detected	Detected	Detected	Mutant	Toxigenic & PCR Ribotype 027 C.Diff Detected
Detected	Detected	Not Detected	Wild type	Toxigenic C.Diff Detected
Detected	Not Detected	Detected	Wild type	Toxigenic C.Diff Detected
Detected	Not Detected	Detected	Mutant	Toxigenic & PCR Ribotype 027 C.Diff Detected
Detected	Not Detected	Not Detected	Wild type	Toxigenic C.Diff Detected
Not Detected	Detected	Detected	Wildtype	Toxigenic C.Diff Detected
Not Detected	Detected	Detected	Mutant	Toxigenic & PCR Ribotype 027 C.Diff Detected
Not Detected	Detected	Not Detected	Wildtype	Toxigenic C.Diff Detected

SUBJECT: CLOSTRIDIUM DIFFICILE (C.DIFF) BY PCR USING VERIGENE MULTIPLEX MOLECULAR SYSTEM	POLICY: 7500-100
	PAGE 1
DEPARTMENT: Laboratory	EFFECTIVE:
REVISED:	

QUALITY CONTROL:

The VERIGENER System uses a series of automated on-line quality measurements to monitor instrument functionality software performance, fluidics, test conditions, reagent integrity, and procedural steps each time a test is performed. A series of automated on-line procedural checks guide the user through the testing process each time a test is performed. CDF test barcode and specimen information are linked upon entry into the VERIGENE Reader to help prevent misreporting of results.

CDF is a **'specimen-to-result'** detection system wherein DNA is isolated from unformed stool specimen and specific detection is performed on an oligonucleotide array housed within the Test Cartridge.

To prevent reagent dispensing errors, all reagents are prepackaged in ***single-use disposables,*** including Stool Prep Buffer Tubes, Reagent Trays, and Cartridges.

Several levels of **controls built into CDF** ensure that failures at any step within CDF are identified during the procedure or in the end-point image analysis of the Test Cartridge.

Assay Controls:

- **Internal Processing Control 1 (INT CTL 1)** is an artificial DNA is a hybridization control construct along with the detection oligonucleotides are included within the Extraction Tray and the Test Cartridge. If the signals from INT CTL 1 are invalid, a no call result (No Call – INT CTL 1) will be obtained and the test should be repeated.

- **Internal Processing Control 2 (INT CTL 2).** ***Bacillus subtilis*** serves as an extraction & amplification control. This control is automatically added by the Processor *SP* to each specimen prior to the extraction step. The primers and detection oligonucleotides are included within the Extraction Tray, Amplification Tray and the Test Cartridge. Repeat test if the following occur:

  a. If the signals from INT CTL 2 are invalid, then a no call result (No Call – INT CTL 2) will be obtained.
  b. If the result is No Call - INT CTL 2 then the likely cause of the failure is in either the extraction or the amplification part of the procedure.

- **The CDF algorithm** utilizes the results from both positive controls and negative control while determining the presence or absence of any other target on the panel. If either of the positive controls or the negative control are invalid, then a **No Call** result will be obtained and the test should be repeated.

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EXTERNAL CONTROLS:

Regardless of the choice of quality control materials, all external quality control requirement and testing should be performed in conformance with local, state, and federal regulations or accreditation organizations as applicable and should follow user's laboratory's standard quality control procedures.

LIMITATIONS:

- A trained health care professional should interpret assay results together with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests.
- The detection of bacterial nucleic acids is dependent on proper specimen collection, handling, transport, storage, and preparation, including extraction. Failure to observe proper procedures in any of these steps could lead to incorrect results.
- There is a risk of false negative results due to sequence variants in the CDF targets of the assay.
- A negative result for *Clostridium difficile* should not be used as the sole basis for diagnosis, treatment, or patient management decisions.
- Performance characteristics were not established for patients < 2 years of age.
- Because identification of the PCR ribotype 027 strain of *C. difficile* is by detection of binary toxin (*cdt*) gene sequences and the single base pair deletion at nucleotide 117 in the *tcdC* gene, calls identifying PCR ribotype 027 strains by CDF should be considered presumptive.

CDC 2009048 toxinotype XIV/XV (non-PCR ribotype 027) will be reported as "Toxigenic *C. difficile*Detected" and "PCR ribotype 027 Detected" using CDF.

ALTERNATE METHOD:

Alternative testing in the absence of the PCR is the **C.Diff Quik Chek by EIA.** It is also recommended that the EIA method of testing should be used during the extended hours (Night Shift) where only one certified scientist is available to avoid delay in result of patient.

In the event that SVH is unable to perform testing due to several factors such as **inoperable instrument and there is no back up for testing,** the specimen must be sent to Santa Rosa Memorial Hospital Laboratory**.**

NOTE: Before sending specimens to another laboratory, please keep in mind specimens stability and integrity. Specimen may need to be redrawn in some cases to accommodate other laboratories guidelines.

SONOMA VALLEY HOSPITAL
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Always call the laboratory for guidance on specimen criteria before sending out samples for testing.

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