

# **POINT-OF-CARE TESTING: A "HOW-TO" GUIDE FOR THE NON-LABORATORIAN**

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# POINT-OF-CARE TESTING: A "HOW-TO" GUIDE FOR THE NON-LABORATORIAN

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This document was approved by the AACC Board of Directors in May 2022.

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# POINT-OF-CARE TESTING

## A “HOW-TO” GUIDE FOR THE NON-LABORATORIAN

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### INTRODUCTION

Point-of-care testing (POCT), or near-patient testing, is diagnostic testing conducted close to the patient, often by clinical personnel outside of the laboratory. POCT is regularly performed by personnel without a laboratory science degree or credentialing in laboratory medicine. POCT provides faster turnaround of test results that can expedite patient care decisions, in part because a sample does not need to be transported to a laboratory and requires little to no sample processing. The potential of POCT to streamline patient management and elevate the patient experience, as well as improve patient satisfaction and care outcomes, is increasing the popularity of this delivery option for diagnostic testing. A wide range of tests, testing products, and devices are currently available on the market. Manufacturers are continuously developing new or improved instrumentation that is simpler, is easier to use and maintain, and can provide laboratory-comparable test results.

However, implementing POCT can present many challenges. In the US, all laboratory testing is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) law, regardless of where the test is conducted or what type of facility provides testing (1). POCT is subject to CLIA regulations, which vary depending on the complexity of the test. Minimal requirements exist for simple tests, like urine pregnancy and whole blood glucose, to which CLIA refers as waived complexity. More complex testing, such as blood gases, requires a variety of documentation to meet the CLIA requirements. Method verification, written policies and procedures, timely operator training and competency, manufacturer’s directed maintenance, quality control, management of reagent supply and storage, proper disposal of hazardous waste, and adequate environmental management practices

for operator and patient safety are all required for more complex POCT. Worldwide, laboratory regulations vary by country, and local regulations may be more or less stringent than the US CLIA regulations.

### Scope of Document

This guidance document is intended for non-laboratorians who are involved in setting up a process or physical space designed to provide testing at or near where patient care is provided. This guide presents the challenges to consider when selecting and implementing diagnostic testing. It also offers tools to address and manage those challenges and offers solutions to overcome barriers faced in various settings, to ensure quality test results that are reliable for patient care. Employees who are charged with addressing these POCT challenges vary by job title and role.

This guide is not meant to be an all-inclusive ‘how to’ set up a POCT laboratory. It is to be used as supportive instruction and education to implement good laboratory practices. The guide is most helpful when used in conjunction with all information provided by the test manufacturer, including the Manufacturer’s Instructions for Use (MIFU) for testing materials, products, and devices that one has selected to provide laboratory testing services to patients.

### GENERAL BENEFITS OF POCT

POCT is performed at or near the patient. This means that testing can be performed quickly at the site where the results will be used with no need to transport specimens. There are many benefits to performing testing at the point of care, including

- Enhances patient satisfaction and experience
  - Enhances patient workflow (triage, immediate treatment, operating room/surgery, medication protocols, etc.)
  - Eliminates the need for sample transport
  - Decreases turnaround time
  - Avoids delay in procedures (operating room/surgery, radiology, simple surgical procedures, etc.)
- Impacts and enhances continuity of care for the patient
  - Allows for counseling to the patient during the visit, which increases patient compliance to the treatment and diagnostic care plan; decreases ‘call backs’ from health-care providers to patients (e.g., tight glycemic control)
  - Avoids escalation of treatment (e.g., testing of residents in a nursing/convalescent home to avoid emergency department/hospital admission)
- Test-specific benefits (e.g., allows for finger sticks vs venipuncture)
- Avoidance of antibiotics, improved antibiotic stewardship (in the case of viral infections, pediatric use cases, others [e.g., UTIs])

## Cost-Benefit Analysis

POCT can be more expensive to perform than central laboratory testing, but savings in other areas of care can justify the cost. If a test can be performed on-site, when a patient is with the provider, then the advantage of immediate treatment and consultation can be invaluable. Patient satisfaction is increased when results can be shared during the physician appointment and the care plan can be immediately outlined. POCT can also be useful for management of antibiotic resistance, allowing providers to explain why an antibiotic is not necessary based on the POCT results. For an urgent care center, having laboratory results available on-site enhances the ability to treat patients in real time and potentially decreases the patient wait time. However, a cost-benefit analysis ought to be performed to ensure that added cost of POCT will improve patient outcomes and/or patient satisfaction.

## POCT IN VARIOUS HEALTHCARE SETTINGS

### Health System: Hospital Settings

POCT in inpatient hospital settings is useful in situations where immediate results are needed to diagnose or treat a patient, usually to avoid escalation of their condition or decide on immediate treatment. In some cases, a POC test can ensure that valuable operating room/surgery or procedure rooms do not experience delays due to patients not having pre-procedure testing completed before arrival. In other cases, where delay in treatment (e.g., tPA for stroke victims) can lead to poorer outcomes, POCT is invaluable.

In outpatient settings, performing testing at the time of the patient visit means the patient can receive treatment during the visit, obviating a need to travel to a collection site for specimen collection. The clinician can address the test results immediately and advise the patient on their care. Keeping a close watch on patient results—for example, hemoglobin A1c—can lead to better disease management.

### A. Inpatient Settings

1. Triage
2. Trauma center/emergency ICU, NICU, PICU
3. Operating rooms/surgeries – several distinct types (e.g., transplant)
4. Extracorporeal membrane oxygenation (ECMO) center
5. Catheterization lab/cardiology
6. Stroke center
7. Cardiac rehab
8. Radiology/imaging center, interventional radiology
9. Coumadin clinic/coagulation clinic

### B. Outpatient Settings

1. Triage
2. Antenatal clinics (Ob-Gyn)
3. Oncology clinics
4. Urgent care clinics and rapid care centers
5. Geriatric clinics
6. Pediatric clinics
7. Diabetes/endocrinology clinics
8. Infectious disease clinics
9. General practitioner clinics
10. Ambulatory surgical settings
11. Congestive heart failure clinic (cardiac rehab)
12. Radiology/imaging center, interventional radiology
13. Coumadin clinic/coagulation clinic
14. Mobile health clinics
15. Helicopter, ambulance, airplanes
16. Executive health clinics

## Health System: Laboratory Settings

### A. Laboratory

1. Rapid response laboratory
2. Deployed laboratory services (ER stat labs)
3. Emerging infectious disease laboratory/biohazard/disaster planning lab

## Health System: Nontraditional Settings

Because of the SARS-CoV-2 pandemic, infectious disease testing has become ever more decentralized. To contain the pandemic, many sites where large numbers of individuals are gathered are requiring negative tests and are offering testing at the ven-

ue. Cruise ships and other locations that are far from healthcare sites often use POCT to care for their customers. Due to the rise of telehealth, convenient ‘off-site’ testing is becoming more necessary. Mobile health needs portable, easy-to-use devices to bring healthcare to the population and make healthcare more accessible to all.

#### A. Other Testing Sites/Locations

1. Airlines, airports
2. Cruise ships, shipping ports
3. Mobile health clinics
4. Pharmacies
5. Sporting events, races, festivals, concerts, marathons
6. Nursing homes
7. Long-term acute care and skilled care
8. Rehabilitation centers
9. Public school and university/student healthcare centers
10. Employee health centers
11. Disaster relief post/military medical tents (field hospitals)
  - May be in conjunction with or contiguous to a local hospital
12. Expeditions – e.g., Mount Everest
13. Home health, visiting nurses
14. Hospital at home
15. Travel clinics/screening for travel
16. Community testing
17. Native American reservations (Indian Health Service)
18. Health fairs
19. Blood collection centers

One approach to start or expand a POCT service is to consider the goals of the facility and the needs of the patient population to be served by adding POCT. Those planning the service should summarize their goals, ensure that the solution under consideration will accomplish those goals, and align the testing plan with the facility’s mission and strategic objectives. **Table 1** outlines examples of possible goals in adding or expanding current POCT, and questions to consider.

After the testing program proves to be successful in delivering the outcomes that meet the goals of the organization, the program management of the facility’s POC program may call for periodic evaluation of services provided to customers (patients and clinical staff providing direct patient care). Additionally, clinical staff may advance requests for additional POC tests or expansion of testing menus into new testing sites.

## TESTING METHODS CURRENTLY AVAILABLE

### Features Shared by POCT Devices

In broad terms, it is common that a ‘point of care (POC) testing device’ is either small and of a weight easily considered to be ‘handheld,’ or is at least portable from one physical location to another (toted by hand or via a wheeled cart, aka ‘mobile lab’ or ‘lab on a cart’).

Typically, a POC testing device is designed to be used with or without connectivity (a means of interfacing to the electronic medical record). Another design inclusion is the ability to ‘lock out’ operators unless they meet required compliance qualifications and to ‘lock out’ testing being performed if quality control requirements have not been met.

Specimen integrity checks—detections for insufficient quantity or inadequate, poor-quality specimens—are helpful features that manufacturers incorporate into POC devices.

POC device manufacturers also include features to track or document cleaning and/or maintenance, including filter changes and optical standard checks.

### Clinical Applications and Laboratory Modalities

#### A. Clinical Applications

##### Hematology

The use of hematology analyzers in POC or near-patient settings for complete blood count (CBC) analysis requires careful consideration of the specific clinical diagnostic needs of the target patient population. The choice of the analyzer may be driven by the prevalence of specific diseases or, for pediatric patients, by age. A CLIA-waived instrument may be considered in some settings but not in others. For example, CLIA-waived CBC analyzers like the Sysmex XW-100 are not intended for use in hematology-oncology patients and children under two years of age. Recently FDA-approved analyzers are not intended for use in children under the age of two years or three months (PixCell Hemoscreen™ and SightOLO®, respectively). In addition to considering the target patient population, it is important to note that some hematology instruments can perform a 3-part differential while others offer a 5-part differential. A 3-part differential may not be sufficient for a clinic that sees patients with diseases leading to eosinophilia or basophilia. The reportable ranges of the parameters offered by specific instruments should match the values expected in the specific patient population, to minimize the number of repeated draws or of specimen referred to the central lab.

## Coagulation

Several methodologies and instruments are available for monitoring coagulation in POC settings. Testing for Prothrombin Time/International Normalized Ratio (PT/INR) in monitoring of chronic anticoagulation therapy and for platelet responsiveness to therapy can be useful in specific settings, such as anticoagulation clinics, catheterization labs, interventional radiology in hospital settings, etc. More complex testing methods are available that provide a comprehensive assessment of the coagulation process in more complex patients. In recent years, thromboelastography has emerged as a valuable methodology to determine the coagulation status of patients undergoing major surgery, in intensive care settings, or for hemophilia patients with inhibitors. The use of these instruments in the POC setting is driven by clinical needs, and concerns about sample stability, requiring immediate processing in near-patient settings, can be determined by lab management on a case-by-case basis.

## Infectious Disease

Rapid diagnostic tests (RDT) have been used for many years in the quest to diagnose infectious diseases at the point of care. There are lateral-flow, immunochromatographic tests readily available to be performed as waived complexity tests while a patient waits for their results. Currently available and new to POCT are nucleic acid amplification tests (such as PCR or RT-PCR). These assays are performed using bench-top equipment.

## Cardiovascular Disease

POC tests have tremendous potential for improving cardiovascular disease (CVD) care. With the ability to offer high-quality biomarker measures in a variety of clinical settings, including acute care, outpatient clinics, clinical research centers, personal households, rural areas, and developing countries, POC testing can ensure that more people have access to CVD testing. In the operating room/surgery, intensive care unit, cardiac catheterization unit, and emergency department, real-time feedback is critical to maximize care and customize therapies in rapidly changing health scenarios. Quantitative CVD risk assessment and clinician-patient risk discussions are important components for optimal CVD prevention, according to current CVD prevention guidance geared toward individualized therapy recommendations based on unique benefit-harm assessments for a given patient (2). Pre-visit POC testing is a novel technique for providing tailored, guideline-recommended primary preventive treatment. Commonly used POC tests in cardiac care measure cardiac troponin (cTn) T and I. POC high-sensitivity cTn (hs-cTn) tests may become available soon; however, evidence is required to ensure that new POC hs-cTn tests meet analytical and clinical guidelines. In addition to measuring cardiac troponin, several POC devices are available for measuring thrombosis serum biomarkers, such as D-dimer, and for markers of coagulation and platelet function.

## Other Specific Diseases

There are many POCT options for additional diseases and clinical applications. These include, but are not limited to, tests for pregnancy, some cancers, diabetes, and renal disease, and for critical care. **Table 2** highlights POCT use examples for these conditions. The FDA maintains a searchable list of all approved home and lab tests for your reference (3).

### A. Laboratory Modalities

#### Immunoassay

Immunoassay options for point of care will involve either individual tests (lateral flow, etc.) or an instrument platform. These antibody-focused assays are ideal and common for many targets, such as protein detection, drug testing, or even infectious disease.

An instrument platform will typically take some amount of space in an office or laboratory and require training for the user. While a laboratory can include multiple platforms, each addition will require more space and training. Thus, it is important to choose an option that may cover multiple (or all) needs for immunoassay POC testing for your facility. It will also be critical to consider the associated workflow with the platform and ensure it is meeting the requirements that are justifying a POC platform.

For tests that are individual and do not require any dedicated equipment, a facility can more easily have several distinct types of testing kits from various manufacturers to achieve their desired menu offering. However, there is still value in familiarity for your facility staff. It will be critical to analyze the workflow and turnaround time and ensure that the overall needs are being met by the solution.

#### Molecular Biology

Molecular POC tests are becoming more readily available as their speed and cost becomes more conducive to POC needs. They can be excellent solutions for detecting infectious disease or other molecular markers, but they cannot detect antibodies, proteins, or chemicals. Some platforms will provide only a qualitative answer, while others will provide a quantitative answer for how much of the molecular target is present.

Typically, a molecular assay has the potential to be more specific and sensitive than an immunoassay, but that is not always true or beneficial. For example, a molecular flu test may have the ability to identify a specific strain of influenza. However, it might only identify flu A or B, which can also be achieved with an immunoassay. Additionally, higher sensitivity may not always be a beneficial feature. Some studies show that a small amount of *Clostridium difficile* can sometimes be found in a perfectly healthy individual. Since a molecular test may detect that small/normal amount when it is not the cause of a symptom, treatment may be initiated when it is not necessary or appropriate. As seen in the example of



*C. difficile*, evaluating the clinical utility of each test is necessary to prevent unhelpful diagnoses or treatment.

## General Chemical Analysis

POC chemistry analyzers provide wide test menus, including electrolytes and metabolic and lipid panels, and may include immunoassay methods as well. POC chemistry analyzers may specifically target urine or blood analytes, or a disease condition that requires specific biomarkers, such as diabetes (glucose, or HbA1c, or microalbumin/creatinine ratio), myocardial biomarkers (troponin I, cardiac myoglobin, NT-proBNP), Alzheimer's disease (Amyloid beta-42), and others. While some POC analyzers use technologies similar to larger lab-based analyzers, others use specific technologies like microfluidics (e.g., lab-on-a-chip) or centrifugal microfluidics, and specific sensor methodologies like optical sensors, electrochemical transducers, and others (4). Novel technologies geared toward use in resource-limited settings include paper-based analytical devices and electrospun fiber-based biosensors (5). Microfluidic devices may allow storage of reagents in liquid or lyophilized forms and their release and manipulation when the assay is performed.

## HOW TO SET UP A POCT LABORATORY Regulatory Requirements and Certification

All US locations performing any laboratory testing must obtain a certificate to perform testing from The Centers for Medicare & Medicaid Services (CMS)/CLIA. All testing that involves a sample taken from a patient and that has results used in diagnosis, treatment, or monitoring of that patient must be performed at a site with a CLIA certificate.

The available certificates are:

- Certificate of Waiver
- Certificate of Registration (obtained with initial application; will then become Certificate of Compliance or Accreditation)
- Certificate of Compliance: will be inspected by CMS/CLIA; additional inspection fee will be charged
- Certificate of Accreditation: will be inspected by an entity approved by CMS (College of American Pathologists, The Joint Commission, The Commission on Office Laboratory Accreditation (COLA), etc.). These entities will charge a separate fee for signing up and inspection
- Certificate of Provider-Performed Microscopy (PPM) Procedures. This topic will not be discussed as part of this document. PPM can only be performed by specified providers. All PPM testing is categorized as moderate complexity testing. Waived testing can also be performed under a Certificate of Provider-Performed Microscopy.

The application form for a CLIA certificate is found on the CMS/CLIA website and must be filled out completely and sent to CMS/

CLIA, which will send an invoice for payment (6). Upon receipt of payment, the certificate will be issued. The certificate must be displayed at the testing site.

## Test Complexity & Regulatory Compliance

The FDA determines test complexity. Only waived testing can be performed by a site with a Certificate of Waiver. CMS defines waived testing as simple tests with a low risk for an incorrect result. They include certain tests listed in the CLIA regulations, as well as tests cleared by the FDA for home use. Moderate complexity testing can be performed in a laboratory or near-patient setting with either a Certificate of Compliance or Certificate of Accreditation. Waived testing can also be performed under these certificates. High complexity testing is normally not performed in a POC environment and will not be discussed in this document. A searchable CLIA database is available to help determine the complexity of a test (7).

Regulations for the facility performing waived testing under a certificate of waiver are minimal. Besides obtaining the appropriate CLIA certificate, the MIFU must be followed. Any deviation from the MIFU would make the test high complexity, so following all applicable instructions is essential. Instructions for performing testing must be available to testing personnel. Anyone who has been trained can perform waived testing, and the requirements for CLIA Laboratory Director do not require laboratory background. Quality control must be performed per MIFU. State or local accreditation requirements may need to be considered and implemented.

Regulations for moderate complexity training are more stringent. There are specific requirements for CLIA Laboratory Director, technical consultant, clinical consultant, and testing personnel. Competency assessment, training, quality control, verification and validation of devices and test kits, and quality management are all specified in the regulations, and will be discussed individually in this document. All sites with either Certificate of Compliance or Certificate of Accreditation can also perform waived testing.

The FDA may also grant Emergency Use Authorization (EUA) when necessary, as for the SARS-CoV-2 pandemic. Newly developed tests will be provided temporary approval from the FDA to be used as stated in the EUA letters. If the letter states that the test can be used in POC situations, then it can be treated as a waived device/kit. If the letter states that it can be used in a laboratory only, then it must be managed as a moderate complexity test.

It is imperative to comply with all regulations for POCT. Ensure that the laboratory addresses the following questions:

- Do current employees meet regulatory qualifications for their assigned roles?

- Do you have the correct personnel properly certified to perform the testing?
- Do you need the test to be CLIA-waived?
- Is there a current CLIA Certificate available?
- If the testing needs cannot be satisfied by a lower complexity CLIA-waived test, do you meet the requirements of a higher level of complexity testing?

## Environment & Facility Needs

Additional considerations to review beyond which kit or device to purchase include the laboratory equipment needed and facility requirements (**Table 3**).

Laboratory environments are dictated by the testing that is performed and what the manufacturer dictates in their package inserts. Laboratories must ensure that they have met proper temperature control, lighting, humidity, air quality, water quality, and altitude expectations. Some instruments are equipped with internal detectors that will alert the user, while others rely on manual documentation to verify.

All testing will require some element of personal protective equipment (PPE). The type and level of PPE will be defined by what testing is being performed. Laboratory waste management should be considered for biohazard disposal of regulated waste. Management of waste can be contracted out or maintained at the laboratory, depending on your laboratory's need. Ensuring occupational health and security of staff is important. Laboratories should have a route for health assessments of laboratory staff and for the safety/security of the laboratory itself (reference CLSI for specifics) (8).

Factors to be defined:

1. Temperature
2. Lighting
3. Humidity
4. Altitude

## Facility Requirements

The "facility" is the physical space (e.g., environment) that encompasses the POC laboratory. If the lab is a shared activity space, involve all stakeholders of each activity conducted in the lab design. Stakeholders may include the owners, lab managers, lab users, faculty and staff, patient representatives, and facilities and maintenance personnel.

Next, consider practical environmental limitations starting with the physical size of the space and identify how much counter/bench top space will be required for each activity, equipment storage requirements (e.g., coordinate lab furniture capacity with the height and weight of the lab equipment), and the num-

ber and type of users that will be working within the space. Using diagrams and workflow plans, consider how the lab/POCT users will coordinate effective and efficient use of the space. Doing so will define which counter space will be dedicated to "clean" vs "soiled" spaces to minimize contamination of patient samples and the environment and will improve workflow processes.

Consult Environmental, Health, and Safety (EH&S) experts to ensure that the lab/POC facility minimizes safety hazards and includes all required components. Based on the types of tests being performed, a handwashing sink or eyewash station may be required. Plan for chemical storage and containment in the facility. Cleaning and disinfecting supplies for the POC device or instrument must comply with the MIFU; the product used to clean and disinfect the countertop surface is in line with the countertop materials (not necessarily the same as the instrument product required).

Coordinate changes to the HVAC, electrical, plumbing, or other mechanical systems with building and maintenance engineers. In addition to mapping out the spatial use of the lab, determine the power and backup power requirements for any lab equipment.

If the testing facility or counter space can be accessible by patients or non-laboratory personnel, introduce measures to maintain security of the testing equipment, electronics, and protected/personal health information (PHI).

## Test System

### A. Method Verification

Decisions on standardization of POCT equipment are based on scientific and technical evaluation of the options, within the clinical context. Standardization is increasingly important as equipment becomes more complex and the potential for Information Technology (IT) connectivity increases. There can be circumstances where patients may request to perform the tests themselves. This can be beneficial, e.g., in the case of people with diabetes, for patients learning new skills for the first time, or for those who wish to gain independence. While in the hospital setting, only test results from hospital-approved POC devices should be used when adjustments to treatments are being made.

Method evaluation and verification provide objective evidence that a method is fit for purpose, meaning the quality test performance for a specific intended use is fulfilled (CLSI EP15). There are standards associated with ISO and with CLIA regulations, which do not identify exactly what a laboratory needs to do to fulfill the regulations. The guidance for how to do each part of a method verification can be found in the CLSI documents outlined below.

- Verification Requirements

- Trueness/Accuracy: Measurement for comparison to truth (CLSI EP9) (9,10)
- Precision: Measurement of the variability of the new test (CLSI EP5) (11)
- Reference intervals (CLSI C28) (10)
- Analytical measurement range: linearity/calibration verification (CLSI EP6) (12)
- Correlation: if there is more than one instrument in the lab for a specific analyte, how well does the new instrument compare to the current instrument
- With accreditation, users/lab staff must participate in the verification studies
- Other Considerations:
  - Sensitivity: ability of an assay to identify patients with a specific condition (true positive)
  - Specificity: ability of an assay to identify patients without a specific condition (true negative)

Common statistical analyses performed in the clinical laboratory are outlined below.

- Statistical Analyses
  - Paired T-test, ANOVA (Analysis of Variance)
  - Linear regression (slope, y-intercept, covariance)
  - Mean, standard deviation (SD), coefficient of variation (CV)

## B. Instrument Overview

It is essential to understand the testing methodology, comprehend the manufacturer guidelines, determine the sample characteristics, and establish the user base before commencing testing. The quality goals for the instrument should align with the regulatory standards, keeping in mind the instrument limitations. A detailed instrument document can be prepared for each instrument that has the following salient features:

1. Describes the intended/most appropriate use of the instrument, including anticipated area where this may be used
2. Description of methodology, including sample type, minimum volume needed, measuring range, specificity claims and limitations, testing interval
3. Any patient populations the instrument/test should not be used for
4. Limitations stated by the manufacturer
5. Instrument requirements, (e.g., electricity/battery, refrigeration for consumables, infectious waste disposal)
6. Regulatory status (FDA, CE, etc.)
7. Quality goals: published analytical goals for each instrument

## C. Instrument Performance Evaluation & Method Verification

Before commencing evaluation, it is essential to determine that the device is performing according to manufacturer's

specifications. As stated in CLIA's Verification of Performance Specifications, "To verify the manufacturer's established reportable range for the test, choose samples (e.g., previously reported patient or proficiency testing samples with abnormal high and abnormal low values, quality control (QC) materials, or calibration materials) with known values at the highest and lowest levels the manufacturer claims accurate results can be produced by the test system" (13).

Device optimal performance is investigated by running matrix appropriate material in the following studies and referring, when necessary, to the manufacturer for the appropriate materials.

1. Precision (verified by repeat measurement of samples at various concentrations and activities within and across multiple test runs over a period of time) (14)
2. Accuracy
3. Linearity/reportable range
4. Reference intervals

## D. Reagents

Managing reagents and controls for your test systems will require a variety of concepts. After you have collaborated with vendors on quotes and purchasing, you will have identified the necessary amount of product. It is imperative to manage your purchasing to maximize product ordered while keeping storage space and expiration dates in mind. Identify storage requirements within manufacturer's guidelines and ensure you have the appropriate refrigeration, ultra-low freezer, room temperature, and/or humidity space. Your laboratory should also have a system to maintain a record of these storage requirements, either automated monitoring or manual logs.

The reagents or controls may need to be prepared for use. Your laboratory will need to have specific items on hand, such as Clinical Laboratory Reagent Water (CLRW)/deionized (DI) water or calibrated pipettes, to ensure the product is prepared correctly. For new shipments of reagents and controls, you will need to follow CMS and the manufacturer's guidelines for verification of the new product.

If the test is not purchased as a 'kit' with all components included, determine reagents and disposables needed based on the MIFU.

## E. Calibration Verification

Many POC devices are manufacturer calibrated; however, calibration verification is crucial for POCT testing. Three samples (low, middle, and high) spanning the reportable range of the test are run as unknowns, and the values obtained are compared to the known values of the calibration verification material as per CLIA guidelines. Depending on the type of POCT device and its com-

plexity, manual calibration or automated calibration of the POCT device may be required.

If necessary, calibration instructions will be found in the instrumentation user manual. Each time the calibration is performed, it must be completed how and when the manufacturer states. Do not deviate from the MIFU. Calibration timing is to occur at the specified intervals plus after any major repair of the instrumentation.

## F. Controls and Quality Control

Prior to using QC materials, initially test QC to verify that obtained values fall within the manufacturer's range. These verified controls will be used to ensure that new lots of reagents are evaluated against the current lot of reagents in use. Your laboratory director will establish what limits to use for acceptability criteria with both QC and reagent verification requirements. Laboratories must be able to associate patient testing with specific product lot numbers. Instrumentation often has this capability within its software. If there is not an association within the instrumentation, you must keep a log for association.

1. Reagents and controls: collaborating with vendors on quotes and purchasing/managing expiration dates
2. Proper storage and management of storage with temperature/humidity requirements
3. Verifications of shipments with required frequency/timing from manufacturer and CMS
4. Awareness of supply chain issues (stay in contact with vendors and be responsive to product recalls, shortages, etc.)
5. Setting QC ranges, lot-to-lot and troubleshooting/need for reconstitution (pipettes and calibration)
6. Use of logs

For proper documentation of quality control, QC logs containing Internal QC (IQC) results obtained should be maintained with date/time, lot number, and user ID. IQC review logs and troubleshooting records should be prepared. Sigma Metrics analysis of the IQC data may be performed to monitor the quality of testing. Risk assessment of each stage of patient testing can be performed according to the CLSI EP23 standard (15).

## G. Individual Quality Control Plan

The Individual Quality Control Plan (IQCP) is designed to mitigate risk associated with non-waived testing, except pathology and subspecialties, in each laboratory and to provide an effective quality control program (16,17). The IQCP can reduce the frequency of CLIA-mandated, daily QC, in lieu of manufacturer-engineered QC processes for the POCT device (15). The IQCP will address all areas of testing in the pre-analytic, analytic, and post-analytic phases of testing. It will establish and outline acceptable QC to meet CLIA QC regulations and determine quality

standards to reduce the likelihood of errors in laboratory testing. The completed IQCP will need to be signed by the CLIA Laboratory Director prior to use with the testing system. The CLIA Laboratory Director will also need to sign if any changes occur to the IQCP over time.

There are three parts to a complete IQCP:

1. Risk Assessment (RA)
2. Quality Control Plan (QCP)
3. Quality Assessment (QA)

The Risk Assessment is performed to determine the potential sources of error in the testing process. Identifying what potential errors might occur in each phase of testing can be applied to the five components of RA (listed below). Sources of identification in each component could be from, but are not limited to, manufacturer's package inserts, regulatory requirements, proficiency testing, personnel education, personnel training, personnel competency, QC data, QA information, and a physical review of testing materials or testing location.

The five components of the RA must be dissected with possible categories to ensure all risk of error is mitigated:

1. Specimen: Patient preparation, specimen collection, specimen labeling, specimen storage and stability, transportation, processing, acceptance, and rejection
2. Test System: Inadequate sampling, detection of sample errors, interferences, mechanical or electronic failure detection, optics, barcodes, calibration, internal or external controls, temperature, LIS, and result reporting
3. Reagent: Shipping, storage conditions, preparation, and expiration dates
4. Environment: Temperature, humidity, ventilation, light, noise or vibration, utilities, and space
5. Testing Personnel: Education, experience, training, competency, and staffing numbers

The Quality Control Plan is a written document that will outline the laboratory practices and procedures to reduce risk and errors in the test process. Quality control testing data should be collected over a specific time period that will vary depending on what frequency for QC is determined. Data can include electronic QC, internal and external QC, proficiency testing, calibration, maintenance, and testing personnel assessments.

The Quality Assessment is a continuous process intended to monitor effectiveness of the Quality Control Plan. When a potential risk is identified in a testing system, the QA will allow for mitigation and evaluation of a change in the QCP to occur in real time. At least annually, the QA should be evaluated in depth and signed off (approved) by the CLIA Laboratory Director.

## Quality Management

Every lab is required to have a written Quality Management Plan. Topics must include general laboratory systems, confidentiality of patient information, specimen identification and integrity, complaint investigations, communication, personnel competency assessments, and proficiency testing. The laboratory must monitor, assess, and correct problems when encountered. The plan must cover pre-analytic, analytic, and post-analytic areas of testing and follow written policies and procedures for an ongoing mechanism to ensure quality.

The post-analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of post-analytic systems quality assessment reviews with appropriate staff.

### A. Proficiency Testing

All sites performing moderately complex testing must also perform proficiency testing. Performance of proficiency testing ensures that all lab systems are operating accurately. It must be purchased from a provider approved by CMS. Unknown samples will be sent to the site and must be performed by staff who are performing patient testing. Testers must attest that they perform the samples testing in the same manner as patient tests. It is illegal to compare proficiency testing results between labs, and illegal to refer the proficiency testing specimens to another lab. The results will be compared to peers also performing those tests. Eighty percent is considered acceptable; however, any result below one hundred percent requires investigation and resolution. If proficiency testing fails repeatedly, then the lab could receive an order to cease performing that test until the problems are resolved. Refer to your accreditation for instructions.

### B. Maintenance and Repairs

If your test method includes instrumentation, you will need to evaluate your contract for service, instrument downtime, and repairs. This will often be included in the purchase for a limited amount of time and will require annual renewals for future needs. When a major repair has occurred, the instrument will need to be verified with calibration and QC prior to placing back into use, and instrument logs should include these details.

1. Maintenance: Contractual repairs and system service contracts
2. Reverification (calibration/QC) after major repairs

### C. Method Limitation

Limitations with test methods, identified and listed in the operator's manual and manufacturer's package inserts, define any re-

strictions for use or variance in expected results. It is necessary to understand and operate within these limitations. Use of any test method outside of the limitations is considered "off-label" and makes the test "high complexity." Be cautious with introducing off-label testing, as high complexity testing has numerous added regulatory requirements that can be difficult to maintain.

## Documentation

Documents for running and maintaining POC laboratories require understanding and upkeep. If changes occur, there should be a way to track changes and ensure that staff understand updated procedures. Written policies and procedures must always be accessible to operators, electronically or printed. Care should be taken to ensure that only the most recent version is in use. Documents used for training and competency should meet all the guidelines set by CMS and other regulatory agencies that the laboratory reports to. These documents need to be retained for future inspection readiness, and patient confidentiality must always be maintained. Document retention time will depend on the type of testing.

The following provides a list of documents to be prepared for POCT testing; also review the References and Addenda sections:

1. Change management records
2. Policies and procedures
3. Training and competency checklists
4. QC logs and troubleshooting actions
5. Method verification records
6. Maintaining records for the appropriate amount of time: method validation studies, training/competency forms/quality management
7. Quality management: improvements/complaints and follow up logs
8. Test order and result reporting requirements. Critical result documentation/Critical Call logs and follow ups with the clinical team
9. Interfacing verification records

### A. Test Reports

By regulation, the following items must be included in patient reports:

1. For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number
2. The name and address of the laboratory location where the test was performed
3. The test report date
4. The test performed
5. The test result and, if applicable, the units of measurement or interpretation or both
6. Any information regarding the condition and disposition of

- specimens that do not meet the laboratory’s criteria for acceptability
7. Pertinent “reference intervals” or “normal” values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results
  8. The laboratory must immediately alert the individual or entity requesting the test when any test result indicates an imminently life-threatening condition, or panic or alert values

## Personnel Roles and Qualification Requirements for Moderate Complexity Testing

When evaluating new POCT, and prior to implementing POCT in a clinical setting for patient care, it is important to identify and define personnel roles and responsibilities and assure personnel qualifications meet all local (county, state, country, etc.) and accrediting organization (if applicable) requirements.

### A. Organizational Charts

Establishing an organizational chart can support effective communication by outlining reporting relationships. The first addendum provides two examples of organizational charts. A) a comprehensive and hierarchical organizational management structure that groups personnel with similar skills, work responsibilities, and qualification requirements (18); B) a simplified organizational chart illustrating the CLIA-personnel requirements for a POCT laboratory.

### B. Director

The POCT lab director is responsible for the overall operation, administration, and compliance of the POCT lab with applicable regulations, including employment of qualified personnel who are competent to perform POCT procedures and result reporting. The lab director must demonstrate active involvement in the POCT lab operations, be available to staff as needed, and implement a comprehensive quality management system (e.g., policies, quality indicators) to achieve accurate, reliable, and timely testing (19). The POCT lab director must maintain direct oversight of select responsibilities that cannot be delegated to others depending on local regulations, including but not limited to:

1. Ensuring high-quality POCT performance (i.e., pre-analytic, analytic, post-analytic phases of testing) that is appropriate for the patient population
2. Performing on-site assessment that the physical and environmental conditions of the POCT lab are adequate and appropriate for the testing performed
3. Ensuring that the environment is safe for employees
4. Ensuring sufficient numbers of appropriately qualified, ed-

- ucated, experienced and/or trained personnel are available
5. Reviewing and approving all new policies as well as current policies annually or biennially (as required by regulations) or when a major change has occurred
6. Providing written delegation of personnel responsibilities and duties

The use of a POCT laboratory director site visit form (Addendum 7) with periodic completion of the form by the POCT lab director is an approach to demonstrate lab director involvement in POCT lab operations and quality assurance. Daily, monthly, or quarterly site visits by the POCT lab director is common to ensure high-quality testing and compliance with local regulations. Moreover, annual review of a POCT lab personnel roster by the POCT lab director is a method to ensure appropriately qualified personnel and delegation.

The lab director must meet minimum qualification requirements that can vary depending upon the complexity of testing as well as local regulations and accrediting organization standards under CLIA in the United States (20). Other standards may apply outside of the US.

When setting up a POCT lab, selecting a lab director with board certification in lab medicine or clinical pathology specialty with expertise in POCT and regulatory requirements commensurate with director responsibilities is beneficial. Continuing education resources are also readily available for individuals who need continuing medical education credit hours to meet minimum qualification requirements (20).

### C. Clinical Consultant

A clinical consultant is required for moderate complexity POCT labs in the US. The POC lab director may simultaneously serve as the clinical consultant or delegate, in writing, a qualified individual responsible for clinical consultation. Clinical consultants must be available to provide consultation regarding appropriate test order utilization to meet clinical needs and interpretation of test results, ensure test result reports contain all pertinent information (e.g., reference intervals), and communicate with providers and the healthcare team any issues related to the quality of test results reported or delay in test turnaround time (21).

Minimum qualifications for serving as a clinical consultant under CLIA federal law include:

1. Be qualified as a laboratory director for moderate-complexity testing as defined in the Code of Federal Regulations (19) under § 493.1405 Standard; Laboratory director qualifications; or
2. Be a Doctor of Medicine, doctor of osteopathy, or doctor of podiatric medicine and possess a license to practice in the state in which the lab is located.

#### **D. Technical Consultant/Competency Assessors**

When planning the setup of a POCT lab that will perform moderate complexity testing, the POCT lab director should identify and delegate (if applicable) at least one individual who meets qualifications to serve as a technical consultant (Addendum 6). A technical consultant is responsible for the technical and scientific oversight of the POCT lab that includes but is not limited to:

1. Selecting test methodology appropriate to meet clinical need
2. Verifying test performance characteristics
3. Enrolling and participating in external quality assessment programs (i.e., proficiency testing approved by regulatory agency)
4. Establishing a comprehensive quality assurance program
5. Troubleshooting and resolving technical issues
6. Identifying training needs and assuring in-service training and education
7. Evaluating the competency of all testing personnel performing moderate complexity testing and assuring that testing personnel maintain competency to perform quality testing

Candidate qualifications for technical consultant should be carefully reviewed because there are many nuances in the acceptable qualification criteria under CLIA federal law in the United States. Please refer to CLIA federal law for a comprehensive list of acceptable technical consultant qualification criteria (22). It is noteworthy and somewhat controversial that technical consultant qualification criteria for moderate complexity chemistry and hematology subspecialties under CLIA law can exceed technical supervisor qualification criteria for high complexity testing. More specifically, individuals with a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution must have at least two years of lab training and/or experience in non-waived testing in chemistry and/or hematology subspecialty areas. These more stringent qualification criteria may be, in part, because technical consultants have the important responsibility of assessing competency of testing personnel from various educational backgrounds with minimal training in clinical laboratory sciences and lab medicine practices. Identifying individuals who meet technical consultant qualifications with two years training or experience can sometimes be challenging and necessitate that the POCT lab director simultaneously serve as technical consultant during the initial setup of a POCT lab.

#### **E. Operators/Testing Personnel**

Testing personnel who perform POC testing for patient care are often referred to as POC operators. POC operators are responsible for patient preparation for POC testing, specimen collection, performing quality control and patient testing, documenting QC and patient test result(s) in the patient chart if there is no connectivity, completing routine maintenance (e.g., cleaning/disin-

fection, labeling reagents with open and expiration dates), and performing basic troubleshooting in accordance with MIFU and institution procedures, if applicable. Importantly, POC operators are responsible for completing training and competency assessment for POC testing in a timely manner.

POC operators typically have minimal education in laboratory medicine; more commonly, POC operators have diverse educational backgrounds and are healthcare professionals (e.g., nurses, respiratory therapists, perfusionists, anesthesia technicians, providers, and others) in various clinical disciplines. In the US, CLIA federal law does not define qualification requirements for testing personnel performing waived testing only. POC laboratory leadership must ensure that waived testing personnel meet the facility-defined minimum requirements and obtain records of training and competency assessment. Individuals who plan to perform moderate complexity POC testing must meet minimum qualification requirements of a high school diploma (or equivalent) together with documentation of training appropriate for the testing performed prior to analyzing patient specimens, and possess a current license issued by the state in which the POC laboratory is located if such licensing is required.

### **Training and Competency Assessment**

#### **A. Training**

Training protocols for each test system that is being implemented at the site will need to be performed. In addition, it is good laboratory practice to perform training on proper documentation, quality control procedures, proficiency testing procedures, instrument maintenance, and personal protective equipment (PPE) or other safety needs. In a site performing non-waived testing, the technical consultant (designated by the CLIA Laboratory Director) should develop a training program that encompasses these items. Training can be performed by anyone proficient with the instrument/test kit.

For waived testing, the only regulatory requirement is to follow the MIFU, and each test system's instructions for use will include training requirements.

Testing should not begin until all operators have been appropriately trained.

#### **B. Competency Assessment**

Once training has occurred, and operators are performing testing, competency assessment must be performed at the prescribed intervals. Competency must be assessed after training based on your local accreditation requirements. There are several methods for performing competency assessment: blind testing, quizzes, direct observation of testing, etc. The method of compe-

tency assessment for waived testing is determined by the CLIA Laboratory Director.

For non-waived testing, the technical consultant (designated by the CLIA Laboratory Director) is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

Procedures for staff competency evaluation must include, but are not limited to:

1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing
2. Monitoring of test results recording and reporting
3. Reviewing intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of all performance of instrument maintenance and function checks
5. Assessment of test performance by analyzing previously evaluated specimens and internal blind testing samples, or external proficiency testing samples
6. Assessment of problem-solving skills

### C. Corrective Action

When issues are observed in test performance or patient result errors, operator retraining must be performed on the test systems where the errors occurred. It is necessary to document the steps taken to retrain the operator (8).

## Specimen Collection

Specimen collection processes and procedures should be documented and available to all staff working in the collection and processing area of the laboratory. The laboratory should adhere to all regulations and standards, as well as accreditation agencies, governing specimen collection. If it is easier to maintain the most current procedural documents by electronic means rather than maintaining paper binders and manuals, verify that this is acceptable with the appropriate regulatory agency.

Helpful elements during specimen collection and handling processes include (23):

1. Ensure that personnel regulations for specimen collection are followed
2. Review how to prepare the patient for specimen collection

3. Determine whether specific timing is required for specimen collection
4. Prepare the specimen collection container and know the amount of specimen to be collected
5. Prepare any fixatives or special media; understand specific fill volumes, and proper mixing methods
6. Understand patient and specimen identification requirements
7. Document clinical data properly, when required
8. Understand and utilize correct specimen storage requirements, including temperature and processing (e.g., centrifugation required)

The same adherence to proper patient and specimen identification written procedures must be in place for specimens collected for POCT analysis. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules also must be followed including all regulations and standards pertaining to the testing site. Maintaining patient and specimen confidentiality must continue during and after specimen collection through the process of storage and transportation, as needed.

Collecting specimens for POCT does not differ from methods and precautions used in conducting collections for clinical laboratory specimens. Laboratory best practices are as important during POCT specimen collection as in specimens collected for tests performed in the central or reference laboratory. While regulations regarding specimen identification may differ, the recommendation is to include two patient-specific identifiers on the specimen label.

Follow all instructions provided by the POCT manufacturer to avoid collection and pre-analytical errors. Instructions include any patient preparation required to produce a quality specimen and the correct interpretation of results.

- Examples include: is the patient required to fast for tests such as glucose or lipids? The dietary impact on laboratory test results is complicated and cannot be simply separated into categories of "fasting" and "nonfasting" patient status (24). Significant variations in some routine test results after a regular meal indicate that fasting duration should be carefully considered when performing tests to prevent spurious results (25).
- Additional questions: When should the sample be collected (e.g., first morning sample)? Has the sample been collected properly (e.g., a manufacturer recommendation may be to collect a finger stick sample on the side of a finger, or after wiping away the initial collection drop)?

If the POCT specimen is collected at the time of other lab requests, then order of draw, proper mixing to facilitate anticoagulant mixing or proper clotting, and meeting the 'fill line' requirements on the tubes remain consistent with approved written policies



of the facility. Following specimen collection parameters such as allowable tourniquet time and meeting patient safety measures (for patient and specimen identification), including all National Patient Safety Goals, is required (26).

Many POC professionals considering a POC method or analytical device may choose one that uses whole blood. This eliminates processing steps and the need for centrifugation. Turnaround time to result for the POCT is shortened and exposure of the POC operator to biohazards is reduced due to less specimen manipulation. Whole blood samples include collections from venipuncture, arterial sticks, and finger sticks.

Other sample types collected for POCT include urines, upper respiratory swabs, washes (nasal, saliva, sputum, nasopharyngeal), and stool.

Although fewer steps occur during the pre-analytical phase of POCT than in a central laboratory, this testing phase is meaningful, and caution must be taken to avoid introducing error. Among controllable pre-analytic variables, specimen collection is most critical (25). Pre-analytical errors occur related to specimen collection, patient and specimen identification, handling, processing, transporting, and storing prior to analysis. Errors include those created during collection, including hemolysis, clotting, tube filling (under or overfilling), related to the length of time the tourniquet is applied (for example, total or ionized calcium measurements should have a tourniquet applied for less than a minute), or related to aliquoting of original samples, decapping or unscrewing of caps, centrifuging, and delivery of samples (23). Criteria for sample rejection should include all the causes of pre-analytical error.

If specimen processing requires centrifugation, follow the manufacturer's instructions for operation of the equipment. The operating speeds of the centrifuge must be regularly calibrated according to accreditation or facility regulations. Revolutions per minute (RPM) or Relative Centrifugal Force (RCF) calibrations should be performed only by an authorized service representative of the manufacturer, or an appropriately trained clinical engineer employed by the facility. Consult the operating manual of the equipment model in use for specifics on maintenance, cleaning frequency, and cleaning materials to use (27).

Specimen collection supplies such as blood collection tube and collection devices (e.g., heel lancets, culture swabs, and transport media) must be used within the manufacturer's date stamp on the label (27).

Sample transfer and device loading are aspects of POCT that can cause pre-analytical and analytical errors. Issues such as bubbles, micro clots, and clots can occur. Training on proper technique and management oversight of day-to-day operations can help

prevent the use of incorrect techniques and continued practice should take place at testing sites.

### **A. Potential Interferences in Specimens**

Aside from those elements that cause pre-analytical errors, precautionary measures should include checks for potential interferences that can cause erroneous results. The manufacturer will include these factors in the MIFU, and package insert.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests. Although patients typically are requested to list all their prescribed and over the counter medications when they visit their provider, if a patient forgets to recite them all, or if the provider does not recognize the possibility that a specified medication contains biotin, then the effect of the biotin may not be noticed when the laboratory test result is received by the provider.

Hemolysis can be difficult, and sometimes impossible, to detect in whole blood specimens used at the POC. This includes finger stick collections. Hemolysis can be a rejection criterion (e.g., magnesium and potassium testing).

Some manufacturers build in determination of serum indices within the analysis of the analyte. Serum indices are useful in examining the potential of hemoglobin, bilirubin, and lipids to interfere with the analytical assay (23).

Icteric samples can also have variable effects on assays (25).

Turbidity of the specimen can be a criterion for rejection of a POCT specimen. Especially in waived testing where whole blood, including finger stick collections, is the only allowable specimen, techniques used in the clinical laboratories may not be available in the POC testing station. The most effective and practical way to minimize interferences from highly lipemic samples is to remove the lipids. Dilution of the specimen will limit the sensitivity of the assay (23).

Capillary samples collected by fingerprick can be inadequate for testing if the patient's peripheral circulation is compromised. Many patient conditions can affect peripheral circulation, for instance sepsis, shock, diabetic ketoacidosis, etc. Samples collected from an arm where intravenous solutions or blood products are being infused can lead to contamination of the specimen.

Many other supplements or drugs can interfere with testing; each testing MIFU should be read thoroughly, and the patient history examined to determine if anything the patient is taking could impact the testing being performed.

If there are questions about the accuracy of POCT, or if the re-

sults obtained are unexpected, patient samples should be sent to a central laboratory. Procedures must be in place for lab operators to address abnormal test results. In addition, if results are flagged as questionable by the POC methods being utilized, those samples should also be repeated at a central lab location.

## **B. Other Challenges in POCT Related to Specimen Collection**

One of the typical benefits of using POCT is the usual need for less specimen per test. However, any 'margin of error' inherent in using a larger specimen is negated.

The sampling of blood via intravascular needles, cannulas, or central lines is common, particularly in intensive care units. Before the sample is taken, the central line should be flushed with heparin, and a minimum of twice the line volume, approximately 2-5 ml blood, and should be discarded to avoid sample contamination with infusion solutions or medications. The time between the last infusion and blood sampling should be at least 15 minutes. Caution needs to be taken when POCT systems are employed, as they are more sensitive to interfering substances than large central laboratory devices (8). Of particular interest in POCT, blood collected for blood gas analysis must be controlled to a high degree. Blood for gas analysis is highly susceptible to changes in partial pressure of oxygen (pO<sub>2</sub>). Anaerobic conditions during collection and handling are essential and highly dependent on the composition of room air. Factors that must be controlled during collection are removal of all air bubbles, use of the proper anticoagulant, appropriate use of plastic syringes, the temperature of storage before analysis, and the length of delay between collection and analysis of blood (28). Similarly, POCT glucose testing may not be appropriate for critically ill patients (29).

Virtually all drugs may affect the results of clinical laboratory tests that include both *in vivo* (pharmacologic) and *in vitro* (interferences and methodologic) effects. Depending upon the assay format, biotin interference results in either falsely low or high values (25).

## **C. Challenges in selecting safety equipment and PPE related to specimen collection**

Rules of universal precaution, including PPE worn by collectors, apply and reflect the approved, written protocols of the facility to protect the employee from risk and harm. Rules of universal precautions apply to collecting POCT specimens.

One difference between a collector of the POCT compared to collecting specimen going elsewhere for processing and analysis is that, due to the nature of POCT, the specimen collector may also perform the test (POC operator). If this is the case, the collector must be diligent to protect themselves from inherent risks and harm and consider the impact of engaging in multiple tasks in

the workflow. Often, the POC operator is the collector of the specimen and then immediately uses that specimen for analysis prior to conducting other (non-laboratory) duties. Protecting the patient (and subsequent patients) is paramount to reducing the potential of risk and harm of exposure to the patients as part of the POC operator's workflow. Changing PPE following completion of testing is an important consideration.

Consider splash shields and/or biosafety cabinets based on the manufacturer plus government agency recommendations (such as the US Centers for Disease Control and Prevention) (30). Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, is an important advisory document recommending best practices for the safe conduct of work in biomedical and clinical laboratories (31). The MIFU may also include required or recommended PPE for collecting specimens used in POC molecular testing (nasal, NP, for example) in particular.

## **D. Disposal of Waste/Waste Management Related to Specimen Collection Only**

Follow all laws, regulations, and accreditation standards governing disposal of medical waste.

After venipuncture is completed, the needle must be covered using the built-in safety shield. Lancets used for finger sticks must be single-use. Disposal of the venipuncture needle or the lancet must be in a sharps container (hazardous waste receptacle designated for needles).

Beware of urine collection cups that have embedded needles used to fill vacuum tubes to be sent for urine culture from the same cup used for POCT urinalysis or other testing.

An alternative receptacle for sharps, depending on facility waste policies, are biohazard cardboard boxes with plastic liners (such as red bags).

The proper disposal of swabs may be determined by local or facility waste policies. One guide on how to dispose could be if the swab was used in a procedure that removed the sample from the swab (e.g., the swab is swished in a liquid solution that pulls the virus or bacteria off the swab, then the test is performed on the eluate). If the sample is no longer on the swab, it would not be a hazard to dispose of the swab in regular trash. If the sample or a remainder of the sample is on the spent swab, then disposal into a biohazard bag is appropriate.

Follow all laws, regulations, and accreditation standards for the removal, deletion, or cloaking of protected health information (PHI) identified on the specimen label prior to disposal of any receptacle, vial, tube, cup, etc.

Follow all laws, regulation, and accreditation standards for securing soiled utility rooms or housekeeping closets that store bio-hazard and hazardous waste.

## E. Specimen Transport

In the event that the POC test sample needs to be referred (sent out of the collection station) to a reference lab for confirmation or further studies, care must be taken to ensure the integrity of the specimen during storage and transport. These concerns may include the use of a lab lock box, maintenance of the required storage temperature, and assurance that the specimen can proceed to the next stop in the process before its integrity suffers and the specimen must be rejected due to the receiver's qualifications.

## Connectivity

When installing any POC test analyzer for an existing or new laboratory device, record analyzer results. Patient laboratory results are required by accreditation to be associated with a patient's medical record. One means for result recording is using an electronic method through an interface between an analyzer and the patient's electronic medical record.

While POC testing is designed to place devices near the patient and provide results to the caregiver as quickly as possible, the same ease of use and potential distance between testing and a laboratory facility may present a difficulty in recording test results into a patient's medical record in a timely manner. Various connectivity solutions are currently in use. Some manufacturers have developed their own software to enable test results to pass from the POC device to the Lab Information System (LIS), resulting in records within the Hospital Information System (HIS) or Electronic Medical Record (EMR). There are also vendor-neutral middleware solutions that can connect many POC devices, regardless of manufacturer, and push test results into the LIS and HIS.

### A. Considerations

When considering the addition of a new testing platform, it is crucial to consider the connectivity capabilities offered by the manufacturer:

1. Assessing current state—is this a brand-new setup or is the current platform or facility being replaced or enhanced? Is the new testing platform already validated with preexisting connectivity?
2. Connectivity options—will the device utilize one-way or two-way communication? Is it capable of wireless setup, or is hardwiring and physical connection required? Is a docking station or Lantronix Device Server necessary?
3. Is middleware required (vendor or third party) or can the device connect directly to the LIS or EMR?

4. Instrument operation considerations—how has the manufacturer designed the device to work with operator IDs, patient IDs, results comments, and other patient information?
5. Instrument management—how is instrument QC performed? How does patient testing management meet regulatory guidelines?

### B. Terminology and Project Plan

Addendum 13 provides a list of current IT connectivity terms to serve as a resource during POCT device implementation and interfacing with LIS/HIS. It is crucial that the CLIA Laboratory Director or project manager develops or refers to a project/implementation plan for device installation and interfacing to ensure that all processes are correctly executed and that the POCT device is correctly configured. See Addendum 5 for a project plan template. This template can be expanded as needed depending on the project at hand.

The project manager should be prepared to work closely with the instrument vendor to learn how to program the new device, how to establish and maintain connectivity, and how to service the device.

### C. Data Transmission and Troubleshooting

When a POC device malfunctions or stops transmitting data to the LIS/HIS, the assigned POC Coordinator (POCC) needs to understand the connectivity components and how each device connects to the network to troubleshoot and manage the error (e.g., via Wi-Fi or Ethernet). Some POC devices may utilize a Lantronix Device Server (Lantronix box) to aid in transmission and communications between the POC device and computer, or between multiple devices. These external device servers allow one to access, monitor, and control equipment through the Internet, and understanding how they function (e.g., by examining their blinking light frequencies and patterns) can help troubleshoot connectivity issues.

Transmitting results into patient records quickly and accurately is another important function of your POC device(s). Software now enables a process called Admission-Discharge-Transfer (ADT), which is the transfer of patient information from the HIS to a POC device. This allows for the POC device user to positively identify the patient being assessed at the time of testing, preventing potential misidentification of patient results.

### D. Competency Tracking - Connectivity

Some middleware products have developed an interface between an institution-based eLearning system and the POCT middleware. This eLearning interface allows for competency tracking regardless of department or device and can be used to identify

operators by department and assign annual reviews by defined categories. Quizzes and other testing materials can be linked to annual review procedures and to meet regulatory requirements. Quizzes may mimic POC testing and/or include interactive learning materials. The institution-based eLearning system can also be used to track dates of competency and expiration. In some systems, automatic recertifications can occur based on defined criteria. By using an automatic approach to competency tracking, the efficiency and productivity of the POC laboratory and end user can significantly increase.

## THE FUTURE OF POCT

Many POCT devices are available on the market, and there has been a rapid increase of options in the past few years. This is largely due to medical care trending towards patient-centered care, which has been accelerated by the SARS-CoV-2 pandemic. POCT appears to be capable of creating a balance between rapid diagnostic testing used on-site in the acute care setting with system-centered care using large main laboratory or reference laboratory testing. The appeal of POCT is the potential for quicker clinical decision-making that allows for convenient real-time diagnosis and treatment within one patient care event. Outcomes for immediate patient care and future long-term care have steadily improved with the ability to obtain testing results without the delays that may be associated with traditional reference laboratory testing.

The future of POCT will likely bring new testing for a wide variety of uses, such as the following (32):

- Mobile wearable devices
- Transcutaneous monitors
- Breath alcohol testing, breath hydrogen/*H. pylori* testing
- Continuous glucose monitoring
- Lab-on-a-chip (LOC)
- DNA testing
- Molecular PCR
- Sepsis
- Stroke markers
- Epidemic and pandemic testing

With emerging technologies, it is imperative that stakeholders collectively identify what testing is needed and which method or platform best meets the needs for patient-centered care. A team of people should be involved in these discussions: clinical laboratorians, physicians, compliance personnel, and end user representatives. The success of future POCT relies on partnering for investigation, implementation, and monitoring quality over time.

## Author Contributions

All authors confirmed they have contributed to the intellectual content of this paper and have met the following four requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

## Authors' Disclosures or Potential Conflicts of Interest

Upon manuscript completion, all authors completed the author disclosure form. Disclosures and/or potential conflicts of interest: **Employment or Leadership:** J.H. Nichols, The Journal of Applied Laboratory Medicine, AACC; G.A., Lahey Hospital & Medical Center, Burlington, MA; K.D., Tricore Reference Laboratories; E.B.D.M., Bronson Health System, AACC CLS Council Chair Elect; K.H., Werfen, AACC CPOCT Division Nominating Committee Member, AACC CLS Nominating Committee Member; P.A.M., Clinical Laboratory Standards Institute POC Expert Panel Chair; D.M., ProciDx Inc, Lucira Health; C.R.O., AACC; N.K.S., Board of Director, ComACC. **Consultant or Advisory Role:** C.B., Sysmex Diagnostics; K.D., Werfen Advisory Board; P.A.M., Werfen POCT Advisory Board; N.K.S., Werfen Acute Care Diagnostics POC Advisory Council. **Stock Ownership:** D.M., ProciDx Inc, Lucira Health. **Honoraria:** K.D., AACC CLS Forum; P.A.M., Werfen POCT Advisory Board; K.H., AACC CPOCT Regional Bootcamp and Annual Meeting **Research Funding:** S.D, Department of Science and Technology, Government of India. **Expert Testimony:** None declared. **Patents:** None declared.

## Role of Sponsor

Sight Diagnostics (Sight) provided commercial support for this publication. Sight agreed that the content of this publication will be unbiased and educational in nature and not promotional. AACC is dedicated to ensuring balance, independence, objectivity, and scientific rigor in all educational activities. AACC received feedback from Sight during the development of this document and reviewed the content for scientific accuracy. AACC made final decisions on the subject matter expert writing group members and scientific content contained within this guide.

## Acknowledgments:

The writing group thanks the AACC Board of Directors, AACC Academy Council, AACC Science & Practice Core Committee, and Sight leadership for their careful review of this document. Special thanks to Kristen Hauck for proofreading.

## TABLES

Table 1: Adding POCT to a New Facility

| Possible Goals of Adding POCT                       | Questions to Answer   | Additional Considerations   |
|---|---|---|
| Clinical Need                                       | <ul style="list-style-type: none"> <li>• How will physicians use the results to improve patient care?</li> <li>• What are the advantages of POC testing vs. conventional testing in your specific clinical setting?</li> <li>• Will putting testing in the hands of clinical personnel who are justifying the clinical need mean 'off label' use (e.g., specimen type not adhered to)?</li> </ul> | <ul style="list-style-type: none"> <li>• There may be benefits that justify additional cost or capability requirements.</li> </ul>                                    |
| Faster Turnaround Time (TAT) to Meet Clinical Needs | <ul style="list-style-type: none"> <li>• What is the current TAT?</li> <li>• What is the target TAT?</li> <li>• Is there a 'MUST ACHIEVE' TAT?</li> </ul>   | <ul style="list-style-type: none"> <li>• Does the platform meet the necessary targets?</li> <li>• What additional equipment, skills, or labor is required?</li> </ul> |
| Additional Menu                                     | <ul style="list-style-type: none"> <li>• Is that menu available on current platforms?</li> <li>• What will be the volume of these additional tests?</li> </ul>  | <ul style="list-style-type: none"> <li>• Are there additional tests on the new platform that should be considered?</li> </ul>   |
| Reduce Batching                                     | <ul style="list-style-type: none"> <li>• Are you trying to achieve more 'first in first out' results?</li> <li>• Will this increase the number of controls run?</li> <li>• Could this increase the dead volume of some assay kits?</li> </ul>   | <ul style="list-style-type: none"> <li>• Can POC match the throughput needed at the facility?</li> </ul>  |
| Eliminate Older or Retired Platforms                | <ul style="list-style-type: none"> <li>• Are there end-of-life platforms that need to be replaced, thus considering POC replacements?</li> </ul>  |   |
| Reduce Sample Size                                  | <ul style="list-style-type: none"> <li>• Pediatric, neonatal populations</li> <li>• Patient satisfaction</li> </ul>   |   |

Table 2: Clinical Applications of POCT

| Clinical Need/ Application     | Testing Platform/ Methodology      | Assay/Use Examples  | Strengths   | Weaknesses  |
|--------------------------------|------------------------------------|---|---|---|
| <b>Hematology</b>              | Traditional Cell Counting          | <ul style="list-style-type: none"> <li>Blood counts (full CBC and differential or selected parameters)</li> </ul>   | <ul style="list-style-type: none"> <li>TAT</li> <li>Cost</li> <li>Simplified operator training and QC</li> <li>IQCP options</li> <li>Specimen convenience (finger prick), if approved in IFU</li> </ul> | <ul style="list-style-type: none"> <li>Moderate complexity</li> <li>Specimen collection challenges</li> <li>Cost</li> </ul>   |
|                                | Novel Optical/Visual Methods       | <ul style="list-style-type: none"> <li>Full CBC</li> </ul>  |   |   |
|                                | Hemoglobin only                    | <ul style="list-style-type: none"> <li>Hb</li> </ul>  |   |   |
|                                | Flow Cytometry                     | <ul style="list-style-type: none"> <li>CD4 count</li> </ul>   |   |   |
| <b>Coagulation</b>             | Clotting                           | <ul style="list-style-type: none"> <li>Ambulatory/home anticoagulation management (INR)</li> <li>ACT and other assays for operative coagulation management, bleeding, hypercoagulability, coagulation inhibitors</li> </ul> | <ul style="list-style-type: none"> <li>CLIA-waived for some devices</li> <li>Rapid sample processing, avoids tubing, storage, transit issues</li> </ul>   | <ul style="list-style-type: none"> <li>Poor correlation with the lab-based assay</li> <li>Moderate-complexity</li> </ul>  |
|                                | Viscoelastic                       | <ul style="list-style-type: none"> <li>Intraoperative and post-operative monitoring</li> </ul>  |   |   |
|                                | Platelet                           | <ul style="list-style-type: none"> <li>Responsiveness to platelet therapy</li> </ul>  | <ul style="list-style-type: none"> <li>CLIA-waived for aspirin</li> </ul>   |   |
|                                | D-Dimer (immunoassay)              | <ul style="list-style-type: none"> <li>VTE exclusion</li> </ul>   |   |   |
| <b>Infectious Diseases</b>     | Q-PCR, Isothermal amplification    | <ul style="list-style-type: none"> <li>Influenza, RSV, Strep A, HIV, STIs, SARS-CoV-2</li> <li>Procalcitonin</li> </ul>   | <ul style="list-style-type: none"> <li>Sensitivity and specificity</li> <li>Measure viral load in infection</li> <li>Identify residual disease</li> <li>CLIA-waived</li> </ul>                          | <ul style="list-style-type: none"> <li>Detection limited to nucleic acids</li> <li>TAT</li> <li>Cost</li> <li>Sensitivity</li> </ul>  |
|                                | Lateral-flow based antigen testing |   |   |   |
| <b>Cardiovascular Diseases</b> | Cardiovascular Diseases            | <ul style="list-style-type: none"> <li>Troponin I, high-sensitivity troponin, cardiac myoglobin, BNP, NT-proBNP</li> </ul>  |   | <ul style="list-style-type: none"> <li>Patients need to be monitored using same methodology due to lack of harmonization between methods</li> <li>Assays lacking harmonization may require additional studies to confirm results</li> </ul> |
|                                | Chemical or colorimetric           | <ul style="list-style-type: none"> <li>Cholesterol, LDL, Lp(a)</li> </ul>   |   |   |

Table 2: Clinical Applications of POCT (continued)

| Clinical Need/<br>Application                            | Testing Platform/<br>Methodology                       | Assay/Use Examples   | Strengths  | Weaknesses   |
|--|--|--|--|--|
| <b>Specific diseases<br/>or conditions:</b><br>Pregnancy | Qualitative strip-based<br>testing                     | <ul style="list-style-type: none"> <li>Beta-hCG</li> </ul>                               | <ul style="list-style-type: none"> <li>TAT</li> <li>Cost</li> <li>Simplified operator training and QC</li> <li>Specimen convenience (finger prick, urine, etc.)</li> </ul> | <ul style="list-style-type: none"> <li>Patients need to be monitored using same methodology due to lack of harmonization methods</li> <li>Assays lacking harmonization may require additional studies to confirm results</li> <li>Specificity</li> <li>Quantitation (qualitative, semi-quant)</li> <li>Reliability dependent on pre-analytical process</li> <li>Confirmation of POC results with laboratory tests</li> </ul> |
| Cancer   | Qualitative strip-based<br>Testing<br><br>Immunoassays | <ul style="list-style-type: none"> <li>Prostate-specific antigen (PSA)</li> </ul>        |  |  |
| Diabetes   | Qualitative strip-based<br>Testing                     | <ul style="list-style-type: none"> <li>HbA1c, glucose, ketones</li> </ul>                |  |  |
| Renal disease  | Immunoassays   | <ul style="list-style-type: none"> <li>Creatinine</li> </ul>                             |  |  |
| Critical care  | Chemical or<br>colorimetric, blood gas/<br>sensors     | <ul style="list-style-type: none"> <li>Blood gases, electrolytes, CO-oximetry</li> </ul> |  |  |

**Table 3: Laboratory Equipment and Facility Requirements**

| Category  | Specifics   |
|---|---|
| Lab Furniture/Lab Workspace                             | Benchtops or tables (fixed or flexible)<br>Work stools, chairs<br>Phlebotomy station<br>Carts<br>Lighting<br>Data ports<br>Electrical outlets<br>Limited access doors/security (keys, code, card access)    |
| General Lab Equipment                                   | Pipettes<br>Scales<br>Centrifuge<br>Incubators<br>Spectrometers<br>Handwashing sink<br>Clinical Laboratory Reagent Water (CLRW) source<br>Signage<br>Refrigerator<br>Biohazard fume hood(s)<br>Dead air box |
| Consumables   | Pipette tips<br>Weigh boats<br>Testing reagents<br>Calibrator and QC consumables<br>Specimen collection items (tubes, lancets, syringes, gauge needles, tourniquets, bandages, etc.)                        |
| Temperature and Humidity Monitoring and Storage Systems | Size considerations<br>Min/max thermometers<br>Wireless temperature and humidity monitors<br>Cold storage<br>Frozen storage<br>-80°C storage<br>Alert notification process                                  |
| Electronics and Office                                  | Computer<br>Printer<br>Printer paper and ink cartridges<br>Barcode scanner<br>Batteries   |
| Safety and Hygiene                                      | Eye wash<br>PPE (gloves, masks, lab coats, etc.)<br>Germicidal wipes<br>Hand sanitizer<br>Soap<br>Paper towels<br>First-aid kit<br>Fire extinguisher<br>Spill kit   |



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## USEFUL LINKS

1. AACC Guidance Document on Management of Point-of-Care Testing  
[https://www.aacc.org/-/media/Files/AACC-Academy/Publications/POCT-Management\\_20200601Final.pdf?la=en&hash=6F7D66FE5EA83CA-0B0AA8385529287D829D843BD](https://www.aacc.org/-/media/Files/AACC-Academy/Publications/POCT-Management_20200601Final.pdf?la=en&hash=6F7D66FE5EA83CA-0B0AA8385529287D829D843BD)
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<https://www.cdc.gov/>

# **POINT-OF-CARE TESTING**

## **A “HOW-TO” GUIDE FOR THE NON-LABORATORIAN**

ABEL G, BRUGNARA C, DAS S, DAVID K, DEATON-MOHNEY EB, HALVERSON K, MANN PA, MOORE D, NICHOLS JH, ONDRACEK CR, AND KORPI-STEINER N.

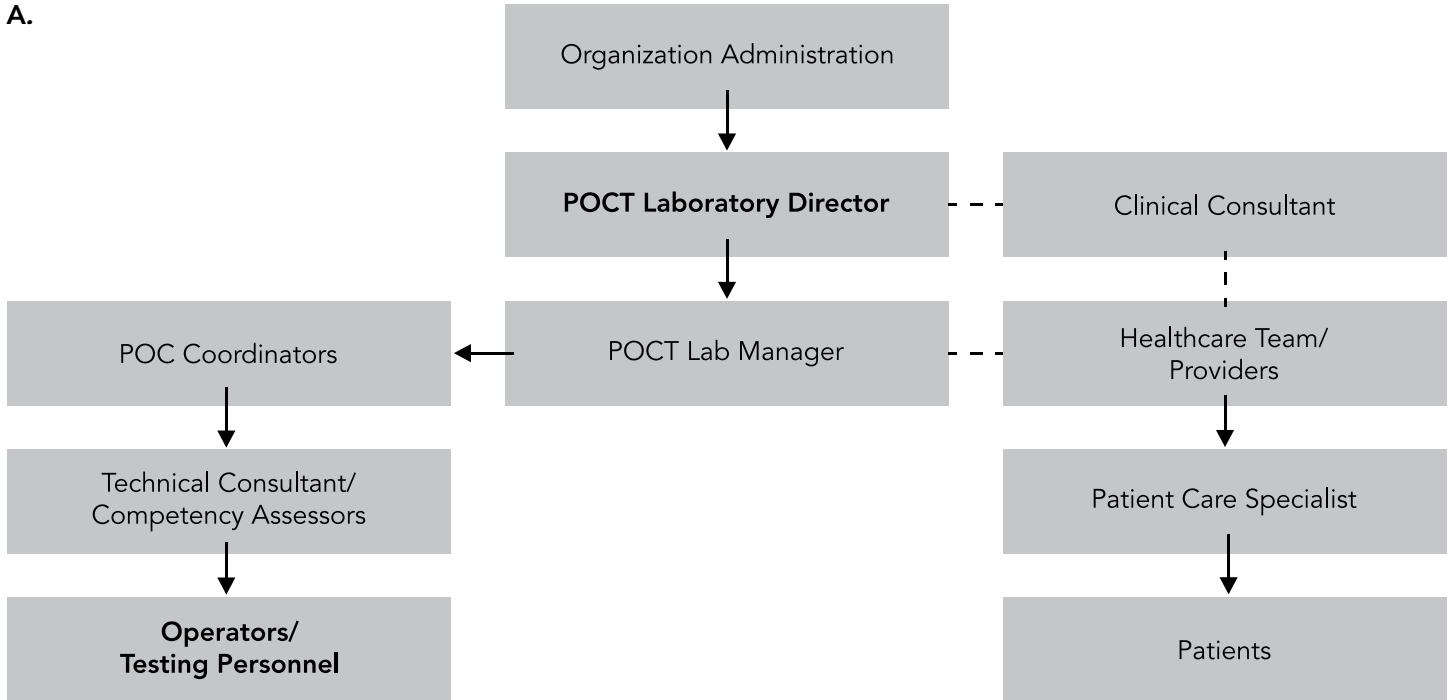
### **ADDENDA**

1. POCT Organizational Charts
2. Generic Needs Assessment
3. Request for New Testing Form
4. New POCT Implementation Form
5. Project Plan
6. Technical Consultant Document
7. Laboratory Director Site Visit Form
8. Quality Management Template
9. Waived Testing Initial Training: Urine Pregnancy
10. Waived Testing Annual Performance Evaluation: Urine Pregnancy Test
11. Moderate Testing Initial Training
12. Moderate Complex Annual Performance Evaluation
13. POCT Connectivity Glossary
14. POCT Glossary

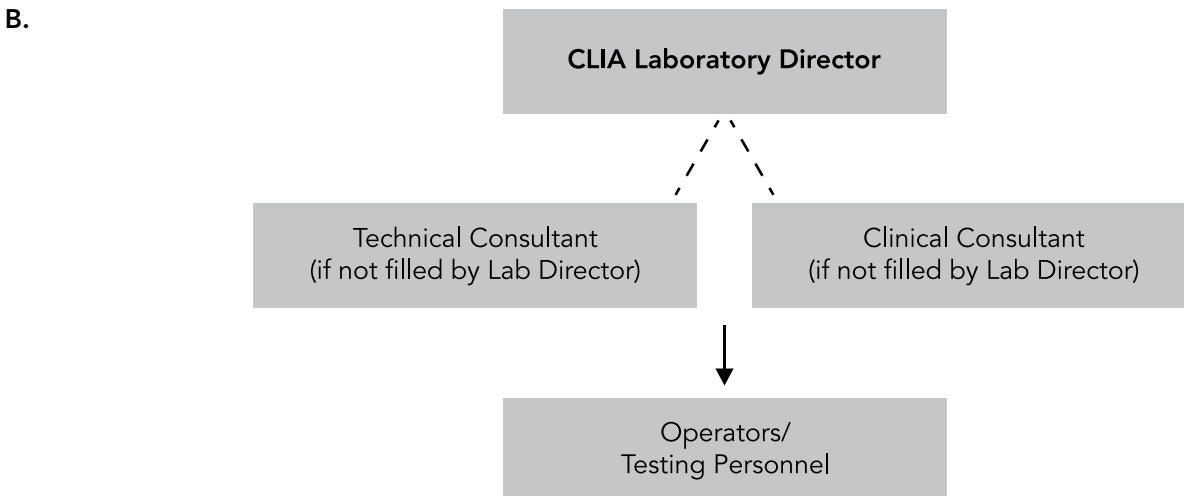
# 1. POCT ORGANIZATIONAL CHARTS

For reference only, individual POCT laboratories may have different needs

- A. Comprehensive POCT organization chart
- B. POCT organization chart with CLIA-required positions



- \*Bold: Essential positions to be filled in a POCT laboratory
- \*POCT Lab Director can, if qualified, also serve as Clinical Consultant and Technical Consultant
- \*POC Coordinators and Healthcare Providers can, if qualified, also serve as the Technical Consultant



## 2. GENERIC NEEDS ASSESSMENT

1. Product requested
2. Requestor contact information
3. Product methodology
4. Product manufacturer
5. Product Maude report
6. Risk/benefit to patient
7. Cost analysis
8. Questions to ask:
  - a. Will this replace a product?
  - b. Who will perform the testing?
9. Clinical conditions used
10. Frequency of use estimated
11. Conflict of interest
12. Training needed
13. Locations for use
14. Supporting documents
15. Compliance for testing

### 3. REQUEST FOR NEW TESTING FORM

#### Instructions

Complete all fields of this form. The cost analysis worksheet is a tool to help you determine the costs associated with the testing you are requesting. Purchasing and the point of care team can help you work through those details once method selection is complete.

#### General Information

Requesting site \_\_\_\_\_ Date of request \_\_\_\_\_

Contact person \_\_\_\_\_ Phone number \_\_\_\_\_

Department Corp and cost center number \_\_\_\_\_

#### POCT Planning:

Do you have a CLIA certificate?  No  Yes

CLIA Form # (Please attach a copy) \_\_\_\_\_ Expiration \_\_\_\_\_

Will this site be accredited by Joint Commission?  No  Yes  Other

Do you have a temperature monitored refrigerator available? (Some methods require this)  No  Yes

Estimate of number of potential users \_\_\_\_\_

Job categories of potential users \_\_\_\_\_

CPT code \_\_\_\_\_

#### Approved Test Methods in use

Please check the approved methods you would like to perform:

##### Waived Testing

- |  |  |   |  |  |                               |
|--|--|---|--|--|-------------------------------|
| <input type="checkbox"/> Glucose               | <input type="checkbox"/> Group A Rapid Strep | <input type="checkbox"/> Glucose Urine Dipstick | <input type="checkbox"/> Urine Automated Chemistry | <input type="checkbox"/> Urine Pregnancy | <input type="checkbox"/> INR  |
| <input type="checkbox"/> pH Analysis - Vaginal | <input type="checkbox"/> Hemoglobin          | <input type="checkbox"/> Guaiac Occult Blood    | <input type="checkbox"/> HbA1c                     | <input type="checkbox"/> Mono            | <input type="checkbox"/> Lead |
| <input type="checkbox"/> COVID                 | <input type="checkbox"/> Flu A & B           |   |  |  |                               |

Waived testing sites must agree to provide two levels of competency evaluations for staff. The point-of-care department will train and authorize two Trainers/Competency performers per practice to perform direct observation of test performance prior to patient testing and annually thereafter. Staff will also take a quiz to assess knowledge of procedure and problem-solving skills. Personnel in practice to be checked off as Trainers/Competency performers.

## Moderately Complex

Blood Gas       ACT       Oxyhemoglobin/Total Hemoglobin       Provider Performed Microscopy

Moderately complex testing sites must agree to provide six levels of competency assessment including:

- Directly observe test performance, including patient preparation, specimen handling, processing, and testing.
- Monitor the recording and reporting of test results.
- Review worksheets, QC records, PT results, and preventative maintenance records.
- Directly observe performance of instrument maintenance and function checks.
- Assess test performance using previously analyzed samples.
- Assess problem solving skills.
- Evaluate and document testing personnel performance at least semiannually for the first year and annually thereafter.

### Test Methods not listed above (if no new test methods are requested skip to Acknowledgement)

Test name \_\_\_\_\_

Instrument or device and manufacturer \_\_\_\_\_

Number of instruments \_\_\_\_\_

Has Compliance New Services Research Assist Template been submitted to Compliance?       No       Yes

### Test complexity classification:

Waived       Moderately complex       Provider Performed Microscopy Procedure

Number and type of personnel to perform test \_\_\_\_\_

### Assessment of Need

Clinical justification (patient benefits not obtainable by testing sent to laboratory, including turnaround time):

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---

---

Cost justification (including offsetting cost savings, i.e., cost savings with decreased turnaround time):

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Current approximated turnaround time from time of collection to lab result: \_\_\_\_\_

Current daily test volume sent to the laboratory: \_\_\_\_\_ /day

Anticipated daily volume of POCT: \_\_\_\_\_ /day

Anticipated daily volume sent to the lab after implementation of POCT: \_\_\_\_\_ /day

## Acknowledgement

### Evaluation of Request

Recommend Approval. Test meets requirements

Do Not Recommend Approval. Reason: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Pending. Need additional information: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Point of Care Coordinator Laboratory Admin. Director \_\_\_\_\_ Date \_\_\_\_\_

*Copies of the Request will be submitted to the Laboratory Medical Director after review and recommendation.*

### Final Evaluation by Laboratory Medical Director

Approved

Not Approved. Reason: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Laboratory Medical Director \_\_\_\_\_ Date \_\_\_\_\_

## Point of Care Testing Program - Cost Analysis Worksheet

Date Prepared: \_\_\_\_\_ By: \_\_\_\_\_

Test Site: \_\_\_\_\_ Phone \_\_\_\_\_

Test Name: \_\_\_\_\_

Kit/Instrument: \_\_\_\_\_

### Equipment

Instrument Cost: \$ \_\_\_\_\_ Number of instruments: \_\_\_\_\_ Total Capital Cost: \$ \_\_\_\_\_

Annual repair and maintenance expense: \$ \_\_\_\_\_ Life of instrument in years: \_\_\_\_\_

Interface cost: \$ \_\_\_\_\_ Annual fees: \$ \_\_\_\_\_



## Supplies and Controls

The manufacturer should be able to provide wastage and cost per test estimates.

Reagents and disposables, cost per test: \$ \_\_\_\_\_

Annual volume, patient tests: \_\_\_\_\_

Annual volume, repeat/wastage: \_\_\_\_\_

Annual volume, controls, proficiency testing: \_\_\_\_\_

Annual volume, Total: \_\_\_\_\_

Annual cost per test: \$ \_\_\_\_\_

*(Reagents & disposables cost per test multiplied by total annual volume)*

Annual cost of controls/proficiency testing: \$ \_\_\_\_\_

Total: \$ \_\_\_\_\_

*(Add annual cost per test and annual cost of controls/proficiency testing)*

## Labor Costs

Set up time covers the time it takes to prepare for testing. Include time spent to gather supplies and equipment, clean, calibrate, and maintain the instrument before and after all testing is done. Test time includes the time it takes to collect a specimen, perform the test, and log results.

Set up time, in minutes \_\_\_\_\_

Test time, in minutes \_\_\_\_\_

Labor cost per hour: \$ \_\_\_\_\_

## 4. NEW POCT IMPLEMENTATION FORM

Requesting Unit: \_\_\_\_\_

Test being requested: \_\_\_\_\_

### Pre-Approval

1. Decide on testing to be provided
  - a. Instruments/kits to purchase
    - i. Does new device/test Intended Use include your patient population? Examples include infants/children, oncology patients, and critically ill.
    - ii. Does the new device/test have new and innovative technology?
    - iii. Will new device/test improve patient outcomes?
      1. Examples include fewer call backs, improved TAT, more efficient treatment, or healthcare follow ups?
    - iv. Does the new device/test offer a clinical sensitivity/specificity similar to current testing being offered?
    - v. Does the new device/test being implemented have customer service and operator training provided by the manufacturer or distributor?
      1. Does the manufacturer or distributor provide installation and customer support, or is this outsourced to a third party?
    - vi. Review device/test system requirements such as:
      1. Frequency of QC, ability to enable IQCP, calibration and calibration verification requirements (if applicable).
  - b. Reagents/supplies to purchase
    - i. Direct sale versus reagent rental agreements
    - ii. Ensure enough quantities are available to complete performance verification and training. This can be coordinated with the manufacturer/distributor.
    - iii. Review reagent and supply shelf life
  - c. Physical specifications for area, including space
    - i. Ensure appropriate environment of care is available and ready for refrigerated and frozen supplies, if applicable.
    - ii. Ensure the space meets the power requirements, has appropriate lighting, and has network/computer/internet connectivity (if needed).
  - d. Review Instrument Features
    - i. If onboarding a new instrument, does this device have all the features your facility needs/desires? Some examples are:
      1. Operator ID/Operator lockout, QC lockout, various reference range entry, result recording (connectivity, print out, fax, etc.), data storage for patient, QC and PT results.

### Rollout

1. Validation Plan
  - a. Waived-follow manufacturer's instructions
  - b. Non-Waived
    - i. IQCP (the IQCP can reduce the frequency of CLIA-mandated, daily QC, in lieu of manufacturer-engineered QC processes for the POCT device)
      1. IQCP Creation
      2. IQCP Approval
    - ii. Validation plan created
      1. Plan approved/denied by medical director
  - c. Ensure supplies for validation
  - d. Validation plan executed
  - e. Validation approved or additional validation required, per medical director
2. Device and Supply Acquisition

- a. Programs instruments, as needed
- 3. Test Location
  - a. Determine appropriate physical location for devices and supplies
  - b. Determine if refrigerator/freezer is needed
- 4. Document Creation
  - a. Procedure Creation
    - i. Creation
    - ii. Approval by CLIA medical director
  - b. Training Document Creation
    - i. Observation checklist creation
    - ii. PowerPoint or training resources
      - 1. Vendor provided
      - 2. Self-developed
  - c. Additional Document Creation
    - i. Creation of other necessary documents, as needed
      - 1. QC Log
      - 2. Maintenance Log
      - 3. Patient Result Log
      - 4. Temperature Log
    - ii. Approval of additional documents
- 5. IT Requirements
  - a. Which software packages are needed?
    - i. Purchase of servers/software /drivers, if needed
  - b. IT Builds
    - i. Test Results
    - ii. Test Result Units
    - iii. Reference Ranges
    - iv. Critical Ranges
    - v. LIS builds (if needed)
    - vi. Middleware builds
    - vii. EMR builds
  - c. IT Testing
    - i. System Validation/Verification
    - ii. Approval of System Validation/Verification
- 6. Operator Training
  - a. After 90% of staff have completed the training, testing can begin
  - b. Provides instrument access to devices for all operators, as applicable
  - c. Training may be performed by vendor representative
- 7. New Test Go Live
  - a. Production validation
  - b. Audits to ensure method and regulatory compliance
  - c. New test is added to the site's test menu
  - d. New test is added to the regulatory agency menu, if applicable

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## 5. PROJECT PLAN

*This template can be expanded as needed depending on the project at hand*

### Summary

#### Purpose

The purpose of this workbook is to collect and document information necessary and relevant to complete the preimplementation and implementation project phases of Your Specific Project:

| Account Information      |  |
|--------------------------|--|
| Hospital(s)/Testing Site |  |
| City                     |  |
| State                    |  |
| Contact Name(s)          |  |
| Department/Resources     |  |
| Email                    |  |

## Implementation Plan

### Analyzer & Software Implementation Plan

| Phase                                 | Activity                                     | Roles and Responsibilities*  |      |      |          |   |
|---------------------------------------|--|------------------------------|------|------|----------|---|
|                                       |  | V PM                         | V OS | V IT | Customer |   |
| Pre Installation                      | Weekly communication begins                  | R                            | P    | P    | P        |   |
|                                       | Project development                          | R                            | I    | I    | P        |   |
|                                       | Deliver project plan                         | R                            | I    | I    | I        |   |
|                                       | Security documents                           | I                            | I    | R    | R        |   |
|                                       | Server discovery discussion                  | I                            | I    | R    | P        |   |
|                                       | Middleware discussion                        | I                            | I    | R    | R        |   |
| Installation                          | Server installation                          | I                            | I    | P    | R        |   |
|                                       | Software configuration                       | P                            | P    | R    | P        |   |
|                                       | Interface set-up and testing                 | I                            | I    | P    | R        |   |
|                                       | Analyzer(s) install                          | I                            | R    | I    | I        |   |
|                                       | Analyzer(s) verification                     | I                            | R    | I    | P        |   |
|                                       | Key operator training (Software & Analyzer)  | I                            | R    | I    | P        |   |
|                                       | Operator Training on Analyzer                | I                            | R    | I    | P        |   |
|                                       | Go-live                                      | Go-live confirmation review  | P    | P    | P        | P |
|                                       | Pre Go-live                                  | Move from Test to Production | I    | I    | P        | R |
| Deploy analyzer(s)                    |  | I                            | P    | I    | R        |   |
| Monitor and troubleshoot as necessary |  | I                            | R    | I    | P        |   |
| Post Go-live                          | Continue to monitor and troubleshoot systems | I                            | P    | I    | R        |   |
|                                       | Conduct project de-brief                     | R                            | P    | P    | P        |   |

| Roles       |  |   |
|-------------|--|---|
| Responsible | Person responsible to perform the activity               | R |
| Informed    | Person kept informed on the status of the activity       | I |
| Participate | Person who will be needed to participate in the activity | P |

| *Key:    |                        |
|----------|------------------------|
| V PM     | Vendor Project Manager |
| V OS     | Vendor Onsite Support  |
| V IT     | Vendor IT              |
| Customer | Customer Team          |

## Implementation Timeline

### Single Site Installation Plan

| Milestones   | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | etc. |
|--|---|---|---|---|---|---|---|---|---|----|------|
| Contract Awarded                                   | █ |   |   |   |   |   |   |   |   |    |      |
| Contract Booked                                    | █ |   |   |   |   |   |   |   |   |    |      |
| Installation Preparation Meeting - On Site/Virtual | █ |   |   |   |   |   |   |   |   |    |      |
| Project Development                                |   | █ | █ |   |   |   |   |   |   |    |      |
| Workflow Design                                    |   | █ | █ |   |   |   |   |   |   |    |      |
| Weekly Communication Begins                        | █ | █ | █ | █ | █ | █ | █ | █ | █ | █  | █    |
| Deliver Project Plan                               |   | █ | █ |   |   |   |   |   |   |    |      |
| Server Installation                                |   | █ | █ | █ |   |   |   |   |   |    |      |
| Software Configuration                             |   |   | █ | █ | █ | █ |   |   |   |    |      |
| Interface Set-up and Testing                       |   |   | █ | █ | █ | █ |   |   |   |    |      |
| Analyzer(s) Install                                |   |   |   | █ | █ | █ | █ | █ |   |    |      |
| Analyzer(s) Verification                           |   |   |   | █ | █ | █ | █ | █ |   |    |      |
| Key Operator Training                              |   |   |   |   |   |   | █ | █ | █ | █  |      |
| Operator Training                                  |   |   |   |   |   |   |   | █ | █ | █  |      |
| Go-live Confirmation Review                        |   |   |   |   |   |   |   |   |   | █  |      |
| Move from Test to Production                       |   |   |   |   |   |   |   |   |   |    | █    |
| Deploy Analyzer(s) to Designated Sites             |   |   |   |   |   |   |   |   |   |    | █    |
| Other(s)   |   |   |   |   |   |   |   |   |   |    |      |

## Implementation Schedule

|          |             | M     | T  | W  | R | F | S  | S  | M | T | W | R | F | S | S | M |    |
|----------|-------------|-------|----|----|---|---|----|----|---|---|---|---|---|---|---|---|----|
| Location | # Analyzers | Month | X  |    |   |   |    |    |   |   |   |   |   |   |   |   |    |
| Site A   |             | PW    | IT | HI | V | V | VS | VS |   |   | T | T | T | T | T |   | GO |
|          |             |       |    |    |   |   |    |    |   |   |   |   |   |   |   |   |    |

|                                     |    |
|-------------------------------------|----|
| Prework                             | PW |
| Interface prep, install and testing | IT |
| Hardware Install                    | HI |
| Verification Studies                | V  |
| On Site Training                    | T  |
| Go Live                             | GO |
| Additional Vendor Support           | VS |

## 6. TECHNICAL CONSULTANT DOCUMENTATION

Employee: \_\_\_\_\_

Dept: \_\_\_\_\_

### Per Federal law (CLIA) and Accreditation Organization (CAP) standards:

- CLIA Lab/POCT Director must approve and delegate Technical Consultants, in writing.
- Only Technical Consultants may perform competency assessment for testing personnel performing moderate-complex testing.
- Technical Consultants must have documented evidence indicating education and experience qualifications, successful completion of annual competency assessment for point-of-care testing, as well as documented Technical Consultant (TC) training and annual TC competency assessment thereafter.

#### Requirements for a Technical Consultant

Documented evidence of individual's education (i.e., diploma/transcript) meeting TC requirements which at minimum comprises a bachelor's degree in a chemical, physical, biological, or clinical laboratory science.     Yes     No

Documented evidence that individual has at least 2 years of experience in non-waived point of care testing.

- Indicate the POC test system(s) that the individual has successfully completed training and competency assessment (for at least 2 years):

### Technical Consultant Responsibilities:

- Understand the difference between POCT training versus competency assessment.
- Understand accrediting body requirements for testing personnel training and competency assessment.
- Train testing personnel on approved POC test systems and assures that all staff members are trained to perform tests accurately, report results promptly, accurately, and proficiently.
  - Completes POCT training form; sends the training form with testing personnel diploma to POCT office for filing.
- Evaluate the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately, and proficiently.
  - Completes POCT competency assessment form for each testing personnel and returns to POCT office for filing.
  - Understand that if testing personnel fails to successfully and independently demonstrate competency, this must be documented on the POCT competency assessment form. The user is required to complete re-training prior to patient testing, with reassessment of competency within 6 months of the original competency assessment date, or revocation of testing privileges.

***By signing, trainee indicates understanding of Technical Consultant role, responsibilities, and requirements.***

Employee: \_\_\_\_\_

Date: \_\_\_\_\_

POCC Technical Consultant: \_\_\_\_\_

Date: \_\_\_\_\_

***By signing, CLIA Lab/POCT Director is delegating employee as Technical Consultant with roles and responsibilities indicated above.***

CLIA Lab/POCT Director: \_\_\_\_\_

Date: \_\_\_\_\_



## 7. LABORATORY DIRECTOR SITE VISIT FORM \*DISCLAIMER: FOR REFERENCE ONLY

Laboratory Location: \_\_\_\_\_

Date: \_\_\_\_\_

Check box for items discussed or reviewed during visit

|                          | Discussed Items                                 | Comments |
|--------------------------|---|----------|
| <input type="checkbox"/> | Quality Control                                 |          |
| <input type="checkbox"/> | Quality Management Plan (QI Monitors)           |          |
| <input type="checkbox"/> | Proficiency Testing                             |          |
| <input type="checkbox"/> | Safety/Physical and Environmental Conditions    |          |
| <input type="checkbox"/> | Instrumentation, Service Contracts, Maintenance |          |
| <input type="checkbox"/> | Staffing + Personnel + Budgets                  |          |
| <input type="checkbox"/> | IT/Laboratory Medical Records Review            |          |
| <input type="checkbox"/> | Clinical Consultation                           |          |
| <input type="checkbox"/> | Continuing Education                            |          |
| <input type="checkbox"/> | Method Validation                               |          |
| <input type="checkbox"/> | Recalls + Backorders + FDA notices              |          |
| <input type="checkbox"/> | Policies and Procedures                         |          |
| <input type="checkbox"/> | Point of Care Testing                           |          |
| <input type="checkbox"/> | CAP Preparedness and Accreditation              |          |
| <input type="checkbox"/> | Other   |          |

Medical Director \_\_\_\_\_

## 8. QUALITY MANAGEMENT TEMPLATE

To access the full form, please visit [www.aacc.org/pocthowto](http://www.aacc.org/pocthowto)

### Directions

1. Fill in columns with your Lab name, Quality Management (QM) Essentials, and Calendar Quarter (Q1, Q2, Q3, Q4) for items that are specific to your department's quality management.
2. Add your specific item(s) in the appropriate column.

Examples below:

| Lab | Item(s)   | QM Essential         | Quarter |
|-----|---|----------------------|---------|
| BMH | Haemonetics BMH<br>(Emergency Dept. - Upgrade Unit) | Equipment Management | Q3      |
| BMH | New Lab   | Process Management   | Q3, Q4  |

| QM Essentials Defined             |  |
|-----------------------------------|--|
| Organization and Leadership       | Long range planning (e.g., strategic planning)   |
| Customer Focus                    | Monitoring of customer satisfaction  |
| Facilities and Safety Management  | Safety programs  |
| Supplier and Inventory Management | Personnel hiring and orientation processes, job descriptions, and performance evaluations                |
| Equipment Management              | Selection of suppliers, contractors, or consultants  |
| Process Management                | Change management  |
| Documents and Records Management  | Documents revision process, off-site records storage   |
| Information Management            | Maintenance of confidentiality of information, oversight and coordination of laboratory computer systems |
| Nonconforming Event Management    | Recording and management of complaints   |
| Assessments                       | Monitoring and reporting of quality indicators, Internal and external assessments                        |
| Continual Improvement             | Root cause analysis (RCA) process  |

## 9. WAIVED TESTING INITIAL TRAINING: URINE PREGNANCY EXAMPLE

Date: \_\_\_\_\_

Trainer should review all material listed below, display the test procedure and reference procedure during training. File completed form appropriately and retain for 2 years.

Employee Name: \_\_\_\_\_

Employee Number: \_\_\_\_\_

| Checklist  | Employee Initials | Trainer Initials |
|--|-------------------|------------------|
| <ul style="list-style-type: none"> <li>• Reads and understands the procedure and understands where to find Package Insert for reference.</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer discusses principle of test procedure so that trainee understands purpose and intended use of test.</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer identifies materials to perform test and Employee knows location of materials needed.</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Employee verbalizes proper patient identification, sample collection and handling with Trainer.</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer demonstrates test procedure and discusses with Employee.</li> </ul>   |                   |                  |
| <ul style="list-style-type: none"> <li>• Employee performs the procedure including the following:               <ul style="list-style-type: none"> <li>◦ Demonstrates proper sample collection with use of the appropriate collection device and handling.</li> <li>◦ Organize work area for testing.</li> <li>◦ Performs quality control (QC) on both negative and positive controls.</li> <li>◦ Decontaminate instrument and clean work area, including disposal of hazardous</li> </ul> </li> </ul> |                   |                  |
| <ul style="list-style-type: none"> <li>• Data entry               <ul style="list-style-type: none"> <li>◦ Use of Patient/QC documentation log</li> <li>◦ Test ordering</li> <li>◦ Reporting patient results in the EMR</li> <li>◦ Discusses normal ranges</li> </ul> </li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Completes Learning Quiz with 100%</li> </ul>  |                   |                  |

Comments: \_\_\_\_\_

I validate that this operator has demonstrated, under my supervision, adequate performance of the skills related to this procedure.

Trainer Signature (full name): \_\_\_\_\_

Date: \_\_\_\_\_

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## 10. WAIVED TESTING ANNUAL PERFORMANCE EVALUATION: URINE PREGNANCY TEST EXAMPLE

Employee Name: \_\_\_\_\_

Employee Number: \_\_\_\_\_

If person above has been deemed a trainer/competency performer for this method by the POCT staff or Current Trainer/Competency Performer, please circle: **COMPETENCY PERFORMER**

POCC or Current Trainer/Competency Performer must sign below:

\_\_\_\_\_

### Instructions to the Employee:

1. Required Annually: Completion of Learning Quiz with 100% as part of annual minimum working requirements
2. Review the procedure and locate the package insert.
3. Perform the procedure with quality control (negative or positive controls) and patient sample with records management on documentation log, while being observed.
4. Your performance will be based on how well you follow the procedure. You may refer to the written procedure during the performance of the procedure. If the evaluation of your performance is unsatisfactory, you will be given instructions for corrective action and will complete an Initial Training document.
5. If you find that the written procedure is unclear or missing necessary information, please make note in the employee section below.
6. Sign next page at completion of competency for Employee.

### Instructions to the Competency Performer:

1. Collect either negative or positive QC for the employee to demonstrate the procedure.
2. Directly observe the Employee perform each step of the procedure on QC and on a patient. If any step of the procedure is performed incorrectly, please note this in the Comments section and retrain from Initial Training document.
3. Test the Employee's problem-solving skills with a question or observe the Employee resolving a problem.
4. If the procedure is followed correctly, mark as satisfactory. If there are steps that are not followed, then mark unsatisfactory and describe the corrective action necessary to obtain a satisfactory rating.
5. Sign next page at completion of competency for Competency Performer.
6. Upon completion of form, file appropriately and keep for 2 years.

### Competency Performer to check mark Satisfactory or Unsatisfactory:

|                                | Satisfactory | Unsatisfactory |
|--------------------------------|--------------|----------------|
| Assessment of Sample Handling  |              |                |
| Assessment of Quality Control  |              |                |
| Assessment of Test Performance |              |                |
| Assessment of Data Management  |              |                |
| Assessment of Problem Solving  |              |                |

If Competency is documented as Unsatisfactory in any category:

- Competency Performer will list any comments pertinent to unsatisfactory status
- Competency Performer will complete document with signatures from both Competency Performer and Employee
- Competency Performer will proceed with a new initial training and complete new document for initial training

Competency Performer Comments for Unsatisfactory: \_\_\_\_\_

---

**Upon Completion of Competency:**

Competency Performer: \_\_\_\_\_ Date: \_\_\_\_\_

Employee: \_\_\_\_\_ Date: \_\_\_\_\_

## 11. MODERATE TESTING INITIAL TRAINING

Date: \_\_\_\_\_

Trainer should review all material listed below, display the test procedure and reference procedure during training. File completed form appropriately and retain for 2 years.

Employee Name: \_\_\_\_\_

Employee Number: \_\_\_\_\_

| Checklist  | Employee Initials | Trainer Initials |
|--|-------------------|------------------|
| <ul style="list-style-type: none"> <li>• Reads and understands the procedure</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer discusses principle of test procedure so that trainee understands purpose and intended use of test.</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer discusses System Overview (analyzer and all materials used)</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer discusses location and handling of analyzer, components, and QC</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Trainer discusses calibration, quality control and maintenance.</li> </ul>  |                   |                  |
| <ul style="list-style-type: none"> <li>• Employee performs the procedure including the following:               <ul style="list-style-type: none"> <li>◦ Demonstrates proper sample handling at time of test.</li> <li>◦ Organize work area for testing and performs sample analysis.</li> <li>◦ Performs quality control (QC) on one level</li> <li>◦ Performs one level blind patient sample.</li> <li>◦ Decontaminate instrument and clean work area, including disposal of hazardous waste.</li> </ul> </li> </ul> |                   |                  |
| <ul style="list-style-type: none"> <li>• Data entry               <ul style="list-style-type: none"> <li>◦ Discusses normal ranges. Test ordering</li> <li>◦ Discusses critical ranges and documentation. Discusses normal ranges</li> <li>◦ Printing and recalling patient results</li> </ul> </li> </ul>   |                   |                  |
| <ul style="list-style-type: none"> <li>• Completes Learning Quiz with 100%</li> </ul>  |                   |                  |

Comments: \_\_\_\_\_

Employee: I feel competent in the subjects/tasks/competencies noted above:     Yes     No

If NO, I feel I need additional training with the following subjects/tasks/competencies:

\_\_\_\_\_

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Trainer: I have reviewed this employee's competency in the above-named functions and determined them competent for testing.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## 12. MODERATE COMPLEX PERFORMANCE EVALUATION

Employee Role: Adequately perform each standard with minimal prompting by Technical Consultant

Technical Consultant Role: Observe and assess each standard for adherence of procedure and identify areas of needed improvement.

Date: \_\_\_\_\_  1<sup>st</sup> Competency (2 – 7 month)  2<sup>nd</sup> Competency (8 – 12 month)  Annual

Employee Name: \_\_\_\_\_ Employee Number: \_\_\_\_\_

Note: The Employee and Technical Consultant shall sign off on each applicable section of POCT as they are completed. The Technical Consultant can be an education nurse, charge person, preceptor, or individuals with expertise approved by the POCC.

| Both Employee and Technical Consultant will initial each item as Meets Standard or Does Not Meet                                       | Meets Standard Employee | Meets Standard Technical Consultant | Does Not Meet* Employee | Does Not Meet* Technical Consultant |
|--|-------------------------|-------------------------------------|-------------------------|-------------------------------------|
| <b>Read entire procedure</b> (Policy/Procedure for – Name of Blood Analysis System)  |                         |                                     |                         |                                     |
| 1. Direct Observation of Instrument Maintenance Performance/Function Checks  |                         |                                     |                         |                                     |
| • Demonstrates cleaning  |                         |                                     |                         |                                     |
| • Discusses all instrument components  |                         |                                     |                         |                                     |
| • Discusses running, interpreting Quality Control  |                         |                                     |                         |                                     |
| • Discusses when and how to repeat QC (identifies out of range and components for new QC test).  |                         |                                     |                         |                                     |
| 2. Direct Observation of Routine Patient Test Performance  |                         |                                     |                         |                                     |
| • Demonstrates proper sample mixing technique  |                         |                                     |                         |                                     |
| • Analyzes and interprets patient sample   |                         |                                     |                         |                                     |
| 3. Monitoring the Recording and Reporting of Test Results Including Critical Results   |                         |                                     |                         |                                     |
| • Discuss reference and critical ranges  |                         |                                     |                         |                                     |
| 4. Assessment of Test Performance through Internal blind Samples (Use of QC material to simulate patient sample)                       |                         |                                     |                         |                                     |
| • Performs unknown blind sample without error.   |                         |                                     |                         |                                     |
| • Assay range: _____<br>Result: _____  |                         |                                     |                         |                                     |
| 5. Evaluation of Problem-solving Skills  |                         |                                     |                         |                                     |
| • Discusses failed results   |                         |                                     |                         |                                     |
| • Discusses troubleshooting guide (new card, turn analyzer off and on, soft reboot).   |                         |                                     |                         |                                     |
| • Completes Learning Quiz  |                         |                                     |                         |                                     |
| 6. Quality Cross Check and QC rotated amongst staff with records in POC office. (No initialing required Employee/Technical Consultant) |                         |                                     |                         |                                     |

Comments (\*required for all Does Not Meet) : \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

If any standard is documented as Does Not Meet by either Employee/Technical Consultant or Employee does not feel competent, a new Initial Training will need to be performed and documented.

Employee: I feel competent in the subjects/tasks/competencies noted above:     Yes     No

If NO, I feel I need additional training with the following subjects/tasks/competencies:

\_\_\_\_\_  
Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Technical Consultant: I have reviewed this employee's competency in the above-named functions and determined them competent for testing.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



### 13. POCT CONNECTIVITY GLOSSARY

**ADT:** An admission, discharge, and transfer (ADT) system is a backbone system for the structure of other types of business systems. Using the ADT system, patient information can be shared, when appropriate, with other health care facilities and systems (McGonigle, D., & Mastrain, K., 2012).

**DHCP:** Stands for “Dynamic Host Configuration Protocol.” DHCP is a [protocol](#) that automatically assigns a unique [IP address](#) to each device that connects to a [network](#). With DHCP, there is no need to manually assign IP addresses to new devices. Therefore, no user configuration is necessary to connect to a DHCP-based network. Because of its ease of use and widespread support, DHCP is the [default](#) protocol used by most [routers](#) and networking equipment.

**Docking stations:** Docking stations may also refer to hardware used to connect [tablets](#), [smartphones](#), and other portable devices to one or more peripherals. However, these devices are generally called “docks” and typically have fewer I/O connections than a laptop dock.

**FTP:** “File Transfer Protocol.” FTP is a protocol designed for transferring files over the Internet. Files stored on an FTP server can be accessed using an FTP client, such as a web browser, FTP software program, or a command line interface.

**Hardwired Computers:** Built into a computer’s hardware and thus not readily changed. (Of a terminal) connected to a computer by a direct circuit rather than through a switching network. (Of electrical or electronic components) connected by hardwiring.

**HTTP:** “Hypertext Transfer Protocol.” HTTP is the protocol used to transfer data over the web. It is part of the Internet protocol suite and defines commands and services used for transmitting webpage data.

**HTTPS:** “HyperText Transport Protocol Secure.” HTTPS is the same thing as HTTP but uses a secure socket layer (SSL) for security purposes. Some examples of sites that use HTTPS include banking and investment websites, e-commerce websites, and most websites that require you to log in.

**Interface:** A common boundary or interconnection between systems, equipment, concepts, or human beings. Computer hardware or software designed to communicate information between hardware devices, between software programs, between devices and programs, or between a device and a user.

**Lantronix:** Lantronix Device Servers enable M2M communications either between the computer and serial device, or from one serial device to another over the Internet or Ethernet network

using “serial tunneling.”

**Middleware:** Middleware has two separate but related meanings. One is [software](#) that enables two separate programs to interact with each other. Another is a software layer inside a single [application](#) that allows different aspects of the program to work together. The most common type of middleware is software that enables two separate programs to communicate and share data. An example is software on a Web [server](#) that enables the [HTTP](#) server to interact with scripting engines like [PHP](#) or [ASP](#) when processing webpage data. Middleware also enables the Web server to access data from a [database](#) when loading content for a [webpage](#). In each of these instances, the middleware runs quietly in the background, but serves as an important “glue” between the server applications. Middleware also helps different applications communicate over a computer [network](#). It enables different [protocols](#) to work together by translating the information that is passed from one system to another. This type of middleware may be installed as a “Services-Oriented Architecture” ([SOA](#)) component on each system on the network. When data is sent between these systems, it is first processed by the middleware component, then [output](#) in a standard format that each system can understand.

**Remote Access:** The ability to access your computer from a remote location. Programs like PC Anywhere (Windows), Remote Access (Mac), and Timbuktu (Windows and Mac) allow users to control remote computers from their local machine. In order for a remote access connection to take place, the local machine must have the remote client software installed and the remote machine must have the remote server software installed. Also, a username and password are almost always required to authenticate the connecting user.

**Remote Desktop:** Remote desktop technology makes it possible to view another computer’s desktop on your computer. This means you can open folders, move files, and even run programs on the remote computer, right from your own desktop. Both Windows and Macintosh computer support remote desktop connections, though they use different implementations.

**Servers:** A server is a [computer](#) that provides [data](#) to other computers. It may serve data to systems on a local area network ([LAN](#)) or a wide area network ([WAN](#)) over the Internet.

**SQL:** “Structured Query Language,” and can be pronounced as either “sequel” or “S-Q-L.” It is a query language used for accessing and modifying information in a database.

**SSL:** “Secure Sockets Layer.” SSL is a secure protocol developed for sending information securely over the Internet. Many web-

sites use SSL for secure areas of their sites, such as user account pages and online checkout. Usually, when you are asked to “log in” on a website, the resulting page is secured by SSL.

**Virtual:** Virtual machines provide similar functionality to physical machines, but they do not run directly on the [hardware](#). Instead, a software layer exists between the hardware and the virtual machine. The software that manages one or more VMs is called a “hypervisor” and the VMs are called “guests” or virtualized instances. Each guest can interact with the hardware, but the hypervisor controls them. The hypervisor can start up and shut down virtual machines and also allocate a specific amount of system resources to each one.

**VPN:** A “virtual private network” allows the extension of a private network across a public network in a secure, potentially protected manner.

**Wi-Fi:** Wi-Fi is a wireless networking technology that allows computers and other devices to communicate over a wireless signal. It describes network components that are based on one of the 802.11 standards developed by the IEEE and adopted by the Wi-Fi Alliance. Examples of Wi-Fi standards, in chronological order, include: 802.11a; 802.11b; 802.11g; 802.11n; 802.11ac. Wi-Fi is the standard way computers connect to wireless networks. Nearly all modern computers have built-in Wi-Fi chips that allows users to find and connect to wireless routers. Most mobile devices, video game systems, and other standalone devices also support Wi-Fi, enabling them to connect to wireless networks as well. When a device establishes a Wi-Fi connection with a router, it can communicate with the router and other devices on the network. However, the router must be connected to the Internet (via a DSL or cable modem) in order to provide Internet access to connected devices.

**Wireless:** Any system or device, as cell phone, for transmitting messages or signals by electromagnetic waves.

## 14. POCT GENERAL TERMS GLOSSARY

**Admission-Discharge-Transfer (ADT):** Notifications sent when a patient is admitted to a hospital center, transferred to a different facility, or discharged

**CLIA:** Clinical and Laboratory Improvement Amendment. The Centers for Medicare & Medicaid Services (CMS) regulates laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA)

**ECMO:** Extracorporeal membrane oxygenation

**EMR:** Electronic Medical Record

**HIS:** Hospital Information System

**IQCP:** Individualized Quality Control Plan, and is the formal policy name for the alternative CLIA quality control (QC) option that will provide for equivalent quality testing for 42 CFR 493.1250 (16)

**LOC:** A lab on a chip device integrates laboratory functions on a single integrated circuit (or chip) to achieve increased automation and high-throughput screening (33)

**MIFU:** Manufacturer's Instructions for Use

**Non-waived testing:** Refers to moderate and high complexity testing. Laboratories or sites that perform these tests need to have a CLIA certificate, be inspected, and must meet CLIA quality standards (34).

**pO<sub>2</sub>:** Partial pressure of oxygen

**Personal Protective Equipment (PPE):** Equipment and clothing worn to minimize exposure to hazardous materials (e.g., gloves, lab coats, lab goggles, etc.)

**Point-of-care (POC):** The point in time when healthcare provider(s) provide or deliver healthcare products and/or services to patients at the time of care

**Point-of-care coordinator (POCC):** An individual who assures quality testing and accurate test performance through operator training, competency assessment, equipment monitoring, equipment maintenance and troubleshooting, quality control review, and proficiency testing

**Point-of-care testing (POCT):** Diagnostic testing conducted close to the patient, often by clinical personnel outside of the laboratory

**RPM:** Revolutions per minute; measurement of how fast a centrifuge rotor performs a full rotation

**STAT:** Short Turn Around Testing; critical tests

**tPA:** tissue plasminogen activator

**Turnaround time (TAT):** Time interval from time of sample submission/collection to the completion of the test/results

**Waived/waived complexity testing:** Waived tests are simple tests with a low risk for an incorrect result. They include certain tests listed in the CLIA regulations, tests cleared by the FDA for home use, tests that the manufacturer applies to the FDA for waived status (35). A CLIA certificate must be obtained for sites that perform waived testing and follow all the manufacturer's instructions (13).

**Quality control (QC):** A system of maintaining standards