ZUCKERBERG SAN FRANCISCO GENERAL
Hospital and Trauma Center

Joint Conference Committee
Regulatory Affairs Status Report for October 2019

I. PENDING SURVEYS

1. DEA annual inspection OBOT/OTOP (due December 2018)
2. CDPH/CMS Dialysis Survey

II. COMPLETED SURVEYS

1.	**FRI**	Fall resulting in a right shoulder fracture 7C	6/25/2019	No Deficiencies
2.	**Complaint**	1N Oral facial maxillary Clinic/cancelled appts	10/3/2019	No anticipated Deficiencies

III. PLANS OF CORRECTIONS: Reports & Updates

1. **Joint Commission Laboratory Survey**

Chapter	Number of findings
Environment of Care (EC)	**2 Standards with 2 Elements of Performance (EP)**
Human Resources (HR)	**2 Standards with 4 Eps**
Infection Control (IC)	**1 Standard with 1 EP**
Quality System Assessment (QSA)	**2 Standards with 2 EPs**
Waived Testing (WT)	**1 Standard with 1 EP**

Details of the findings attached

2. FRI Abuse 7L — **Plan of Correction submitted to CDPH 10/11/2019**
Details of the findings attached

IV. SITE VISITS

Open Case under Investigation by CDPH

1.	**Complaint**	CDPH Quality of Care ACE Unit;	February 2019 – Ongoing
2.	**Complaint**	Nurse staffing – All inpatient units 10/27/2018	January 2019 – Documents Requested
3.	**FRI**	Unnecessary Uretroscopy 3M Cysto Clinic	March 2019 – Ongoing
4.	**Complaint**	SPD	10/7/2019 – Content of complaint unknown
5.	**FRI**	Alleged Sexual Assault 7C	Pending Visit
6.	**FRI**	4 Privacy Breaches 1M, 3M & 4M	Pending Visit
7.	**FRI**	Privacy Breach H38	Pending Visit

IV. FACILITY REPORTED INCIDENTS (FRI)

1.	Privacy Breach	Wd 92	Incorrect Lab Slip given to patient
2.	Privacy Breach	FHC	Incorrect Lab Slip given to patient
3.	Patient Elopement	ED	Injuries sustained
4.	Sexual Assault	7B	Substantiated Patient to Patient inappropriate touching, two related events involving 3 patients

Joint Commission Laboratory Survey,

EC.02.04.03 The laboratory inspects, tests and maintains laboratory equipment		
EP12. The laboratory monitors temperature-controlled spaces and equipment at frequencies established by the laboratory, using manufacturers' guidelines. The temperature is documented.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
Temperature not monitored during weekends and nights in rooms where reagents and specimens are stored, Building 3, ZSFG Likelihood to Cause Harm: Low Scope: Pattern	• Min/Max thermometers have been placed in these areas • Training for staff in area regarding use of thermometers and actions to be taken if readings are out of range • Compliance will be monitored by the Laboratory Director and reported to ALCC, this will continue until three consecutive months of compliance has been reached.	9/19/2019
EC.02.06.01 The laboratory establishes and maintains a safe, functional environment.		
EP28. Work areas have enough space and are configured to efficiently handle and house equipment and reagents. The features of work areas do not adversely affect test outcomes or compromise staff safety.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
The configuration of the laboratory was such that there was insufficient clearance around some equipment (<36") Likelihood to Cause Harm: Moderate Scope: Limited	• The areas identified as non-compliant were reorganized to provide the required clearance • Ongoing, recurrent inspection will be undertaken as part of the ZSFG Environment of Care Rounds and through the UCSF Environmental Health and Safety department. • Compliance will be monitored by the Laboratory Director and reported to ALCC.	
HR.01.04.01 The laboratory provides orientation to staff.		
EP10. Prior to performing laboratory duties, the following are completed: - The laboratory director or supervisor documents that staff have completed orientation and have demonstrated competence in performing their required duties. - The staff member affirms, in writing, that he or she can perform the duties for which orientation was provided.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
Two haematology staff had orientation to their duties, however they had not been assessed for competency prior to performing their duties independently. This was verified by the haematology supervisor. Likelihood to Cause Harm: Moderate Scope: Pattern	• The staff identified at survey have demonstrated competence in all their assigned duties. Preventative analysis • Current Policy did not align with TJC Standards. Documentation and roles/responsibilities were unclear. • Laboratory Policy and Procedure has been revised to comply with the applicable standards, defining required documentation and the staff responsible for undertaking competency assessments • Compliance will be monitored by the Laboratory Director and reported to ALCC.	

Joint Commission Laboratory Survey (continued)

HR.01.06.01 Staff are competent to perform their responsibilities.

EP6. Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is assessed and documented once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation.

Findings, scope and severity	Corrective actions and monitoring	Completion date
The organization could not provide documentation that competency had been assessed at least once every two years for one staff RN on the med/surg unit who performed phlebotomy Likelihood to Cause Harm: Low Scope: Limited	• Competency Assessment on performing phlebotomy procedure was incorporated in the annual skills assessment for inpatient nursing staff and nursing managers were notified about this additional competency requirement on September 13, 2019. • Compliance will be monitored by the Laboratory Director and reported to ALCC.	

EP18. The staff member's competency assessment includes the following: - Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing - Monitoring, recording, and reporting of test results - Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance - Direct observation of performance of instrument maintenance function checks and calibration - Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples) - Problem-solving skills as appropriate to the job (See also WT.03.01.01, EP 6)

Findings, scope and severity	Corrective actions and monitoring	Completion date
The laboratory could not provide documentation that all six methods of competency had been assessed during the initial competency for a new hire RN in the emergency department who performed non-waived blood gas testing. Likelihood to Cause Harm: Moderate Scope: Limited	• The POCT non-waived blood gas testing procedure and form on competency were revised to include the additional “competency assessment” using six methods after initial training and before employees performs blood gas testing. • Compliance will be monitored by the Laboratory Director and reported to ALCC, this will continue until three consecutive months of compliance has been reached.	

EP20. After the first year of employment, each staff member’s competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented. Note: For waived testing competency requirements, refer to the 'Waived Testing' (WT) chapter.

Findings, scope and severity	Corrective actions and monitoring	Completion date
Two microbiology staff members competence had not been assessed for all laboratory testing performed. Likelihood to Cause Harm: Moderate Scope: Pattern	• The Microbiology Competency Assessment Policy was revised to include the following areas: a. Created a grid to display competency categories across the lab with their corresponding required 6 levels of competency. b. Added Gram Stain as a competency assessment category. c. Revised the monitoring frequency for new employees • The Microbiology Competency Policy was revised to now include competency for initial, 6-month, and annual for all new employees and for new procedures. Preventative analysis • Current Policy did not align with TJC Standards. • The specific competency for “gram stain” had previously been considered part of a larger process and therefore proficiency had been assessed as part of that process, not separately as required by the TJC Standard. • Compliance will be monitored by the Laboratory Director and reported to ALCC.	

Joint Commission Laboratory Survey (continued)

IC.02.01.01 The laboratory implements its infection prevention and control activities.		
EP1. The laboratory implements its planned infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
The organization had not performed a risk assessment to regarding the installation of auxiliary air conditioning units and floor fans in the chemistry department to address potential infection control or safety risks for personnel working in the laboratory environment. Likelihood to Cause Harm: Moderate Scope: Limited	• A risk assessment was immediately completed by the facilities, infection prevention and control department and the Environmental Health and Safety Department at ZSFG. • Proactive infection control assessment of airborne bacteria was undertaken, with no detectable increase in environment bacteria than in areas without the additional air conditioning units and fans • ZSFG Laboratory leadership will round, on a monthly basis, to ensure that no new fans or air conditioners have been added without a risk assessment being undertaken. • Compliance will be monitored by the Laboratory Director and reported to ALCC, this will continue until three consecutive months of compliance has been reached.	
QSA.02.03.01 The laboratory performs calibration verification.		
EP5. The laboratory follows its procedure for calibration verification. The calibration verification performance is documented.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
One piece of laboratory equipment (had been calibrated, however the calibration verification was not signed by the senior supervisor, division chief or laboratory director per ZSFG Laboratory Policy. Likelihood to Cause Harm: Low Scope: Limited	• The calibration verifications were signed by the division chief during the survey. • Education of supervisors and specialists who participate in performing calibration verifications and/or routing those reports for signatures was provided. • Internal laboratory policies were reviewed and revised to align with the Clinical Laboratory administrative policy, Governance and Responsibilities for Administrative and Clinical Direction	
QSA.02.08.01 The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.		
EP2. The laboratory performs correlations at least once every six months. The correlations are documented.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
During the survey period, the laboratory did not perform correlations at least once every six months between manual and automated differentials. Likelihood to Cause Harm: Low Scope: Limited	• Education of technical supervisors who participate in reviewing method correlations was provided • The Haematology Section Method Correlation Procedure and the, Haematology Quality Program, were updated to specifically reference correlation between automated and manual differentials. • Compliance will be monitored by the Laboratory Director and reported to ALCC.	

Joint Commission Laboratory Survey (continued)

WT.01.01.01 Policies and procedures for waived tests are established, current, approved, and readily available.		
EP6. Written policies, procedures, and manufacturers' instructions for waived testing are followed. (See also WT.04.01.01, EPs 3–5) Note: Manufacturers' recommendations and suggestions are surveyed as requirements.		
Findings, scope and severity	Corrective actions and monitoring	Completion date
The organization was not performing daily room temperature recordings on weekends and holidays in two areas of the facility, Ward 93 and 6G Clinic, where waived urine pregnancy test kits, urine toxicology reagents and quality control were being stored that required temperature monitoring. Likelihood to Cause Harm: Low Scope: Limited	• A thermometer with a minimum/maximum reading feature was provided to 6G Clinic and Ward 93 so that the user can determine the minimum and maximum temperatures for a period of time. • Users were in-serviced on how to read the minimum and maximum readings, the actions to take if the readings are out of tolerance, where to document the readings and instructions on how to reset the minimum and maximum monitoring on the thermometer. • Compliance will be monitored by the Laboratory Director and reported to ALCC, this will continue until three consecutive months of compliance has been reached.	

CDPH Abuse Allegation 7L Custodial Unit

Tag E 264	**T22. DIV5. CH1. ART3. § 70707. Patients' Rights (b)(2)(2) Considerate and respectful care. (d) all hospital personnel shall observe these patients' rights.**	
Findings cited by CDPH	Corrective actions implemented	Completion date
CDPH found the actions of a SFSD Officer, when using their standard procedure of a distraction blow to address perceived threat from an inmate, as abuse. Title XV and Title XXII do not align in this matter.	• Reviewed and updated abuse training for all SFSD Officers and Cadets stationed at ZSFG, including additional training at Muster. • Re-education for ZSFG staff in the multidisciplinary team regarding the "pre-intervention" huddle undertaken prior to any intervention including use of force • Officer involved was coached and counselled by 7L Unit Commander, the officer was also referred for an Internal Affairs investigation by SFSD to ensure that all relevant precures were followed. • 7L Unit Commander no attends the weekly Security Huddle with SFSD Leadership at ZSFG, DPH Security Director and ZSFG executive leaders. • Targeted training for staff involved in incident.	8/21/2019