City and County of San Francisco
London N. Breed, Mayor

San Francisco Department of Public Health
Dr. Grant Colfax
Director of Health

San Francisco Department of Public Health

*Policy & Procedure Detail**

Policy & Procedure Title: POINT OF CARE TESTING	
Category: General Administration	
Effective Date: 8/3/2019	**Last Reissue/Revision Date:** Click here to enter a date.
DPH Unit of Origin: Click here to enter text.	
Policy Contact - Employee Name and Title; and/or DPH Division: Click here to enter text.	
Contact Phone Number(s): Click here to enter text.	
Distribution: DPH-wide ☒	**If not DPH-wide, other distribution:**

All sections in table required. Updated 3/2014

1. Purpose of Policy

To ensure point of care patient testing at ZSFG is appropriate, yields accurate, reliable and timely results, complies with applicable federal, i.e., CLIA, state and local rules and regulations, and meets Joint Commission standards and expectations.

2. Definitions

1. Point of Care Testing (POCT) refers to laboratory testing performed outside a central laboratory environment, generally near to, or at the site of the patient. POCT is also known as bedside or near-patient laboratory testing. Not considered POCT is monitoring of physiological states where no samples are taken, such as pulse oximetry, measuring bilirubin or hemoglobin through probes applied to intact skin, or breathalyzer testing.

2. Clinical Laboratory Improvement Amendments (CLIA). Federal regulations that set mandatory standards for all clinical laboratory testing in the U.S., including POCT. Based on test complexity, CLIA distinguishes 3 test categories, waived, moderately complex, and highly complex. Specific standards and expectations apply to each testing category.

3. Provider performed microscopy procedures (PPMP). A group of POC tests falling into the moderately complex category of laboratory tests as defined by CLIA. PPMP may only be performed by authorized independently licensed (MDs, DOs) or midlevel practitioners (PAs, NPs, CNMs).

3. Scope

This policy and procedure applies to POCT performed laboratory testing for patient care purposes on the ZSFG campus, including inpatient, emergency department, specific clinics and behavioral health center locations. Not included are SFDPH COPC health centers and clinics, and Laguna Honda Hospital (LHH) locations. POCT at specific campus clinics, COPC and LHH is performed under separate clinical laboratory licenses and procedures under the direction of the respective Medical Directors in each location.

4. Policy

1. POCT is conducted only by authorized personnel who have been trained and deemed competent to perform the specified procedures, according to guidelines established by the Director of the Clinical Laboratory at ZSFG in accordance with CLIA, state and local rules and regulations, and Joint Commission standards.

2. All reagents, test kits, devices and equipment used to perform laboratory tests for patient care on the ZSFG Campus will meet the standards established by the Director of the Clinical Laboratory.

3. Physician and nurse managers and directors who oversee clinical areas where POCT is performed are responsible for ensuring adherence to the standards set forth by this policy.

4. ZSFG POCT Committee will work collaboratively and consultatively with COPC and LHH to ensure POCT across the SFDPH clinical sites is performed appropriately and efficiently.

5. Responsibilities

1. The ZSFG POCT Committee, consisting of the Laboratory Director, Administrative Director and the Point of Care staff of the Clinical Laboratory:
   - meets regularly to review POCT activities at ZSFG
   - reviews and approves proposals for new POCT at ZSFG
   - invites additional adhoc members to serve on the committee to represent POCT stake holders, as needed and appropriate

2. The Director of the Clinical Laboratory:
   - is responsible for all POCT activities at ZSFG
   - ensures compliance with all applicable regulations, rules and standards
   - provides expert advice and information to the POCT Committee, including identifying alternatives to various POCT methods and devices, determining criteria for medical necessity, and identifying procedures for adopting and implementing the tests

3. The Director of the Clinical Laboratory or authorized representative:

   a) screens, recommends and approves all instruments, devices, procedures, reagents, materials and kits used in POCT, including new lots of previously approved reagents, and supplies, and new versions of any established POCT

b) establishes and regularly reviews procedures for all approved POCT, including guidelines appropriate quality assessment processes

c) collaborates with the Medical Staff, Nursing Services, and the Department of Education and Training, in the training of individuals designated as trainers and supervisors of the personnel selected to perform POCT

d) conducts periodic reviews of POCT performance by monitoring for compliance to established guidelines and providing, as required, proficiency test specimens to each site authorized by the Clinical Laboratory to perform POCT

e) conducts periodic inspection of the POCT sites for compliance with regulatory mandates

f) periodically reports on the status and performance of POCT as requested by SFGH oversight committees, including, but not limited to PIPS and MEC

g) monitors utilization of all POCT, communicates with each POCT site, and recommends methods to improve efficiency to the unit performing the tests and to the POCT Committee

h) maintains a current master list of all POCT sites and the types of tests performed at each site (list is maintained in the Clinical Laboratory, phone: 206-8588)

4. Pharmacy and Materials Management:

a) Notifies the Clinical Laboratory upon the arrival of new lots of specified POCT reagents, devices, kits and supplies (e.g., occult blood cards, glucose strips, urine dipsticks, urine pregnancy test kits, etc).

b) Notifies the Clinical Laboratory upon receipt of any shipment of specified POCT materials, supplies or devices.

c) Provides periodic information on utilization and consumption to the Director of the Clinical Laboratory or authorized representative.

5. Each individual POCT Site:

a. identifies appropriate personnel for test performance

b. establishes a budget for the purchase of required equipment, reagents and consumables

c. conducts quality control processes and provides for equipment maintenance as specified by manufacturer, Clinical Laboratory and/or Biomedical Engineering

d. maintains the POCT procedure, as established and approved by the Clinical Laboratory, for any POCT to be performed

e. will have a written policy (aka "IDA- Indication, Documentation and Action Page") defining:

   i. site-specific clinical indications for POCT;
   ii. documentation plan indicating where POCT results will be recorded and by whom;
   iii. clinical actions to be taken for any result (normal or abnormal)

f. selects one individual to serve as general supervisor/coordinator and contact person for POCT at a site. This liaison will be responsible for monitoring all POCT activities at the site including:

   i. Selection and training of personnel who are to perform POCT
   ii. Providing instruction for staff designated to perform specific tests
   iii. Evaluation and certification of the competency of each individual in each approved procedure upon completion of training
   iv. Sending a copy of competency documentation to the POCT office
   v. Maintaining a current list of all personnel authorized to perform POCT at this location and recertify competency in each approved procedure at least annually or as required by regulatory agencies

g. records test results in the patient's medical record and provides test count and billing information as required

h. maintains logs of control results for 3 years as required by California law

   i. follows all required quality controls and performance improvement protocols, including provision of periodic re-testing of patient samples by the Clinical Laboratory as requested; performance of required proficiency tests and

maintenance of all required records

j. monitors appropriate clinical utilization of each test and provide necessary data upon requests

6. Independently licensed and midlevel practitioners who wish to perform non-instrument based waived POCT, or PPMP

- will apply for waived POCT privileges (MDs, DOs) or standardized procedures (PAs, NPs, CNMs), for the specific tests approved at ZSFG they wish to perform
- when approved will comply with applicable ZSFG POCT policies and procedures for each test they perform

those who wish to perform PPMP will participate in semi-annual proficiency testing assigned by the Clinical Laboratory and achieve a passing score of 100% or higher, before performing PPMP

6. Procedures

I. Corrective Actions

1. If a POCT site is out of compliance for a given test or procedure, (e.g., unacceptable quality of test performance or lack of documentation of results or controls, as outlined by policy), the Clinical Laboratory will notify the responsible nurse manager or medical director of the site or service with the request for timely corrective actions to be implemented.
2. If the problem(s) continue(s), the Director of the Clinical Laboratory will notify the appropriate Nursing Director, Service Chief, and ALCC (Accreditation, Licensing and Certification Committee) for corrective action to be implemented, including discontinuation of the test.

II. Process for Requesting New POCT:

1. To apply for new or expansion of existing POCT, the responsible site manager, director or service chief, as appropriate, will fill out an application form (available online in the Clinical Laboratory Manual at http://labmed.ucsf.edu/sfghlab/index.html) and submit it to the POCT Committee**.**.
2. The POCT Committee will review the application and inform the applicant of its decision, i.e., either approved or disapproved with explanation.
3. If the request is not approved, the applicant may request re-evaluation after addressing reasons for rejection of the original test request.

III. Documentation of POCT Order and Result:

1. A valid order must be placed in the EMR (or via manual requisition) before a POCT can be performed.
   All POCT results must be documented in the EMR, via docked device transmission or manual result entry.

7. References/Attachments

a. Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA) @ http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

b. Joint Commission DC standards, current edition

c. Clinical Laboratory Standards Institute, CLSI, formerly National Committee for Clinical Laboratory Standards, NCCLS. Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd ed. CLSI Document POCT4-Ed3 (2016),

d. 4.CLSI, formerly NCCLS. Glucose Monitoring in Settings without Laboratory Support; Approved Guideline, 2nd ed. CLSI Document AST4-A2 (2005), 5.CLSI, formerly NCCLS. Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline, 2nd ed. NCCLS Document C30-A2, August 2002

e. 6.For information on 'waived tests' approved by the Centers for Medicare and Medicaid Services (CMS), go to CLIA-Clinical Laboratory Improvement Amendments-Currently Waived Analytes @ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm. (Current as of Oct. 2013.)