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48667.261 Point Of Care Testing (POCT) Quality Management Plan

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Approval and Periodic Review Signatures

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Periodic review	Designated Reviewer	4/06/2021	3.2	Barbara Haller, MD, PhD Barbara Haller	
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Approval	Lab Director	10/30/2018	3.0	Barbara Haller, MD, PhD Barbara Haller	
Approval	Lab Manager	10/29/2018	3.0	Mary Eugenio-Allen Mary Eugenio-Allen	

Signatures from prior revisions are not listed.

Version History

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Point Of Care Testing (POCT) Quality Management Plan

A. PURPOSE

To ensure accuracy and quality of tests performed at the point of care under the CLIA certificate of accreditation held by the Clinical Laboratory at ZSFG.

B. PRINCIPLES

All POCT procedures follow written policies and are performed in accordance with CLIA regulations and Joint Commission standards on waived testing and provider performed microscopy procedures (PPMP) and non-waived testing. Method validation and technical oversight of POCT is provided by the Clinical Laboratory department. Administrative oversight and support is provided by the POCT Committee, which conducts periodic audits to verify compliance. POCT is governed at the hospital level by administrative policy 16.20 “Point of Care Testing.”

C. STRUCTURE AND OVERSIGHT

Oversight of POCT activities at SFGH is the responsibility of the POCT Committee which at the minimum is comprised of the Director and the Manager of the Clinical Laboratory and the POCT Clinical Laboratory Scientist (CLS) Specialist. Day-to-day support of the POCT program is provided by the POCT Service, a section of the Clinical Laboratory overseen by the Laboratory Director.

D. TESTING PERSONNEL

POCT is performed by qualified licensed staff or other direct health care providers as required by CLIA regulations, Joint Commission standards and California Business and Professional Code. Qualified means approved by the POCT Service upon completion of approved training and competency assessments and verification of education, as necessary.

E. SPECIMENS

Specimen requirements and handling are addressed in the protocol for each POCT procedure. A patient’s identity is verified using two patient identifiers (e.g., name and date of birth or medical record number). Specimen containers must be labeled in the presence of the patient. Unlabeled or mismatched (name and/or medical record number on specimen does not match name and/or medical record number on the test order) specimens, must be rejected and excluded. NOTE: Specimen labeling is not required when testing is performed in the presence of the patient and only the sample from one patient is tested at a time.

F. SAFETY

a. Standard Precautions are used for the care of ALL patients and handling of patient specimens, regardless of their diagnosis or presumed infection status. No special signs or alerts are necessary for implementation.
b. Standard Precautions fall into four broad categories:

i. Personal Hygiene
ii. Personal Protective Equipment
iii. Environmental Issues (The healthcare environment consists of surfaces, equipment (fixed and portable), furnishings, and supplies. It can serve as a reservoir for pathogenic microorganisms. The responsibility for keeping the environment clean is shared by all facility personnel and is based upon the type of item and level of soiling. At a minimum, gloves are to be worn when cleaning environmental surfaces.)
iv. Occupational Health and Safety Issues (Processes for cleaning specialized equipment shall be established by owning areas in accordance with manufacturer's instructions and in consultation with Infection Prevention and Control. Environmental Services will be consulted when applicable.)

NOTE: All principles of Universal Precautions, designed to prevent the transmission of bloodborne pathogens to health care workers, and Body Substance Isolation, designed to prevent the transmission of non-specific pathogens, are incorporated into Standard Precautions. Refer to "Standard Precautions" procedure in the Infection Control Manual on the CHN Intranet website.

G. EQUIPMENT, REAGENTS AND SUPPLIES

1. Method / Test System Validation

The performance of all instruments and test systems used for POCT is verified before they are taken into clinical service. Verification follows at a minimum manufacturer's recommendation for waived test systems, and involves method comparison studies, accuracy, linearity (reportable range), precision and reference range assessments for instruments or test systems classified as moderately complex (non-waived). Only instruments and tests systems which performance has been reviewed and approved by the Clinical Laboratory Director can be used for patient testing. Electrical safety is verified for all instruments that are connected to an electrical power source by the Biomedical Engineering department.

2. Preventive Maintenance

Preventive maintenance is performed per manufacturer's recommendations; completion is documented.

3. Reagent Storage

All reagents used for POCT are stored in accordance with manufacturer's recommendations, or, if not available, per Clinical Laboratory instructions. Storage temperatures are documented as required.

H. QUALITY ASSURANCE PROCEDURES

1. Quality Control (QC)

- **a.** QC for waived tests is performed at the minimum as recommended by the manufacturer of the instrument or test system used. If the manufacturer does not specify QC procedures, the Clinical Laboratory will define necessary QC based on a risk assessment of the test(s) involved.
- **b.** QC for moderately complex (non-waived) POCT utilizes at the minimum two-levels of control run once each day the test is used or, alternatively, follows an approved Individualized Quality Control Plan (IQCP). Refer to IQCP for each non waived POCT procedure.
- **c.** A new lot of Quality Control is verified by POCT CLS Specialist or designee and the manufacturer's ranges will be used due to limited volume of testing. This process has been approved by the Laboratory Director.
- **d.** QC results are reviewed monthly by the Laboratory Director or designee. Any identified issues are acted upon immediately and corrective action taken is documented. Note: See Appendix I for specific QC methods, schedules, and rationale by test category.

2. Proficiency Testing (PT)

- **a.** PT challenges offered by an approved provider such as the College of American Pathologists (CAP) are performed on a regular schedule for all moderately complex POCT, including provider performed microscopy procedures (PPMP). The following principles are followed:
  - **i.** PT survey materials are treated in the same manner as patient specimens.
  - **ii.** Referral of proficiency testing specimens to another laboratory or acceptance of a survey intended for another laboratory is prohibited.
  - **iii.** Inter-laboratory communication about proficiency testing samples is prohibited until after the deadline for submission of data to the proficiency testing provider.
  - **iv.** PT challenges are assigned on a rotational basis to ensure that all personnel who perform POCT have equal opportunity to complete PT challenges.
  - **v.** PT results are reviewed by the POCT CLS Specialist, Technical Supervisor designee and by the Laboratory Director. Corrective action plans are written and implemented as necessary.
  - **vi.** PPMP is performed by physicians and midlevel practitioners who participate in an external web-based proficiency testing program administered through the University of Washington, Department of Lab Medicine and overseen by the POCT CLS Specialist or designee.

3. Method Comparison

Method comparison against the primary instrument in the Clinical Laboratory is performed for moderately complex POC tests on a regular schedule but at least twice annually using predefined criteria for acceptable agreement.

4. **Linearity (Reportable Range) Checks**
   Linearity is performed on blood gas and CoOx analyzers every 6 months.

I. DOCUMENTATION OF ORDERS AND REPORTING OF RESULTS

Orders for Point of Care Tests must be documented in the patient's medical record. Results are reported in the patient's medical record by the provider performing the POCT. Specific reporting and notification requirements are provided in POCT site-specific instructions on test indications, result documentation, and clinical actions, referred to as IDA pages.

For specimens that were mislabeled (e.g., specimen performed under the wrong medical record number), report the incident to the POCT CLS who will follow up with corrective actions including correcting the results and crediting the test order. In such cases, the correct patient must be re-drawn and tested. Refer to the ZSFG Clinical Laboratory "Specimen Identification" policy for exceptions and special handling instructions.

J. DOCUMENTATION

1. The POCT Service maintains records of:
   a. Approved POCT Test Sites
   b. Applications for new POCT
   c. Training and Competency Assessments
   d. Evidence of CLIA-required Education of Testing Personnel
   e. Test Volumes
   f. Refrigerator/ Room Temperature Logs

2. POCT Sites maintain:
   a. Quality Control Logs

K. REFERENCES

1. Point of Care Testing, Hospital (SFGHTC) Administrative Policy 16.20
2. Comprehensive Accreditation Manual (CAMLAB) for Laboratory and Waived Testing; the Joint Commission.

L. ATTACHMENTS

1. QC methods, Schedules and Rationale by Test Category

M. DISTRIBUTION

1. Point of Care Master Procedure Book (2M14).
2. Approved Point of Care Testing Locations
3. Via www.SFGH-POCT.org website.

Attachment 1: QC methods, Schedules and Rationale by Test / Test System

I. Waived Tests

Test Name	Quality Control	Frequency*	Rationale
Fecal Occult Blood by Hemoccult	Internal Positive / Negative Performance Monitors	Each Test	Manufacturer's Requirement
Glucose by Accu-Chek Inform	Approved Commercial Control Solution (2 Levels)	Once / 24 hrs.	From precision studies meter can be expected to be stable for at least 24 hours.
Hemoglobin by HemoCue	Approved Commercial Control Solution (2 Levels)	Once / 24 hrs.	From precision studies meter can be expected to be stable for at least 24 hours.
Urinalysis by Dipstick	Commercial Control Solution Kovatrol	Once / week – Chem 2 & 7 Once / 24 hrs. – Chem 10	Test strips stable at room temperature storage.
Urine Pregnancy by SureVue hCG	Internal Control	Each Test	Manufacturer's Requirement
Urine Toxicology	Approved Commercial Control Solution (2 Levels)	Every 30 days	Manufacturer's Requirement
Vaginal pH by Nitrazine Paper	Certified Buffers at pH Levels 4 & 7	Once / shipment	pH paper stable at room temperature.
Creatinine by iSTAT 1 (Abbott)	Electronic QC	Daily	Manufacturer's Requirement
	Liquid QC	Every 30 days	Manufacturer's Requirement

* during use for patient care

II. Moderately Complex Tests

Test Name	Quality Control	Frequency*	Rationale
Activated Clotting Time Hemochron Jr. Signature +	1. Liquid Control (cuvette check) 2. Temperature Check 3. Electronic QC	1. Every 7 days 2. Once / 24 hours 3. Every 8 hours	1. Cuvette performance check (required every 30 days), per IQCP (Caroline- please verify) 2, 3. Manufacturer's and CLIA requirements
Blood Gases, Cooximetry, Electrolytes, Glucose (Na, K, iCa), Hematocrit, Lactate IL GEM4000 IL US, Bedford, MA	1. Internal (IQM) 2. External (CVP)	Multiple / 24 hrs. Every 30 days and each new test cartridge	1, 2. Per manufacturer and IQCP requirements
	1. External (GSE)	1. Twice per year and as needed for troubleshooting	1. Per revised IQCP, GSE need only be performed twice per year and as needed for troubleshooting.
Cooximetry AVOXimeter 1000E	1. Internal Control 2. External Control	1. Daily 2. Weekly	1, 2. Manufacturer's & IQCP requirements
ROTEM Tem Systems, Inc., Durham, NC	1. Internal (EQC) 2. External (liquid) QC	1. Daily 2. Weekly	1, 2. 1, 2. Manufacturer's & IQCP requirements

***** during use for patient care

III. Provider Performed Microscopy Procedures

Test Name	Quality Control	Frequency*	Rationale
Vaginal (Saline/KOH) **Wet Mount** **Urine Sediment**	Proficiency Testing by Providers Performing PPMP	Twice every year	Per CLIA requirements
Fern Test	Microscope QC Check	Daily	Per CLIA requirements

***** during use for patient care