Introduction

Worldwide, one of the fastest growing aspects of clinical laboratory testing is point of care testing (POCT), estimated to be increasing at least 10-12% per year overall and upwards to 30% per year in some testing areas. In contrast, central laboratory testing has grown approximately 6-7% annually.

When first widely introduced, POCT was largely for home use or physician office laboratory (POL) testing. In hospitals, it was considered as supplementary to central laboratory testing. It was not generally regarded as a primary responsibility of centralized pathology services and was often treated by central hospital laboratories with indifference, benign neglect, or frank hostility, and considered as substandard or second tier testing that was unmanageable. Some laboratorians considered POCT to be a potentially disruptive competitor to their services. POCT was also an added responsibility that many laboratories or nursing services found difficult to assume. The attitude of POCT as an inferior stepchild or orphan testing has changed with government regulations, the growth of the technology, an expanding perspective and spectrum of healthcare services, and different expectations from healthcare providers and consumers. Decentralized patient care and access to testing in under-served areas are key elements in the evolving expansion of POCT.

POCT continues to mature both as a technology and in the eyes of healthcare providers, laboratorians, regulators, administrators, and vendors. While the technology has become more varied and robust and performance has improved, the various groups associated with POCT have grown more realistic and demanding about its potential. No longer does the Everest theory prevail — just because it exists does not mean POCT should be used in all situations. The need for comparability with central laboratory testing, efficacy, operational device and kit fail-safes, management and oversight requirements, operator performance standards, economic indicators, and patient outcome data are all now considerations when deciding whether to employ POCT in specific situations.

POCT is increasingly being seen as a testing modality with performance expectations similar to traditional laboratory testing and requiring the same high standards. Rather than inferior testing or a nuisance, it is increasingly seen as a complementary or alternate type of testing that meets specific care needs and is an integrated part of clinical laboratory services, either; under the formal direction of the central laboratory or with consultation or guidance by laboratory services. POCT should be considered as a part of the continuum of the clinical laboratory’s contribution to healthcare and a fundamental responsibility of laboratory services. It needs to be regarded with the same expectations of quality involving the total testing process, covering the pre-, intra-, and post-analytic phases of testing. As healthcare reform changes the perspective from fee for service to the optimization of overall patient care, POCT can be a critical factor in streamlining and improving laboratory services.

The Laboratory Director is a mandated and fundamental position required for any clinical laboratory to function. As POCT is now frequently a component of laboratory services, it is essential that pathologist Laboratory Directors see it as their responsibility to be actively involved in all aspects of POCT.

This Tool Kit for Laboratory Directors of POCT testing has been developed by the CAP POCT Resource Committee as a service to CAP members and the laboratory community. It is intended to be a resource for any pathologist who wants to learn about POCT or who has responsibility to guide or direct POCT. It may be used by pathology residents, pathologists who have been long-time directors of POCT programs, or by pathologists who have been recently assigned to lead
POCT programs. Pathologists may also use the Tool Kit to guide other members of their POCT teams. We hope that this Tool Kit encourages more active and effective pathologist involvement in POCT and also serves as a useful resource for those who are already active advocates and leaders in POCT. We see POCT as a prime opportunity for pathologists to truly be “transformational” members of the health care team, demonstrating pathology’s rich value in promoting and ensuring quality laboratory testing, whether it is from a central or decentralized site.

We recognize that this Tool Kit is heavily weighted toward the perspective and experience in the United States. References to international experiences and priorities are included and over time it is the intention to expand that perspective. Clearly, international needs drive the expansion of POCT and will probably influence its use in the United States.

As a web-based resource, the Tool Kit is meant to be a living document. This “second edition” of the Tool Kit and much of the material is an orientation to POCT. It will be actively augmented and edited over time to remain current and focused on practical contents. Some sections are brief now but will be expanded, e.g. POCT technology, a broad and rapidly evolving discipline. Additional “tools” will be continually added and updated. This second edition has been re-formatted as an outline format to make the text less dense and key points more accessible. Readers are urged to provide feedback on this format and whether it makes the Tool Kit easier to use.

The POCT Resource Committee hopes that find the Tool Kit to be a rich and useful resource. We also hope that will offer comments, suggestions, case materials, and questions to keep the document a vital tool. It is our hope that the tools and perspective of this Tool Kit will reflect the best practices and experiences of the CAP membership that is most involved in POCT. The website will instruct on how to participate in this feedback and contribute insights and materials.

Reflecting the essential collaborative nature of POCT, this Tool Kit is also a collaborative venture. The CAP POCT Resource Committee is a multidisciplinary group with membership across all specialties of pathology, representatives from industry and other major laboratory organizations, nurse, technologist, and physician administrator membership. The Tool Kit has all these voices as authors, so the document reflects different perspectives and has different tones. It also is necessarily redundant, because the same considerations need to be reflected in different aspects of POCT. As a web-based document, the reader can access different parts of the document as needed, but some basic information may be repeated. Finally, the Clinical Laboratory Improvement Amendments of 1988 (CLIA88) categories of leadership and responsibilities have much overlap.

The Tool Kit is organized in sections to give a general orientation to POCT and then, using the United States’ CLIA88 framework, it follows the roles and responsibilities of a Laboratory Director for POCT. In depth discussion of specific functions, e.g. test selection and competency assessment, can be accessed as needed in applicable sections.

A. Definition of POCT

To fully understand and appreciate POCT, it is necessary to understand its breadth, encompassing varied sites, uses and technical options.

Note: Although some definitions of POCT include devices such as portable ultrasound, nerve conduction stimulators, etc., this Tool Kit will limit the discussion to laboratory tests inherent in the
CLIA ’88 definition of a laboratory, e.g. “performed on material derived from the human body”, rather than on the body itself. http://edocket.access.gpo.gov/cfr_2009/octqtr/42cfr493.2.htm

a. POCT is referred to by many different terms. Each may specify an aspect of the more general POCT term. Alternate terms for POCT include:
1. Bedside testing
2. Near-patient testing
3. Ancillary testing
4. Satellite testing
5. Remote testing
6. Physician’s office laboratory (POL) testing
7. Patient self-management

b. POCT has several definitions based on geographical, functional, technological, or operational context:
   1. Geographical context—where the test is conducted (outside of the main or core laboratory)
      a. Hospitals (ED, OR, ICU, neonatal care, etc.)
      b. Ambulatory care settings (clinics, physician office laboratories, rural clinics, student health clinics)
      c. Health fairs
      d. Pharmacies
      e. Prisons
      f. Military operations
      g. Visiting nurses
      h. Nursing homes
      i. Patient self-management
      j. Disaster and medical relief
      k. Remote clinics, under developed sites or countries
      l. Transport vehicles (ambulances, helicopters, trains, cruise ships, airliners)
      m. Mobile health vans – blood mobiles, clinics, public events
      n. Corporate healthcare operations
      o. Definitions based on location include:
         i. The analysis of clinical specimens as close as possible to the patient, including bedside, patient care unit or stat response labs that service specified areas—e.g. the “ER or ICU”.¹
         ii. Laboratory and other services provided to patients at the bedside. POCT is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Examples include kits and instruments that are hand carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g., capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (e.g., operating room, intensive care unit). POCT does NOT include limited service satellite laboratories with fixed dedicated testing space.³
2. **Functional context**– rapid or fast turnaround of test results which are readily accessible for patient care;
   a. **POCT** is defined as diagnostic testing at or near the site of patient care. The driving notion behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient will receive the results in a timely manner.
   b. **Near patient testing** is defined as any investigation carried out in a clinical setting or the patient’s home for which the result is available without reference to a laboratory and perhaps rapidly enough to affect immediate patient management.
   c. **Rapid test turnaround times (TATs) and access to results** are assumed to improve patient care and healthcare delivery. Sometimes the central laboratory may assume a POC function and produce very rapid turnaround times but more frequently testing at the point of care produces an overall shorter TAT.

3. **Technologic context**– testing is usually, but not always, conducted with small, portable devices or manual kits. POCT is accomplished through the use of transportable, portable, and handheld instruments (e.g., blood glucose meter,) and test kits (e.g., HIV salivary assay). Cheaper, smaller, faster, and smarter POCT devices have increased the use of POCT approaches by making it cost-effective for many diseases, such as diabetes and acute coronary syndrome.
   a. POCT may be performed on platforms that are also found in central laboratories. These are usually small to midsized instruments amenable to be transported to the patient’s location.
   b. Conversely, the central laboratory may use small POCT devices when these make sense for the volume or type of testing a laboratory provides.

4. **Operational context**– usually performed by non-laboratory personnel who may include:
   a. Nurses
   b. Physicians
   c. Emergency medical technicians
   d. Medical office assistants
   e. Pharmacists
   f. Medics
   g. Patients (self-testing)
   h. **Definition of POCT based on testing personnel:**
      i. Clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing).
      ii. POCT may be performed by laboratory staff who work in POLs, small decentralized laboratories, clinics, or other non-central laboratory sites.

5. **POCT** is a dynamic discipline. With the evolution of technology and changing medical needs, sites, and operators, the definition and spectrum of POCT is expected to change overtime.
REFERENCES

POCT has a variety of advantages and disadvantages that should be weighed when considering POCT as an option.

1. **Advantages**
   a. Rapid test results with the potential to expedite medical decision-making
   b. Small sample volume – patient convenience (capillary fingerstick vs. venous phlebotomy), neonatal and pediatric benefit, and less blood loss and anemia for patients requiring frequent testing (e.g., “ICU”)
   c. Portable devices with wide menu of analytes – allow testing to be performed in a variety of locations, with flexibility to meet the diversity of medical needs
   d. Unprocessed specimen – whole blood analysis not requiring time for clotting, centrifugation or aliquoting
   e. Lean process – testing on-site requires fewer steps than transporting a specimen to a core laboratory, processing, aliquoting, testing, and communicating results back to clinical staff
   f. Clinical staff efficiency – works within the clinical management setting. As the physician examines the patient and determines the need for testing, POCT is conducted and medical care is promptly implemented, avoiding the need for physicians to refamiliarize themselves with a case after test results are returned from a central laboratory
   g. Potential to improve patient outcome or workflow by having results immediately available, especially when POCT results can be linked to patient management in order to move individual patients through the system faster or handle more patients at a time
   h. Ability to provide laboratory testing in a wider variety of sites or circumstances, such as underserved populations, rural areas, and locations with limited infrastructure or personnel (e.g., disaster, accident or military sites)
   i. Reduced potential for sample deterioration – most POC tests are initiated and performed rapidly once the sample is obtained. This reduces the potential changes that may occur to samples sent to the central laboratory due to continued cellular metabolism, cooling, analyte instability, exposure to the environment, etc.

2. **Disadvantages**
   a. Reliability of POCT results
      1. Questionable quality can occur, given the variety of educational and experience levels and turnover of staff that perform the tests
      2. Greater inter-individual variability in results (compared to central laboratory testing) is common
      3. Waived category does not guarantee reliability. Simplicity is deceptive and there are many ways that staff can inadvertently generate a wrong result with waived or “simple” tests.
   b. Cost – per test costs for POCT are often significantly higher than the cost of central laboratory testing. However, the overall cost of care may be lower when POCT is employed, especially if patients may be treated or moved through the system more quickly and care outcomes are improved
   c. Number of testing personnel – the number of operators to manage is orders of magnitude larger than centralized laboratory staff.
   d. Management of POCT is challenging – there can be dozens of sites, hundreds of POCT devices/kits, and thousands of operators to manage to assure quality of testing.
e. Personnel performing POCT may inappropriately use a test kit or device outside of its intended use or the written procedure (e.g. performing guaiac testing on nipple secretions instead of feces).

f. POC tests often employ different methods – POCT methods can have unique interferences and limitations compared to central laboratory methods (e.g. POCT glucose interference from maltose, galactose, xylose).

g. POCT results are not necessarily comparable to central laboratory results - Standard methods may not be used in POCT and thus it may not be possible to compare results across sites (e.g. when patients travel and are tested at different sites, or when treatment protocols derived from more accurate results are being followed). Differences in specimen types, (e.g. serum, plasma, or whole blood,) may also affect results between traditional central laboratory methods and POCT. Thus, clinical protocols based on central laboratory results may need to be revised when utilizing POCT results.

h. Not all methods are appropriate for diagnosis or monitoring treatment. Some POCT may only be adequate for screening with follow up testing required for definitive results.

i. POCT kits and devices may not be FDA approved for all uses that a similar test in the central laboratory can be used for (e.g. waived PT/INR approved for monitoring Coumadin Warfarin therapy but not for diagnosis or assessment of bleeding diathesis).

j. POCT does not necessarily mean improved patient outcome – POCT only provides faster test results. The entire clinical pathway must be optimized to expedite clinical management based on a faster test result in order to achieve improved outcomes.

k. Documentation of test results, normal range values, units, operator ID, internal control results, etc. may be haphazard and difficult to standardize.

l. Documentation of physician order and appropriate information for billing may be problematic.

m. Reagent storage is decentralized and widespread, making management of supplies and monitoring of storage conditions problematic.

n. The significance of an error is not uniform. Producing a false test result at home or in a POL may have less potential for adverse outcome than in an acute care facility where a patient may have a procedure or treatment based on that result (e.g., a false negative pregnancy test followed by a radiology test or a falsely high glucose followed by insulin injection).

o. Error management may be more problematic than centralized testing and harder to track given less control over the testing process.

p. Interfacing results to the electronic patient record may be more difficult.
Current and Projected Technology

A. Introduction/Background

1. Wide arrays of analytic methods are used to perform POCT, ranging from simple (e.g., pH paper for assessing amniotic fluid) to sophisticated (e.g., thromboelastogram for intraoperative coagulation assessment). Initially, POC tests consisted of traditional methods performed in the central laboratory that were simply transferred to POCT settings or put into smaller platforms to allow performance outside of the central laboratory. Subsequently, unique and innovative assays have been designed specifically for POCT (e.g., rapid streptococcal antigen test).

2. Three tests comprise the majority of POCT in the US—urinalysis by dipstick, blood glucose and urine pregnancy. The following is an in-depth discussion on the dipstick urinalysis, the earliest and perhaps the most “basic” POC test. Similar discussions for other types of Point of Care testing will follow in upcoming editions of the tool kit.

B. Urinalysis Dipstick POC Testing: Past, Present and Future

1. In the 1940's and early 1950's several urine chemistry tests (e.g., albumin, occult blood and acetone) were developed utilizing dry reagent tablet technology from the pharmaceutical industry. Although these tests were primarily performed in the laboratory, the ability to place a reagent tablet in a tube, add urine, mix and visually read the result led to the ability to move urine testing back to the patient’s side. The next technological breakthrough was the discovery of the enzyme glucose oxidase which led to the first rapid and specific test for glucose which allowed for the detection and management of diabetes mellitus.

2. Utilizing a combination of technologies from the newspaper industry liquid urine chemistry reagents were applied to paper and dried using an Egan tunnel (i.e., originally used to dry newspaper ink). Reagent impregnated papers having different chemistries were slit into square pads which were laminated and adhered to a plastic backing. This was the advent of the first true POC device best known as the urine dipstick which was developed in 1957. A dipstick could contain one or more different chemistries but only required the user to dip the stick into a urine sample, remove and read the results visually at a set of given times.

3. Over the next two decades additional chemistries were added to detect total protein, ketones, nitrite, specific gravity (SG) and leucocytes (WBC). Although visual detection of these strips was cost effective; visual acuity, reagent pad timing and color blindness made it clear that instrument read urine dipsticks would be required in the future. Advances in hardware e.g., integrated circuits (ICs), injection molding of plastics and light emitting diodes (LED), and software made it possible to develop a reflectometer which could read each urine strip pad individually at three to four wavelengths at the appropriate reaction time. These instruments eliminated the disadvantages of visually read urine dipsticks. It should be noted that eight of the twelve urine analytes have little practical diagnostic value; however, glucose, occult blood, leucocytes and protein can be useful screens for diabetes, bladder cancer, urinary tract infection and kidney disease. Due to the differences in urine concentration, all of the urine analyte measurements are semi-quantitative (i.e. analyte concentrations are given as ranges).

4. Today several vendors offer a variety of urinalysis dipsticks having anywhere from one to twelve analyte test pads. Advances in high throughput manufacturing technologies during the last 15-20 years have allowed for the automated production of >100 million strips/year. Probably the most significant advancement in urinalysis dipstick testing in recent time was the development of a chemical method for the detection of urine
creatinine. Urine creatinine has replaced specific gravity (SG) as a true measure of urine concentration which has allowed manufacturers to develop a new urine dipstick that measures the albumin to creatinine (A:C) ratio. Utilizing the A:C ratio allows for urine concentration correction which reduces both false positive and false negative microalbuminuria results, thereby improving the detection of early kidney disease.

5. Although the basic urine dipstick technology has not changed over the years, vendors have improved products in three areas: analyte sensitivity, interference resistance and analyte chemistry cross talk. In order to improve urine screening for diabetes some vendors have lowered the sensitivity of the glucose pad. Most vendors continue to improve the sensitivity of their non-hemolysed and hemolysed occult blood in order to detect several disease states with bladder cancer at the top of the list. One of the biggest interferences in urine for some analytes is ascorbic acid (vitamin C). Some manufacturers have added compounds to the analyte pads to reduce or eliminate ascorbate interference. One vendor has also developed an ascorbic pad to indicate the presence of the interferent as a means to correct for it. Finally one vendor developed a sample spreading mesh that covers all analyte pads which ensures uniform dosing of the individual pads while reducing/preventing pad to pad cross talk.

6. Advances in rapid prototyping (e.g., stereo lithography and soft tooling) have enabled manufacturers to quickly test product look and feel. Instrument displays were improved by using new technologies, such as liquid crystal display (LCD) and touch screens. Miniaturization of urine analyzers was driven by advances in the electronic industry. In the area of light detection, analyzers have used photodiodes, avalanche photodiodes, charge coupled detector (CCD) arrays and more recently CCD cameras. All of these technologies migrated into urinalysis from other consumer products (e.g., CCD arrays are used in barcode readers). In the area of optical illumination of urine dipsticks, the light emitting diode technology (e.g., chip on board LEDs and the white LED) has allowed manufacturers a low cost, more efficient and reliable alternative to incandescent light sources and filters. Optical grade plastics have significantly reduced the cost of lenses and waveguides compared to their glass counterparts. Some current urine analyzers have the ability to image the entire strip (e.g., 11 chemistries at once) rather than reading the individual pads.

7. A couple of other improvements in the electronics industry like field programmable print circuit boards, increased memory, and computing power have led to major improvements in existing urine analyzers. Reprogramming mother boards, or a printed circuit board (PCB) allows for changes in next generation instruments (a.k.a., future proofing) and prevent costly PCB redesign. Increased memory capacity led to the ability to perform software upgrades using flash cards (i.e., technology developed for the digital camera). Newer instruments have commercial computer operating systems onboard which allow increased computing power for complex algorithms like automatic strip identification. Symbology in the form of barcode readers has enabled urine analyzers to easily identify patients, operators, samples and product type. Finally a few of the recent instruments are highly connected via hardwired bi-directional serial ports and Ethernet connectors. In addition some systems are equipped with wireless connectivity in the form of Blue Tooth and WiFi. Technological advances during the last 15-20 years have allowed manufacturers to produce low cost urine analyzers that eliminate the subjective nature and associated errors with visually read urine dipsticks.

8. Predicting the future in any area is difficult at best. The future changes will come in the areas of: improved reagent performance, miniaturization of urine analyzers, product format changes, reagentless detection and new analytes. For the most part this will be driven by the need to reduce sample handling while increasing the amount of clinically relevant information obtained from a given sample.
9. In the area of improved strip performance we will see what is referred to as smart reagents and strips. Smart reagents will be more quantitative based on lot specific calibration of all analytes and will also have humidity and temperature checks that will not allow compromised strips to give test results (i.e., failsafe mechanism). Smart strips will utilize “watermark” technologies, such as, 2-D barcodes, IR dyes, hologram and/or powder radio frequency identification device RFID for individual strips that will include lot number, lot calibration, expiration date and strip identification. Finally smart strips will use clinical diagnostic algorithms to identify patients with urinary tract infections, early stage kidney disease, and diabetics with ketoacidosis.

10. Future urine analyzers will be small portable instruments that will be designed using a technology referred to as “naked or nude electronics”. These are based on techniques like SHE’D which was used on the iPod and iPhone. SHE’D stands for shrink, hide, eliminate and define. It is possible in the future that we will see an iPhone-like device capable of reading urine strips via its digital camera and being fully connected so it can send the data to care givers wirelessly.

11. In order to minimize urine sample handling in the future, at least three possible approaches are to miniaturize the urine dipstick thereby reducing urine volume requirement, placing the reagent detection technology into a urine collection cup (a.k.a., smart cup) and finally utilizing reagentless technology in a “smart toilet”. There are several potential means to miniaturize existing urine strips (e.g., make them skinnier or shorter) but the use of new dispensing technologies and substrates could make it possible to develop a strip having one pad (current size) with all 10-15 analytes that could be read on small portable instrument. A smart cup would have all of the analyte detection technology in the cup so that a patient would urinate in the cup and the cup would be instrument read (e.g., optically or electrochemically), thereby minimizing sample handling. The ultimate sample handling solution would be the smart toilet which is in development. The smart toilet will measure at least three to four analytes in diluted urine collected by the toilet via near- or mid-infrared spectroscopy. Reagentless technology utilizing near infrared NIR or mid infrared MIR spectroscopy could be utilized to detect several urine analytes and therefore completely change current technologies.

12. Finally we will see several new urine analytes that will require alternative technologies (non-dipstick) to perform. Today some other urine analytes are detected using lateral flow immunoassay technology, such as, human chorionic gonadotropin (hCG), Drugs of Abuse Urine (DAUs), microalbuminuria (A:C ratio) and human immunodeficiency virus (HIV). Some urine testing is being directed toward alternative sample types like saliva and oral fluid (e.g., Drugs of Abuse and HIV). It is likely we will see new analytes requiring lateral flow immunoassay or molecular technologies (e.g., lab on a chip). New analytes will be in the area of preeclampsia (e.g., soluble fms-like tyrosine kinase-1 (sFlt-1), placental growth factor (PLGF) and endoglin), prostate cancer (e.g., PCA-3) and pancreatitis.

13. The above illustrates that this “simple” test is really a very sophisticated one with potentially dazzling upgrades in the future. The similar discussions on glucose meters and urine pregnancy testing will demonstrate the same principles. Hopefully, these examples will give the reader an insight into how technically advanced all these “easy” devices can be and how much exciting technology is invested in them. Future editions will summarize existing and future technologies for analytes by medical disciplines. The tool kit will try to demonstrate the pros and cons of various systems. We also hope that the discussions will give users new respect for POCT and allow them to compare and evaluate test systems in their own environments. We hope that users will appreciate the need to treat POC test systems with the same attention to detail routinely associated with traditional central laboratory testing.
History

A. The Past, Present, and Future of POCT

“Everything old is new again” by Peter Allen (1944 – 1992), Australian songwriter and entertainer.
Bedside → Central laboratories → POCT

1. In the beginning, all testing was performed near the patient.
   a. As early as 1500 BC urine was noted in relation to diabetic symptoms in Egypt since ants were attracted to the sweetness of urine from diabetics. One of the earliest diagnostic practices was uroscopy, in which urine was visually examined and assessed for sweetness by tasting.

2. Testing moved to central laboratories as hospitals were built (1800-1900’s) and testing technologies were developed.
   a. The development of hospitals and specialized care fostered the creation of laboratories, which required the transport of specimens from the patient to a central testing site. The introduction of advanced and automated technologies also encouraged centralization of laboratory testing. Economies of scale, regulations, and specialized technical staff were further incentives to consolidate testing.

3. Shifts from the central laboratory to POCT and steady growth in the type and number of POC tests performed (late 1900’s to date) have been stimulated by:
   a. Technological advancements:
      1. Method and operation simplification
      2. Lockouts and failsafe mechanisms
      3. Electronic quality control
      4. Interconnectivity with laboratory and hospital information systems
      5. Portability
   b. Demand for faster turnaround times and testing platforms to facilitate patient care (e.g. ICUs, POLs)
   c. Waived testing designation under CLIA88. See below.
   d. Creation of specialty clinics
   e. Desire for self-testing and patient control
   f. Mergers and reorganizations of healthcare systems, resulting in decreased numbers of central laboratories in the US
   g. Need for simple, robust testing tools in developing countries and other sites, e.g. military or disaster, underserved populations. See previous “Definition of POCT” with the multiple sites using POCT
   h. CLIA88 provided a tremendous impetus for growth in POCT. The history of that important legislation is summarized below

B. The Clinical Laboratory Improvement Amendments of 1988 (CLIA88)

1. Soon after Medicare and Medicaid went into effect in 1965, the United States government became aware of the programs’ vulnerability to fraud and abuse. To assure that money was not being siphoned off through overcharging for services and that the
quality of services financed with tax dollars was adequate, the federal government established minimum quality requirements for those clinical laboratories that wished to participate in Medicare. These requirements, collectively known as the Clinical Laboratory Improvement Act of 1967 (CLIA67), officially covered only those laboratories doing business across state lines, which accounted for only a fraction of all US clinical laboratories. Soon, the need to regulate all laboratories performing tests on human specimens became apparent to lawmakers and, throughout the 1970s, amendments to CLIA67 were proposed—to stiffen personnel requirements and to mandate inspections to certify that laboratory facilities meet minimum standards for accuracy and quality control. CLIA67 took longer than many expected to revise. Eventually, the Clinical Laboratory Improvement Amendments were enacted in 1988 (CLIA88).

2. In the meantime, to implement CLIA67, section 5(a) Part F of title III of the Public Health Service Act (42 U.S.C. 262-3) was amended by changing the title to read: “Licensing — Biological Products and Clinical Laboratories” and by adding the requirement (section 353) that any laboratory engaged in interstate commerce (i.e., soliciting or accepting, directly or indirectly, any specimen for laboratory examination or other laboratory procedures) must be CLIA67 licensed. Laboratories were given a full, partial, or exempt CLIA67 license, depending on the scope of the laboratory testing performed. CLIA67 regulations included applicability, license application and renewal, general provisions, quality control, personnel standards, proficiency testing, accreditation and sanctions.

3. By 1972, 100 new amendments to the Social Security Act were made, including changes to the Medicare law. These new amendments established professional standards review organizations (PSROs), groups assembled by the Department of Health, Education and Welfare (HEW) that reviewed medical necessity, and the appropriateness and quality of services paid for with Medicare and Medicaid funds. Only independent and hospital laboratories seeking Medicare/Medicaid reimbursement were regulated under the Social Security Act and each facility type had its own regulations to follow. Later, the Omnibus Budget Reconciliation Act of 1987 was amended to require physician offices that performed more than 5000 tests per year to meet the laboratory regulations. At that time, laboratory testing in both physician office laboratories (POLs) and rural health clinics that did not accept and perform tests on referral specimens were not subject to those revisions because both the Medicare and CLIA67 statutes precluded the regulation of POLs and rural health clinics that performed tests only for their own patients.

4. Beginning in 1987, a series of newspaper and magazine articles were published on the quality of laboratory testing. Simultaneously, television programs were aired concerning the number of laboratories that were not subject to either federal or state regulations. Congress held hearings in 1988 and heard testimony from “victims” of faulty laboratory testing. Specific concerns were raised about the validity of cholesterol screening and the accuracy of Pap smear results.

5. On October 31, 1988, in response to the congressional hearings, Congress enacted Public Law 100-578, the Clinical Laboratory Improvement Amendments of 1988 or CLIA88, which greatly revised the authority for the regulation of laboratories. It was enacted as a means for the Secretary of Health and Human Services to develop comprehensive quality standards for all laboratory testing. Based on the concept of “site neutrality”, CLIA88 was to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. CLIA88 defines a laboratory as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention and treatment of disease, or for assessment of health. Facilities that do not accept Medicare or Medicaid or accept only cash must also be certified under CLIA88. It is the act of performing a laboratory test that defines the requirement of certification and not if or how the test is paid for. The definition of “laboratory” was also expanded to include any site where clinical laboratory
testing occurs. Therefore, sites performing POCT, such as the patient’s bedside, a POL, or clinic, also assumed “laboratory” designation, a concept that was not fully appreciated by some clinical providers.

6. CLIA88 is a user fee-funded government program; therefore, all costs of administering the program must be covered by the regulated facilities. The final CLIA88 regulations were published on February 28, 1992 after more than 70,000 comments and widespread public debate.

7. CLIA88 also introduced the complexity model for test methods. Three categories of tests were established: waived, moderate complexity (including the subcategory of provider-performed microscopy), and high complexity. The more complicated the test, the more stringent the requirements. While CLIA88 specifies quality standards for personnel, patient test management, proficiency testing (PT), quality control, and quality assurance for moderate and high complexity tests, waived testing requirements are minimal.

a. Waived Testing

1. Waived tests were defined under CLIA as “...simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.”

2. According to CLIA88, to perform waived tests, a laboratory must simply:
   a. Enroll in the CLIA program
   b. Pay applicable certificate fees biennially
   c. Follow manufacturers’ test instructions for tests that are FDA-approved for waived testing
   d. Be inspected if complaints or issues arise

3. The original list of waived tests was limited to:
   a. Urine dipstick or tablet testing (bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrates, protein, pH, specific gravity)
   b. Fecal occult blood testing
   c. Ovulation tests for luteinizing hormone (LH)
   d. Urine pregnancy testing
   e. Erythrocyte sedimentation rate (ESR), non automated
   f. Hemoglobin by copper sulfate
   g. Blood glucose testing by meters
   h. Microhematocrit, spun
   i. (Hemoglobin by a single test device was soon added)

4. The concept of waived testing caused a great deal of controversy. Many organizations and groups felt that the proposed amendments to CLIA67 were too strict for all sites to comply with and patients would be denied access to testing so a simpler category of testing was needed. It was felt by other groups that the waived testing category created a dual standard for testing, with some laboratories having higher standards than others. Conceptually, many believed it was not really possible for a procedure to be so simple that the chance for error is negligible, or for a clinically useful test to have a negligible possibility of causing harm. For that reason, accrediting agencies other than the US government, such as the CAP and some states, have imposed stricter requirements on waived testing than are mandated by CLIA88.
5. The numerous comments received about the waived testing category generated concerns both that the criteria were too subjective or too strict. Thus, in February 1993, the US Department of Health and Human Services (HHS) consulted with the Clinical Laboratory Improvement Advisory Committee (CLIAC) and Centers for Disease Control and Prevention (CDC) and it was agreed that the criteria for giving a test waived status needed “clarification”. A moratorium on granting further waived test approvals was instituted until December 1994. In September 1995 proposed clarification criteria were issued by HHS through the Healthcare Financing Administration (HCFA) and Public Health Services (PHS). These were formally adopted in 1997. Any test already approved by the FDA for home use was considered to be simple and have insignificant risk of error and therefore granted waived status. Tests that were substantially similar to already waived tests were given an expedited review process. New applications for waiver status needed to show performance characteristics that demonstrated the test was simple, easy to perform, and essentially error free. Standard protocols for test evaluation were used to remove the subjectivity in deciding that a test met waived criteria. These new criteria included:
   a. Specimens must be direct, not processed or manipulated
   b. Quantitative tests must be fully automated
   c. Qualitative tests are limited to single reagent impregnated devices giving positive or negative results
   d. Failsafe mechanisms must allow no results outside of the reportable range or when the system malfunctions
   e. No invasive trouble-shooting can be necessary. Electronic or mechanical maintenance must not be required.
   f. Instructions must be written at a 7th grade level, clearly defining all steps of the process and actions to be taken if quality control or calibrators were out of range
   g. Operators must follow manufacturers’ instructions; if they do not, the system immediately is classified as highly complex with all the strict requirements governing high complexity tests.
   h. Operators must have access to manufacturer contact information to report problems
   i. Detailed procedures for manufacturer field studies were established to prove the system could perform to expectations with appropriate specimens in non laboratory environments and by the lowest level of operators required

6. These new clarified criteria were also meant to ensure that the operator skills required to perform and interpret waived tests were minimized so that non-laboratory personnel could not disrupt the procedure or introduce error. Since waived testing had no personnel requirements, HHS wanted to ensure that POC tests have minimal chance of producing an erroneous result. One consideration that could not be guaranteed by these new criteria was whether the operators could interpret results properly or recognize the context of a result, even if accurate.

7. Because the requirements for waived testing are significantly less stringent than those for non-waived testing (moderate and high complexity testing), implementation of waived tests became attractive to many facilities. Facilities did not need to comply with the detailed CLIA88 requirements that include sections on accreditation, proficiency testing,
administration, facilities, quality systems (covering all phases of testing and encompassing test verification, competency assessment, result reporting, etc), personnel standards, inspections, and enforcement. The manufacturing community also saw waived test development as a great opportunity for expanded markets, inside and outside of traditional healthcare facilities, since they could promote waived tests as having less regulatory oversight and easier bring and cheaper to use. In fact, HHS in its proposed clarification criteria anticipated that:

a. Manufacturers would benefit from increased sales and distribution of waived tests.
b. Laboratories would benefit from having more waived tests to offer with reduced regulatory burden and decreased costs, especially in underserved or rural areas.
c. Consumers would benefit from having an increased range of laboratory services that were safe and accessible.
d. The rules would drive technology to simpler more widely available laboratory tests.
e. The “universe of waived tests” would expand to the benefit of patients, laboratories, manufacturers, and producers. HHS also acknowledged that the degree of growth of waived testing could not be accurately forecasted, but would depend on market decisions and technologic changes that could not be predicted.

8. While POCT is not synonymous with waived testing, in practice most POCT is waived testing. Therefore, the growth of waived testing has resulted in the expansion and development of POCT, in ways not fully anticipated by HHS.

9. Initially, most POCT/waived tests were simple ones that had been performed in the central laboratory or in home or self testing (e.g., urine dipsticks, fingerstick glucose monitoring, pregnancy testing) and were then redeployed as POCT. Soon, however, manufacturers responded to the growing demand for waived tests by developing new test methods, many designed specifically to be used outside of the traditional laboratory setting by non-laboratory personnel (e.g., hemoglobin A1c in diabetes clinics, prothrombin time and INR in coagulation clinics). As the technical expertise needed to perform some of these new test methods decreased, physicians in specialty areas (e.g., coagulation clinics, HIV clinics, dialysis centers) became interested in assuming responsibility (and revenue) for such tests, rather than sending them to a central laboratory. Similarly, simple POCT devices (e.g., INR) allowed patients who desired more responsibility for managing their health to perform self-testing.

10. There are currently nearly 100 different waived analytes with over 1000 waived test systems and the list is constantly changing. The FDA provides an on-line list of waived tests (analytes and manufacturers), as well as a searchable database of all FDA approved tests that includes the testing category for each.

11. Mergers and reorganizations of hospitals and healthcare systems have resulted in fewer full service laboratories. This has also played a role in the growth of POCT, as a means of maintaining access to commonly ordered laboratory tests. In developing countries, the need to be able to perform tests outside of traditional laboratories, without infrastructure such as refrigeration and power, and using less highly trained personnel is now frequently met by POC tests. For example, the Bill and Melinda Gates
Foundation initiatives to accelerate the eradication of common infectious diseases in developing countries provides millions of dollars in grants each year to develop innovative, affordable ways to diagnose infectious diseases. Such technology will inevitably find its way into the market in developed countries as well.

12. In the US, recognizing the need for testing outside the traditional laboratory, especially in underserved areas, the National Institutes of Health (NIH) through its National Heart, Lung, and Blood Institute, the National Institute for Biomedical Imaging and Bioengineering (NIBIB), and the National Science Foundation (NSF) jointly fund POCT development (e.g., Partnerships for Point of Care Diagnostic Technologies for Nontraditional Health Care Settings and Point of Care Technologies Research Network). This funding supports four national centers researching and developing technologies for different aspects of POCT.

13. Different regulatory requirements, (e.g., CMS, CDC,) International Organization for Standardization (ISO), World Health Organization (WHO), apply to different testing locales, driving the call for international standards in POCT.

14. All these factors have contributed to the steady growth in the type and number of POCT tests performed. In 2010, it was estimated that one billion POCT tests would be performed in US hospitals, and that volume of testing would grow by 12.5% per annum.

C. Drivers of POCT

1. For the foreseeable future, it is anticipated that the trends described above will continue, driving robust growth in POCT. Specific drivers for adoption of POCT will include changes in the testing itself, and in the clinical, regulatory, and commercial environments.
   a. Changes in POCT methodology
      1. Technical advances will make POCT testing more attractive by making it:
         a. More accurate
         b. More robust
         c. Cheaper
         d. Easier
         e. Better interfaced to computerized patient records
         f. More inclusive of quality assurance and documentation features
   
   b. Changes in the clinical environment
      1. Demand for POCT will increase due to:
         a. Economic needs of hospitals for shorter stays and rapid patient turnaround. Test results are needed rapidly not only for reasons of clinical urgency but to ease patient backlog in the emergency department, post anesthesia care unit, or other areas.
         b. Innovative therapies requiring rapid laboratory feedback
         c. The critical shortage of qualified medical technologists, which is likely to worsen
d. Increasing demand for medical support at diverse sites (e.g., sporting events such as marathons, resorts, cruise ships, schools, camps)

e. Increasing demand for rapid testing in outpatient settings (e.g., cancer centers for outpatient chemotherapy)

f. Increasing demand for self testing in patients’ homes

g. Disaster preparedness

h. Underserved populations and underdeveloped regions without the infrastructure or manpower for central laboratory testing and to promote access to care

c. Changes in commercial environment

1. Attracted by the very large growth rates in POCT compared to traditional central laboratory testing, and relatively favorable profit margins, industry will heavily promote POCT.

d. Changes in regulatory environment

1. Continued trend to promote POCT for all the reasons noted above and to foster “personalized” healthcare

2. However, drivers are offset by the potential impact of the 2008 FDA guidance directives that have slowed the introduction of new waived tests.

3. In 2008, in response to the growing numbers of waived tests and concerns regarding testing quality and patient safety, HHS issued more detailed and rigorous guidelines for manufacturers of products intended for waived testing. These guidelines made it more difficult for a product to achieve the waived designation and effectively decreased the numbers of submitted waived test requests, as well as the number of new waived testing products introduced to the market place. The impact of these and future regulations remains to be seen, but concerns have been raised about the potential complexity of some of the analytes on waived devices, (e.g., blood gases and metabolites). A growing concern, as evidenced by recent FDA focus, is the use of similar devices for both patient self-monitoring and intensive care monitoring. A prime example of this is glucose meters used on unstable acutely ill patients in ICUs, where many patient variables affect results and life-threatening treatment may be instituted, (e.g. insulin injection with the potential for hypoglycemia and death).

4. Questions arise about whether there should be different standards for devices or tests used in different care environments, (e.g., pregnancy tests for home use versus used in healthcare settings before radiologic studies).

e. Military applications

1. The US military system is comprehensively organized into echelons of care, ranging from Echelon 1, the most basic care on the battlefield, to Echelon 5, representing tertiary care at an Army hospital. The system is intended to provide access to the highest quality care to soldiers, in return for their service, but also to maximize combat effectiveness. At the lowest echelons of care, POCT may be the only type of laboratory support possible, or the most desirable type, especially for combat or transport settings.
Pathologist as Clinical Consultant

1. CLIA88 defines the role of a Clinical Consultant in subpart M of the regulations. The Clinical Consultant must be qualified and able to render opinions to laboratory clients regarding the diagnosis, treatment and management of patients; be a doctor of medicine, osteopathy, or podiatric medicine; and have a license in the state where the laboratory is located. Responsibilities include:
   a. Being available for consultation
   b. Assisting clients in ordering appropriate tests for clinical expectations
   c. Assuring that reports include pertinent information for test interpretation
   d. Assuring that consultations related to the quality of test results and interpretation specific to patient concerns are communicated to clients

2. This person does not need to be the Laboratory Director, but the role of Laboratory Director is greatly enhanced by also being a pathologist Clinical Consultant who both understands and provides administrative, clinical and technical leadership.
   a. The qualifications for Clinical Consultants are listed in 42 CFR 493.1417
   b. The general duties of a Clinical Consultant are listed in 42 CFR 493.1419

3. In the role of a Clinical Consultant the pathologist acts primarily in his or her capacity as a physician, interacting with other physicians and clinical staff to ensure appropriate test utilization, interpretation and follow-up. This is a valuable service that the pathologist as a physician can uniquely provide. For POCT, this includes responding to requests for new POC tests.

4. The initial Clinical Consultant duties of the pathologist take place when determining whether POCT should be deployed in a particular clinical setting. Questions that should be asked and answered during this period include:
   a. Who will be performing testing (physicians, nurses, others)?
   b. What population will be tested (e.g., age, sex, known diagnosis)?
   c. How will the test result be used (e.g., screening, diagnosis, monitoring)?
   d. Will the result be incorporated into a treatment algorithm?
   e. What are the requirements of the test result (e.g., qualitative versus quantitative, reportable range, low end sensitivity, accuracy, precision)?
   f. What are the advantages and disadvantages to performing this testing at the POC rather than in a centralized laboratory?
   g. Will follow up testing be required with another test and/or by the central laboratory?

5. The answers to these questions will help determine:
   a. If proposed POCT is appropriate in a given clinical setting
   b. The characteristics of the test that will be required

6. Developing test/treatment algorithms:
   a. The Clinical Consultant can significantly impact the appropriate utilization of POC tests, as well as the appropriate use of the results, by working with the clinical team to develop testing/treatment algorithms that incorporate the results of the POC test. Through the use of such algorithms, the user should understand when it is appropriate to use a POC test and what they should do with the result. Such algorithms foster consistent and appropriate test utilization and may provide data useful in the post-implementation follow-up.
   b. When will the test be used?
      1. For diagnosis:
         a. What (if any) clinical findings or prior test findings should be present prior to performing the test?
b. What is the follow-up of a positive test? For example, are confirmatory tests required by either manufacturer recommendations, by regulations, or for medical reasons?
c. What is the follow-up for a negative test?

2. For screening:
   a. What (if any) clinical findings or prior test findings should be present before performing the test?
   b. What is the follow-up of a positive test? For a negative test?

3. For monitoring:
   a. What will the frequency of monitoring be? Is this dependent on clinical findings or merely time delineated?
   b. Does monitoring need to occur at a specific point in time (e.g., post therapy)?
   c. Does the test have important decision levels? How accurate is the test at those levels?
   d. Are critical values needed?
      • How do these relate to critical values in the central laboratory?
      • What are the actions to be taken when such a value is identified?
   e. Are repeat or follow up values required?

7. Educating users:
   a. Once there has been a determination that POCT is appropriate and a specific test has been identified and validated, the role of a Clinical Consultant becomes more educational. Non-laboratorians may not be cognizant of important differences between POC and centralized laboratory tests. In order to assure the results of POC tests are used appropriately, it is incumbent upon the Clinical Consultant to make sure that the users are aware of and understand any potential issues or problems that may occur when using a POC test. These may include but are not limited to:
      1. Potential problems in reading the results of the test (internal controls, color discrimination, etc.)
      2. Appropriate interpretation of the test result
      3. Limitations in test sensitivity
      4. Limitations in the dynamic range of the test
      5. Test specificity and potential interferences
      6. Effects of other clinical conditions on the test result (e.g., anemia, hypoxia)
      7. The effect of sample collection problems
     8. Appropriate follow-up of a positive and/or negative test result

8. Developing testing aids:
   a. Many of the above issues can be addressed through the use of a well-written test procedure, appropriate staff training and competency assessment. However, it is also important to provide as many tools and reminders for the testing staff regarding these issues as possible. Remember that the testing staff will largely be non-laboratorians with many other duties and therefore may not understand the potential for a test to produce an erroneous result unless it is performed in strict compliance with the procedural steps. Providing testing aids will help standardize testing and result reporting practices. These may include but are not limited to:
      1. Preprinted forms or stickers to document POC test results that contain action reminders (e.g., “Glucose values < 50 mg/dL or > 250 mg/dL should be confirmed by the clinical laboratory”, “Testing should not be performed in any patient with a hematocrit less than 25%”)
2. Automated reminders pre-programmed into a testing device
3. Preprinted stickers for use either on the instrument or in the patient’s chart reminding users of a potential problem (e.g., “Falsely elevated glucose results may be seen in patients receiving parenteral solutions or medications containing maltose, galactose or xylose.”)
4. Reminders programmed into the LIS or HIS if POC test results are entered into the systems

9. Troubleshooting:
   a. A final but equally important role of the Clinical Consultant is assisting when problems in POC testing are encountered. Troubleshooting a POC test that is producing apparently erroneous results can be a challenge even for laboratorians. For end-users, who may have a limited understanding of what may impact a POC result, such troubleshooting may be impossible. Therefore, the Clinical Consultant must be prepared to apply his or her understanding of the methodology employed in each POC test to investigate the cause of erroneous results. Sources of error include:
      1. User error in performing the test (e.g., sample application, timing of reading)
      2. User error in interpreting the test result (e.g., inattention to control results, color discrimination problems, incorrect assumptions of what a positive or negative test result looks like)
      3. Sample problems (e.g., contamination, aged sample, inappropriate sample type, inappropriate collection device)
      4. Interfering substances (e.g., skin cleansers, IV solutions, medications)
      5. Patient’s clinical conditions that might impact the test result (e.g., anemia, hypoxemia)
      6. Reagent and/or device storage conditions (e.g., heat, humidity, sun exposure, expired components)
      7. Instrument problems (e.g., contaminated, dirty, out-of-control, improper programming)

10. Benefits of being a Clinical Consultant:
   a. Through the role of the Clinical Consultant, the POC pathologist Laboratory Director establishes himself or herself as a valued member of the care team and an important resource to the clinical staff. It demonstrates the expertise and value that the pathologist can bring to implementing POCT. The relationships that develop through this process can produce positive impacts in other areas of pathologist-clinician interactions. However, this role is best fulfilled in partnership with a POCT Coordinator. The director provides leadership and may make many of these determinations, but the coordinator also has an essential role in providing information and direct support to POCT sites and operators. The most successful POCT program is one in which there is a true partnership between director and coordinator. Best programs also include strong partnerships with clinical and other healthcare colleagues.
Pathologist as Laboratory Director

1. As a director of POCT, a pathologist has not only the opportunity to provide broad oversight and direction, but to be directly involved with the entire spectrum of caregivers in selecting, guiding, and assessing POCT for a wide variety of traditional and nontraditional care environments.

2. The role of Laboratory Director confers legal, regulatory, technical, fiscal and ethical responsibilities on a pathologist. In the US, most of those responsibilities are assigned through the Center for Medicare and Medicaid Services (CMS) via CLIA88. Additional responsibilities or requirements may be defined by states, professional societies, or accrediting agencies, (e.g., the College of American Pathologists (CAP), the Joint Commission (TJC),) or other agencies such as local regulatory bodies. International sites have their own governing bodies but frequently also follow CDC, World Health Organization (WHO), and International Standards Organization (ISO) guidelines. Increasingly, organizations and agencies are looking to set international standards. Future editions of this Tool Kit will emphasize those.

3. The primary leadership roles defined by CLIA88 as noted above are: Laboratory Director, Clinical Consultant and Technical Consultant. Other CLIA88 defined roles are those of Technical Supervisor, General Supervisor and testing personnel. While pathologists may assume any these roles, generally the latter are delegated to technical personnel.

4. Under CLIA88 and state regulations, a Laboratory Director can be a physician or doctoral level scientist with appropriate training and experience. For any POCT that is non-waived, personnel who do not meet this requirement cannot serve as Laboratory Directors. Waived testing has no CLIA88 personnel standards nor Laboratory Director requirements, but some states do have higher standards. It is important to know your state or local requirements to be a Laboratory Director for any type of testing. Individual organizations may also set specific requirements to direct waived testing and it is essential to know those when overseeing a program. The following discussion also applies to non-pathologist physicians and doctoral level scientists as Laboratory Directors, but it focuses on the role of pathologist. Much of the remainder of this Tool Kit applies generally to any Laboratory/medical Directorship roles of a pathologist, but with a focus on POCT.

5. The CLIA 88 regulations are organized into Subparts and Sections. Subpart M addresses personnel requirements for non waived testing, first defining the Laboratory Director. To summarize, the Laboratory Director is responsible for:
   a. The overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures
   b. Recording and reporting test results promptly, accurately, and proficiently
   c. Assuring compliance with applicable regulations

6. The director may perform the roles of Clinical Consultant, Technical Consultant, and testing personnel but he/she may delegate them to qualified personnel. However, the director always remains responsible that all duties are properly performed. A Laboratory Director risks losing his/her ability to direct any laboratory for at least two years if all required duties are not properly carried out. More serious legal consequences may ensue if there is harm to patients or other personnel. Therefore, it is essential that the Laboratory Director maintains an active and effective role in running a laboratory. He/she cannot afford to be a casual or detached director. The director must show active and effective evidence of supervision and assurance of quality.

7. Since no director can perform all duties in a complex operation, he/she must have a good team. For POCT, the first and foremost member of that team is the POCT Coordinator or Supervisor. The responsibilities and support that person needs will be emphasized throughout this Tool Kit. A subsection written by an experienced POCT Coordinator further defines the duties and qualities of this person. Along with a strong
relationship between the director and coordinator, no program can function effectively without also having strong partnerships with clinical and other healthcare colleagues.

8. CLIA88 also introduced the concept of the test complexity model, defining waived, moderately complex (including Provider Performed Microscopy or PPM) and highly complex testing. Much, but not all, of POCT is waived testing as previously discussed. Each complexity level has specific director requirements as outlined in Subpart M (CLIA88 Subpart M), but in general the requirements are similar, especially in hospital or more complex care environments. Even for the less stringent requirements of waived testing, recommendations for best practices exist. In 2005, CMS published findings of routine and focused surveys of waived testing sites and reiterated its recommendations for best laboratory practices. Some states, such as New York, do not recognize different complexity levels for any testing performed in accredited organizations such as hospitals or healthcare organizations. Some accrediting organizations, such as the CAP, require the same or similar standards for any testing performed. While this Tool Kit addresses the spectrum of POCT, the performance standards espoused are for best laboratory practices, regardless of test complexity, consistent with the recommendations and standards of the CAP.

9. General CLIA88 Laboratory Director responsibilities include being accessible onsite or by telephone or electronic consultations as needed and assuming the role of named director on no more than 5 CLIA certificates. In addition, the following essential director responsibilities are summarized:
   a. Quality is assured in all aspects of testing.
   b. There are adequate and safe physical plant and environmental conditions.
   c. Test methodologies are capable of performing for patient care, their performance is verified, and testing personnel performs them as directed.
   d. Proficiency testing is performed as required, results are reviewed and problems are addressed in corrective actions.
   e. Effective quality control and assessment programs are in place.
   f. All test systems have established and maintained levels of performance.
   g. Remediation is taken when test performance deviates from standards and patient results are only reported when test systems are working properly.
   h. Reports have pertinent information for interpretation.
   i. Consultation is available for questions on test quality and interpretation.
   j. Sufficient numbers of properly educated, trained, and experienced personnel are employed to perform all required functions, including supervision and consultation.
   k. Before testing, all personnel must have training and competency assessed.
   l. There are policies and procedures for training, assessing, and remediating testing personnel.
   m. Procedure manuals are available for testing personnel.
   n. The duties of each personnel member are specified in writing for all phases of testing.

10. Additional Laboratory Director responsibilities are defined by other organizations, including the CAP, the Joint Commission, the Commission on Laboratory Accreditation (COLA), and the American Association of Blood Banks (AABB) in the US. Given the comprehensive and detailed duties of Laboratory Director, it is obvious that any director needs education, training, experience, and support to fulfill his/her responsibilities. In this complex environment, having an experienced and dedicated team with adequate resources is fundamental. Again, a key member of the POCT team is the POCT Coordinator. We cannot overemphasize the importance of recruiting and partnering with a great POCT Coordinator as you develop your POCT team. The qualities and role of
this critical person are addressed below in the words of an experienced POCT Coordinator.

11. The above summarizes many of the general requirements for any Laboratory Director. What makes POCT different from a central or traditional laboratory? Previously the unique aspects of POCT were discussed. To summarize:
   a. POCT may be decentralized in numerous sites with different patient care goals and expectations.
   b. Different sites will have different physical capacities and limitations.
   c. Testing personnel are often not formally trained laboratorians; they have wide ranges of education, experience, motivation, and understanding of laboratory science.
   d. Personnel training, oversight, and communication strategies will vary.
   e. There is frequently high personnel turnover or changes; therefore, training and competency assessment is challenging.
   f. Priorities of testing personnel are usually clinical outcome oriented, while laboratorians tend to focus on technical processes.
   g. POCT technologies are varied and rapidly evolving; keeping up with developments and market pressures are difficult.
   h. The complexity model drives different priorities and strategies.
   i. Cost effectiveness models may be different (e.g., higher unit cost/test but possibly lower overall clinical outcome costs).
   j. Clinical needs and developments may be more rapidly changing (e.g., new practice sites, new specialty needs, public demand).
   k. Public policy and regulatory drivers may be more varied and unpredictable.

12. So, given the complexity and uncertainties of POCT, why should a pathologist laboratory Director get involved? A simple answer may be that your contractual relationship with your organization or practice group requires you to do it, but there really are more meaningful reasons to become a “POCT pathologist”. Why get involved in POCT?
   a. As physicians and laboratorians, we are uniquely suited to evaluate, implement and interpret testing for patients on behalf of providers.
   b. We have wide exposure to medical specialties and disease processes.
   c. We are experienced in inpatient and outpatient settings.
   d. We are communicators to many audiences.
   e. We have training and experience in linking medical indications, technical options and performance, and financial implications.
   f. We know how to manage varied personnel.
   g. It is an opportunity to expand our practice horizons and move the laboratory out into direct patient care. POCT is a prime opportunity for pathologists to engage in the “transformation” of the specialty, moving from a background to a leading position in clinical care.
   h. POCT is one of the high growth areas in laboratory testing; pathologists must be involved.
   i. POCT can be frustrating but extremely gratifying in supplying an unmet need and promoting best practices for quality test results. No pathologist actively involved in POCT is ever bored!
   j. POCT is an opportunity to perform value-added functions in an organization and work with a wider spectrum of peers.
   k. POCT gives us the chance to respond more to what our colleagues want from us. The following are examples from a Nurse Director of Ambulatory Care services, and a practicing physician administrator on what they want and need from a laboratory director involved in POCT.
B. What an RN Ambulatory Care Administrator Would Like from a Pathologist POCT Director:

1. A POCT Laboratory Director gives value to an administrator and organization by supporting the clinical team in providing timely and efficient patient care while remaining fiscally responsible to the institution. As numerous POC tests evolve, the administrator relies on the POCT Laboratory Director to make a well-rounded assessment of the impact of POC tests by developing sound business plans to ensure the institution does not invest in a technology that may not offer a significant benefit to patient care and may jeopardize the fiscal health of the institution. Ultimately, the administrator relies on the sound judgment of the POCT director to assess the true benefit of testing while diplomatically dealing with the possible unfounded laboratory demands of non-laboratorians.

2. Too often in the physician’s office decisions are made by practice managers or non-clinical staff who are wooed by sales representatives’ claims of quick and easy results from a POC test that will supposedly generate revenue for the practice. There may be no mention of CLIA certificates or moderate complexity testing requirements. It is a rare physician who inquires about validation studies to evaluate accuracy or comparability with standard methods or considers the impact of control testing, storage conditions, or other issues on results. Along with his/her own team members (such as a POCT Coordinator), the POCT Laboratory Director can tactfully educate peers and practices about these issues so that testing is safe and meets expectations. The director and coordinator then become valued ongoing resources to providers and other members of the team.

3. The POCT Laboratory Director ideally understands the financial implications of POCT to the practice and works to achieve realistic solutions. As a supportive peer, the POCT director can work with the practice to understand realistic expectations. The POCT Laboratory Director is then willing to explore the best means to meet the practice’s needs, using POCT or conventional testing to accomplish the task within the required turnaround time. The POCT director is also an important advocate and resource for regulatory compliance.

4. In summary, the POCT Laboratory Director is a valued colleague who works collaboratively with practitioners and administrators to achieve the highest possible standards of care, using appropriate technology and providing expert knowledge to accomplish the end goal of safe, appropriate, evidence-based patient care.

C. What an MD Administrator Wants from a POCT Pathologist

1. A POCT Laboratory Director gives value to an administrator and organization by supporting the clinical team in providing timely and efficient patient care while remaining fiscally responsible to the institution. As numerous POC tests evolve, the administrator relies on the POCT Laboratory Director to make a well-rounded assessment of the impact of POC tests by developing sound business plans to ensure the institution does not invest in a technology that may not offer a significant benefit to patient care and may jeopardize the fiscal health of the institution. Ultimately, the administrator relies on the sound judgment of the POCT director to assess the true benefit of testing while diplomatically dealing with the possible unfounded laboratory demands of non-laboratorians.

2. Administrator wants:
   a. Oversight of all scientific, medical, technological and support functions in an effective and efficient manner including:
      1. Preparing and managing operating and capital budgets
2. Setting goals and objectives and allocating resources
3. Providing an oversight structure or team to supervise or guide POCT

b. Definition, implementation and monitoring standards of performance including:
   1. The selection, establishment, and supervision of appropriate testing procedures and the standards related to such procedures
   2. The development and implementation of policies and procedures
   3. The accuracy, precision, and clinical relevance of laboratory test results
   4. Sample collection and specimen accessioning and preparation procedures

c. Support for quality improvement, utilization review, risk management and occupational health and safety activities, including:
   1. Ensuring the licensure, certification, or registration of the involved staff
   2. Provision and monitoring of related continuing educational activities of the medical staff, nurses, and other clinical staff, and student or resident clinical education, if applicable

d. Effective communication and interaction with accrediting, regulatory, administrative groups, the medical community, and the patient population served

e. Support for the continuum of care from the community to the health care institution by:
   1. Participating in and, where appropriate, leading the development of local and regional service delivery models
   2. Encouraging laboratory service delivery systems that optimize cooperation among service providers and minimize duplication

f. Leadership in development and implementation of patient-focused laboratory services, including delivery systems that optimize services to achieve the desired health outcomes for patients

D. POCT Coordinator Development and Role

1. In order to support or lead an effective POCT program, a pathologist Laboratory Director needs to use all his/her skills as a leader, communicator, and educator. Essential to that function is recruiting, mentoring, and supporting a POCT Coordinator. Below, in the words of an experienced POCT Coordinator and educator, is a discussion of that role.

2. The role of a POCT Coordinator is a unique one. Many diverse skills are required for the POCT Coordinator to be successful in his/her role. Excellent laboratory technical competencies serve as the basis for the role. In selecting and mentoring a POCT Coordinator, the pathologist Laboratory Director should be aware of the variety of additional skills that will be required. The following are some characteristics to look for when selecting such an individual and provide a framework for mentoring emerging laboratory leaders for the challenging role of POCT Coordinator.

   a. The individual should have a history of a strong patient-centered focus and good customer service experience and skills. Since the coordinator acts as a liaison between the central laboratory and the POCT site(s), the individual should be able to collaborate well with non-laboratory personnel to ensure effective testing operations and promote patient-focused care.

   b. A candidate for POCT Coordinator should have exemplary written and oral communication skills. This individual may be called upon to draft policies and procedures, design training and competency modules, communicate with a variety of healthcare professionals regarding POCT regulatory compliance issues and give presentations to POCT personal. This individual should be comfortable in communicating with all levels of healthcare personnel including patient caregivers, administrators, medical directors, and other senior leaders.
c. The POCT Coordinator should be able to work in partnership with the Laboratory Director, respecting the director's responsibilities, keeping the director apprised of developments, but being independent enough to carry out routine functions and also advise the director. The director and coordinator should have a clear understanding of their roles and relationship. See below.

d. The POCT Coordinator should also be successful in working in and leading teams. Advanced training in process improvement/LEAN/Six Sigma can provide the individual with added tools in facilitating a quality POCT program.

e. The POCT Coordinator should exhibit creative problem solving and strong facilitation and negotiation skills. As a leader, this individual should be able to successfully “respect and leverage separate realities”, while working to establish a common vision and values related to POCT testing. The goal of these efforts is to produce quality POCT testing within the shared realities of laboratory and non-laboratory departments.

f. To support a POCT Coordinator in their role, the following characteristics of a Laboratory Director are desired:

1. Coach and mentor the POCT Coordinator in developing his/her skills for the role.
2. Provide support to the POCT Coordinator by communicating with facility medical/administrative directors when significant regulatory compliance issues are unable to be immediately resolved.
3. Interact with facility administrators and medical directors of other disciplines on a regular basis. Participate in and/or coordinate interdisciplinary committees related to POCT or other laboratory issues.
4. Understand the risks and benefits of POCT implementation in various settings. Be willing to see a POCT issue from all sides and understand it both clinically and administratively.
5. Keep abreast of new POCT technology and new application of current technology and promote discussions regarding such with POCT Coordinators.
6. Be available to meet on a scheduled and unscheduled basis with the POCT Coordinator, both to meet regulatory compliance with oversight and review, but also to offer support, suggestions, and solutions for problem solving. Being a POCT Coordinator is a demanding role, and active director support is essential.

E. Beginning a Point Of Care Testing Program

1. Assuming that we respond to the challenge and get involved in POCT, where do we begin? A first action might be to define your own and the laboratory's relationship to a program.

a. Are you the default or official director of POCT?
b. Is there an existing structure to the POCT program? Is it working?
c. Is the laboratory merely asked to advise on introducing POCT? Do you or other laboratory staff decide on whether POCT is implemented or do sources outside of the laboratory make their own decisions?
d. Is the laboratory looked at as hostile or supportive of POCT?
e. Is there an orderly process for evaluating, implementing and assessing outcomes of POCT?
f. Who has administrative or regulatory responsibility for the program?
g. Who bears the costs of testing?
h. What does your organization expect of you?
2. The answers to those and other questions will determine your next steps, but a recommendation is that you either evaluate your existing formal program or create a structure for your program. Most successful POCT programs have a plan with policies and procedures. Some POCT programs and directors prefer a less structured approach, but at the least, there should be some definition and predictability to your process so it is not haphazard and POCT introduction can become a more rational and reliable process. However, the pathologist Laboratory Director is involved in POCT, is he/she a valued and respected member of that process? The POCT Coordinator is an important position in any program, and should be an official member of a program.

3. Options to consider in establishing, evaluating, or modifying any POCT program and policy include:
   a. Leadership structure: is it centralized or decentralized? Pathologist- or central laboratory-led versus nurse- or clinician-led?
   b. Composition of the leadership or decision making group or stakeholders? Is there an organizational chart?
   c. Should there be a formal POCT committee? Or does a less formalized process work well in your setting?
   d. Will the same structure apply to all sites (i.e., inpatient, outpatient, offsite)?
   e. What are indications for performing POCT? What are the organization’s goals in providing POCT (e.g., service, quality, patient disposition, turnaround times, patient or provider satisfaction, new service lines, cost containment)?
   f. What are the contraindications for performing POCT?
      1. Relative (e.g., staffing)
      2. Absolute (e.g., complexity model, staffing requirements, costs)
   g. What is the process for requesting a new POCT test and evaluating POCT?
   h. Is the process communicated and followed? Is it effective, efficient, or practical?
   i. What is the regulatory organization of the POCT program?
      1. Centralized- main lab CLIA certificate covers all POCT within the organization
      2. Distributed: every site performing POCT has its own CLIA certificate
      3. Combined: some sites are under the central lab and others have their own CLIA certificates
         a. Due to the repercussions of a revoked CLIA certificate (director cannot direct any lab for 2 years, laboratory cannot bill Medicare/Medicaid) and the issues that may arise regarding maintaining regulatory compliance when the testing staff are not laboratorians, there may be distinct advantages to not covering POCT sites with the central laboratory CLIA certificate.
   j. Does the certificate holder have actual responsibility for the program? Is there responsibility without authority?
   k. Is the central laboratory a resource, partner, collaborator, or overseer of POCT? Is it intimately involved or dissociated from POCT?
   l. Is there a cost benefit analysis projected before implementing POCT and is there a post implementation analysis?
   m. What is revenue from POCT? Who bills? Who collects? Whose budget covers costs?
   n. Are there metrics collected (e.g., volumes, consumables, staffing)?
   o. Is there post-implementation analysis of outcomes?
   p. Who oversees testing staff? Who trains, assesses competency, and addresses remediation, education, and recertification?
   q. Who assesses quality control, preventive maintenance, proficiency testing, regulatory compliance?
r. Who orders supplies, follows product recalls, etc.?
s. Is there an established quality management program? Are goals set, monitored, assessed, and reported?
t. Are quality effectiveness and/or outcomes measured?
u. Are there a safety, risk management, and compliance programs?
v. Are there educational and support resources provided or available (e.g., Listservs, peers, professional organizations, skills fairs)?
w. What are relationships with vendors and how are these managed? Is there a central process vendors must follow?
   1. It is often advisable to have POCT vendors deal with the POCT oversight structure rather than dealing directly with clinicians and/or clinical sites so that the motivations and decisions to implement POCT are well grounded.
x. Is there accountability and reporting structure for the program? Is there an annual report? Who receives the report?
y. What are relationships with nursing, material services, facilities, safety, risk management, information services, billing and compliance, medical records, purchasing, fiscal/budgeting/business office?

F. Communication

1. A Laboratory Director needs to be a good communicator and create a culture of communication if his/her efforts at guiding decision making and implementation are to be successful. POCT especially requires a multidisciplinary approach to reaching the wide stakeholder audience. This is another example where having an excellent coordinator and clinical partners is critical to effective communication and building understanding in the interest of high quality patient care.

2. First, the audience needs to be defined and for POCT the following groups need to be considered:
   a. Other pathologists and laboratory professionals who need to offer advice and support a process, especially for specialty testing such as microbiology or coagulation tests.
   b. Providers who request POC tests or will be involved in their use.
   c. Nurses and clinical staff who request POC tests, perform testing, or who will supervise testing.
   d. Administrators, executive committee and board members interested in the provision of services, patient or provider satisfaction, outcomes and costs.
   e. House staff who may perform or use POCT.
   f. Facilities staff who provide or maintain environments.
   g. Information services/computer staff who provide connectivity and reporting capacity.
   h. Patients who receive or request services.
   i. Vendors who need to understand the organization’s rules about promotion, approval, and support of testing services.
   j. Educators who can oversee POC test introductions or program performance.

3. Next, the Laboratory Director needs to consider what needs to be communicated. Examples include:

   k. How to request POCT services; as above, is there a process; who are the contact personnel?
   l. Requirements for quality laboratory services
   m. Responsible personnel for oversight or supervision of specific services; contact persons for problems or questions
n. Standards of care, guidelines, evidence for or against POCT, limitations or indications for POCT, etc.
o. Test performance expectations and requirements
p. Outcomes of POCT; successes or limitations of testing; quality management findings
q. Warnings or risks of POCT (e.g., maltose interference with glucose meters, kit malfunctions)
r. Product updates
s. New POC tests available and specifics of performance (e.g., turnaround times, specimen types, storage conditions)

4. Communication tools include:
k. POCT Coordinator and clinical partners
l. Telephone,
m. Face-to-face dialog
n. In-service education, appropriately aimed at audience and learning level
o. One-on-one training
p. Printed messages posted on devices or in work areas
q. Electronic messages or alerts on POCT devices (e.g., operators cannot continue without receiving and acknowledging messages)
r. Newsletters, posters, published articles
s. Intranet postings
t. Emails, memos
u. Internet resources including continuing education programs, webinars, publications
v. Product or service updates
w. Reporting (e.g., Board, department level, infection control committee, Quality Management)
x. Skills fairs
y. Vendor communications and understanding of organizational policies
z. Vendor provided in-service training or workshops
aa. REPETITION, REDUNDANCY, VARIETY. Essential for any effective communication. Keep the audience engaged at appropriate levels and keep communications varied and as failsafe as possible. Try to minimize operator fatigue to important messages

G. A BUSINESS PLAN TOOL FOR POCT

1. Included in this Tools Section are a series of model tools that a pathologist Laboratory Director can use to evaluate and implement a POCT request or process. A director and laboratory can create its own process but this is a structured approach to considering a request for implementing a POCT test and the process needed to achieve that. Later in this Tool Kit, in the Technical Consultant section and under “Selection of Appropriate Methodologies”, there is an alternate tool for evaluating devices, kits, etc. The tool included here is a more administrative one, with administrative and outcome measures. Obviously, this specific tool can be used for many processes in the clinical laboratory. In further editions of this Tool Kit, there will be case studies illustrating the use of these tools.
2. The tools are only meant to be general guides and may not include every contingency. Each institution has unique characteristics and structures that require customization of these tools.
Pathologist as Technical Consultant

The CLIA88 regulations in Subpart M describe the role of a Technical Consultant for moderately complex testing (or similarly a Technical Supervisor for highly complex testing). That person must provide technical and scientific oversight of the laboratory. He/she does not need to be on site all times but must be available on an as needed basis either on site, by telephone or electronically. The Technical Consultant does not need to be the Laboratory Director, but like the Clinical Consultant role, the Laboratory Director is frequently designated as the Technical Consultant and his or her role is also probably strengthened by taking on this responsibility. Most broadly trained pathologist Laboratory Directors should be able to assume this role for POCT and any POCT director should understand these duties.

1. Duties of the Technical Consultant include:
   a. Selection of appropriate test methods (Section #4)
   b. Verification of test methods (Section #5 to be expanded in the next version of this Tool Kit)
   c. Proficiency testing (Section #6)
   d. Quality control (Section #7)
   e. Resolving technical problems and remedial actions, as needed (will be added to the next edition)
   f. Patient test results: POCT & Connectivity (Section #8)
   g. Patient safety (Section #9) (Not officially included in the CLIA88 Technical Consultant duties but included in this Tool Kit here because it is so inter-related to all the other duties. Patient Safety should be a fundamental responsibility of all Laboratory Director, Clinical Consultant and Technical Consultant functions.)
   h. Staff training and competency (Section #10)
   i. Repeat competency assessment 6 months after initial evaluation for new technical staff and every 12 months thereafter and maintenance of competency elements (Section #10)

2. For waived testing, not all of these duties are required, BUT, not all POCT is waived testing, AND, best laboratory practices should be included in the selection and oversight of ANY testing. As previously noted, various professional bodies, states, and nations require all of the technical elements of non-waived testing to be applied to waived testing.

3. This section includes details addressing most of the above duties. Some of the information may not be applicable for waived testing under CLIA88. Rather, the information provides for best practices for any type of laboratory testing, and is useful information for a Laboratory Director in any setting. As noted previously, many of the functions can overlap with the sections on the Laboratory Director and Clinical Consultant. However, they are included here because they address many technical operations and are presented in some detail.
Pathologist’s Regulatory Role in Addition to CLIA

a. In addition to maintaining compliance with the regulations set forth in CLIA88 the Laboratory Director is also responsible for knowing, understanding and maintaining compliance with other Federal and State regulations that pertain to clinical laboratory testing. In the POCT environment, some of these regulations take on a different perspective and often require different solutions or accommodations than in the clinical laboratory. In this section we will briefly discuss the other agencies and regulations that the POCT Laboratory Director must be aware of and some information on how compliance may be achieved.

A. **Food & Drug Administration (FDA):** The FDA regulates all laboratory tests and devices used in testing human samples for clinical purposes.
   1. The vast majority of POCT is performed using FDA approved kits and/or instruments. A listing of approved waived and moderately complex tests can be found at: [FDA CLIA88 Test Database Search Page](#)
   2. Most FDA enforcement is aimed at tests/kits/reagents that are marketed for clinical use in the U.S. via the 510k Premarket Notification or Pre-Market Approval (PMA) processes.
   3. An overview of Device Regulation and the process to receive FDA approval is available at: [FDA Overview of Device Regulation](#).
      b. Pre-Market Approval (PMA) processes OR in the Code of Federal regulations: 21 CFR Part 814
   4. In terms of POCT, the primary impact of the FDA Approval process is in the manufacturer’s instructions and specifications for the use of the test. Deviation from the manufacturer’s instructions typically will result in the test classification (waived or moderately complex) to immediately be considered ‘high complexity’ with all the ramifications of that classification. Items of particular importance to be cognizant of when initiating a POC test are:
      a. Sample types that are approved for use with the test
      b. Sample collection methods and devices
      c. Sample stability and maximum time from sample collection to testing
      d. Device, reagent, and, if applicable, control material storage conditions. Typically terms such as ‘room temperature’ or ‘refrigerator’ storage are no longer used and manufacturers must specify a temperature range for proper storage. This then, by extension, requires that the temperature of any storage area be monitored. Be sure to note any additional storage conditions such as humidity, light exposure, etc.
      e. Performance of Quality Control: How it is performed, at what frequency, etc.
      f. Reportable range for the test
      g. Requirements for follow-up or confirmatory testing
      h. The testing procedure itself
   5. **Analyte Specific Reagents (ASRs):**
      NOTE: Although it is atypical for POC tests to use ASR’s we have included this section for completeness.
      a. Definition: ASRs are defined as “antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid
sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.” Class I ASR’s may be purchased and used by laboratories to develop specific clinical tests (laboratory developed tests; LDTs) that may be used within the laboratory that developed the test for patient testing without specific FDA approval.

b. There are additional FDA requirements prior to marketing Class II and Class III ASR’s.

   1. Class II ASR: reagent is used as a component in a blood banking test of a type that has been classified as a Class II device (e.g., certain cytomegalovirus serological and treponema pallidum nontreponemal test reagents). 21 CFR 864.4020(b)(2)

   2. Class III ASR: reagent is intended as a component in tests intended either:

      a. to diagnose a contagious condition that is highly likely to result in a fatal outcome and prompt, accurate diagnosis offers the opportunity to mitigate the public health impact of the condition (e.g., human immunodeficiency virus (HIV/AIDS) or tuberculosis (TB)); or

      b. for use in donor screening for conditions for which FDA has recommended or required testing in order to safeguard the blood supply or establish the safe use of blood and blood products (e.g., tests for hepatitis or for identifying blood groups). 21 CFR 864.4020(b)(3).

   c. FDA considers ASRs intended to be used as a component in tests for diagnosis of HIV (including monitoring for viral load or HIV drug resistance mutations) to be Class III ASRs

3. A good deal of information re: ASR’s can be found at the FDA’s ASR FAQ’s page.

6. **Laboratory Developed Tests (LDT’s);**

   NOTE: Although it is atypical for POC tests to be Laboratory Developed Tests we include this section for completeness

   a. For many years the FDA has adopted a position of ‘enforcement discretion’ with regard to Laboratory Developed Tests (LDTs) for clinical use. As long as there were no specific complaints or adverse patient impacts associated with such tests there was no pre-use approval process. Laboratories were free to develop and use such tests clinically provided they performed the appropriate CLIA validation steps.

   b. Many of these LDTs utilize one or more ASR’s as a component of the test process.

   c. Recently the FDA has identified a specific type of LDT that incorporates the results of several ‘tests’ and via some algorithm (typically proprietary) produces a diagnostic, or prognostic ‘score’. These In Vitro Diagnostic Multivariate Index Assays
(IVD Mia's) will require additional pre-clinical use validation and may require FDA approval prior to clinical use.

7. The FDA also provides important updates and information (FDA Medwatch) regarding problems with FDA approved tests/instruments such as manufacturer recalls, tests interferences, safety hazards, etc. which may impact patient or operator safety and/or the quality of the test result. The FDA provides a mechanism to sign up for e-mail alerts regarding specific categories of FDA covered items on this page.

B. Centers for Disease Control and Prevention (http://www.cdc.gov/)
   1. The CDC provides recommendations, and resources for laboratories that may be applicable to POCT testing (search for “point-of-care”) The CDC also provides survey information with regard to use of POCT.
   2. Biosafety: specific information regarding biosafety as it applies to communicable agents can be found at: CDC Biosafety.
   3. An overall review of good laboratory practices for sites performing waived testing may be found at: MMWR 2005 Good Laboratory Practice.

C. Occupational Safety & Health Administration (Federal OSHA,) works to promote workplace safety. In the area of POCT, OSHA standards with regard to personnel protective equipment (PPE), biosafety and biohazardous waste disposal are important to review.

   1. The Needlestick Safety and Prevention Act requires the use of engineering and work practice controls to eliminate or minimize employee exposure to bloodborne pathogens.
   2. Standards
      a. Blood Borne Pathogen Standard (1910.1030) requires the following when there is any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties.
         1. A written Exposure Control Plan
         2. Adherence to “Universal Precautions”: which is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.
         3. Use of engineering controls: (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolates or removes the bloodborne pathogens hazard from the workplace.
         4. Use of work practice controls e.g. reducing the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).
         5. Use of Personal Protective Equipment: specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.
7. **Housekeeping**: Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

8. **Handling and disposal of regulated waste**: Although the amount of biologic sample used in most POCT tests is small, all contaminated materials used in testing must be disposed of in compliance with all applicable federal, state and local regulations.

9. **Hepatitis B vaccination**: The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

10. **Labels and signage**: Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials.

11. **Employee information and training**: The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

b. **Standard Precautions**
   1. In 1996, The CDC combined the requirements of Universal Precautions and those of Body Substance Isolation, using the term Standard Precautions. Standard Precautions are based on the assumption that “all blood, body fluids, secretions, excretions, except sweat, nonintact skin, and mucous membranes may contain transmissible infectious agents” and apply to all patients. Included are rules for hand hygiene, use of personal protective equipment, handling of potentially contaminated equipment/items, respiratory hygiene/cough etiquette, and safe injection practices.


   c. **Chemical safety**: For most POCT hazardous chemical exposure is not a major issue. However, knowledge of the OSHA regulations, the chemicals used in each kit or device, and making provisions for any employee exposure where hazardous chemicals are present is important. Any Material Safety Data Sheets (MSDS) provided by the manufacturer should be available where the device or kit is being utilized.

   3. Twenty-four states plus Puerto Rico and the Virgin Islands have OSHA approved safety programs. While many of these are similar to Federal
OSHA rules many have specific and/or more stringent requirements that the laboratory director must be aware of. Links to specific state programs can be found at: State OSHA’s.

D. **State regulations**

1. There are currently two states that have more stringent laboratory regulations that CLIA88 and have been granted exemption from CLIA regulations: New York and Washington.
   a. Pathologists overseeing point of care testing in the states must familiarize themselves with the laboratory regulations for these states.

2. The following states have some form of laboratory regulation but they are highly variable in their content, requirements and applicability to point of care testing. Pathologists administering point of care testing programs within these states should familiarize themselves with any applicable regulations.

3. The remaining states have no specific laboratory regulations and rely on CLIA88.

E. **International regulations**

1. Various regulations and standards have been developed in other countries with regard to clinical laboratory testing. Many of these are based on the ISO standards; however, there may be significant variations between different countries and regions. Pathologists involved in point of care testing programs should familiarize themselves with the regulations and standards of the country and/or region that they are operating in. Further editions of this Tool Kit will address international regulations in more detail.

F. **Center For Medicare & Medicaid Services & Office of the Inspector General**

1. Medical necessity: Center For Medicare & Medicaid Services (CMS) via National Coverage Determinations (NCD’s) and Local Coverage Determinations (LCD’s) specify the medical conditions that demonstrate medical necessity for certain laboratory tests. Unless the medical necessity requirement is met the test may not be reimbursed by CMS.

2. Medicare patients presenting with test orders where medical necessity cannot be demonstrated should be asked to sign an Advance Beneficiary Notice (ABN) and accept responsibility for payment. When a laboratory determines that, based on diagnostic information received with the test request, that Medicare is unlikely to reimburse for the test, the laboratory must provide the patient with an ABN that allows the patient to either accept responsibility for payment should Medicare deny reimbursement or not have the testing performed. **Information on the requirements of the ABN**
   a. NCD information
   b. LCD information is dependent on the specific Fiscal intermediary (Part A) or Carrier (Part B) that Medicare patient testing is billed through. Knowledge of the LCD’s for your particular region and billing type is required to understand potential reimbursement for POCT. A listing of **Intermediaries and Carriers by state is available.**
3. **Common Procedural Terminology, 4th Ed (CPT-4) codes:** Most laboratory tests, including POCT, are billed via CPT-4 codes. The laboratory must select the most appropriate code for each test billed. CPT-4 codes are developed by the *American Medical Association* and are available annually in book form and via on-line subscription services.

4. **Office of the Inspector General (OIG) Model Compliance Plan for Laboratories:** In order to reduce laboratory fraud and abuse CMS via the OIG developed a billing compliance plan for laboratories. If a laboratory is reviewed with regard to billing practices, the presence of an OIG Compliant plan may mitigate (to some degree) the extent of the audit.

### G. **Health Insurance Portability and Accountability Act (HIPAA)**

1. The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety.

2. In terms of POCT, the primary facets of HIPAA that may be relevant are safeguarding Protected Health Information (PHI), executing Business Associate Agreements, if applicable, and the electronic transmission of test results/PHI.

3. **Protected Health Information:** The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)." "Individually identifiable health information" is information, including demographic data, that relates to:
   a. the individual’s past, present or future physical or mental health or condition,
   b. the provision of health care to the individual, or
   c. the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.13 Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

4. **Business Associate (BA):** In general, BA status may not strictly apply to vendors who are contracted to provide POCT materials. However, it may be prudent to execute Business Associate Agreements (see below) with vendors who provide instrumentation that stores PHI and could be accessed during servicing or repair of the instrument.
   a. In general, a business associate is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. Business associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, and billing. Business associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services.
However, persons or organizations are not considered business associates if their functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all. A covered entity can be the business associate of another covered entity.

b. Business Associate Agreement (BAA): When a covered entity uses a contractor or other non-workforce member to perform "business associate" services or activities, the Rule requires that the covered entity include certain protections for the information in a BAA. In the business associate contract, a covered entity must impose specified written safeguards on the individually identifiable health information used or disclosed by its business associates.

   1. Sample language may be found at: DHHS Business Associate Contracts.

c. Electronic Transmission & Security Standards: The HIPAA Security Rule applies to POCT whenever PHI is stored in a test device or transmitted via electronic means from that device. The specifics of the regulations can be found here.

   1. In terms of POCT, when testing is performed with an instrument, it is important to understand what information is entered and stored in the device, and how is it accessed (e.g., password or user code), and to ensure that such information is removed from the device if/when it is returned to the manufacturer for service, repair or replacement.

d. If the instruments are used to transmit results and PHI to an electronic medical record or other electronic repository, then the manner in which the data is transmitted (e.g., encryption, firewall security) and the security and integrity of the repository must be taken into account.
Pathologist’s Regulatory Role in Addition to CLIA

b. In addition to maintaining compliance with the regulations set forth in CLIA88 the Laboratory Director is also responsible for knowing, understanding and maintaining compliance with other Federal and State regulations that pertain to clinical laboratory testing. In the POCT environment, some of these regulations take on a different perspective and often require different solutions or accommodations than in the clinical laboratory. In this section we will briefly discuss the other agencies and regulations that the POCT Laboratory Director must be aware of and some information on how compliance may be achieved.

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   3. An overview of Device Regulation and the process to receive FDA approval is available at: FDA Overview of Device Regulation.
      b. Pre-Market Approval (PMA) processes OR in the Code of Federal regulations: 21 CFR Part 814

4. In terms of POCT, the primary impact of the FDA Approval process is in the manufacturer’s instructions and specifications for the use of the test. Deviation from the manufacturer’s instructions typically will result in the test classification (waived or moderately complex) to immediately be considered ‘high complexity’ with all the ramifications of that classification. Items of particular importance to be cognizant of when initiating a POC test are:
   a. Sample types that are approved for use with the test
   b. Sample collection methods and devices
   c. Sample stability and maximum time from sample collection to testing
   d. Device, reagent, and, if applicable, control material storage conditions. Typically terms such as ‘room temperature’ or ‘refrigerator’ storage are no longer used and manufacturers must specify a temperature range for proper storage. This then, by extension, requires that the temperature of any storage area be monitored. Be sure to note any additional storage conditions such as humidity, light exposure, etc.
   e. Performance of Quality Control: How it is performed, at what frequency, etc.
   f. Reportable range for the test
   g. Requirements for follow-up or confirmatory testing
   h. The testing procedure itself

5. Analyte Specific Reagents (ASRs):
   NOTE: Although it is atypical for POC tests to use ASR’s we have included this section for completeness.
   a. Definition: ASRs are defined as “antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid
sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.” Class I ASR’s may be purchased and used by laboratories to develop specific clinical tests (laboratory developed tests; LDTs) that may be used within the laboratory that developed the test for patient testing without specific FDA approval.

b. There are additional FDA requirements prior to marketing Class II and Class III ASR’s.

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2. Class III ASR: reagent is intended as a component in tests intended either:
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   b. for use in donor screening for conditions for which FDA has recommended or required testing in order to safeguard the blood supply or establish the safe use of blood and blood products (e.g., tests for hepatitis or for identifying blood groups). 21 CFR 864.4020(b)(3).

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**NOTE:** Although it is atypical for POC tests to be Laboratory Developed Tests we include this section for completeness

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c. Recently the FDA has identified a specific type of LDT that incorporates the results of several ‘tests’ and via some algorithm (typically proprietary) produces a diagnostic, or prognostic ‘score’. These In Vitro Diagnostic Multivariate Index Assays
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B. **Centers for Disease Control and Prevention** ([http://www.cdc.gov/](http://www.cdc.gov/))
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   2. Standards
      a. **Blood Borne Pathogen Standard** ([1910.1030](http://www.osha.gov)) requires the following when there is any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties.
         1. A written Exposure Control Plan
         2. Adherence to “Universal Precautions”: which is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.
         3. Use of engineering controls: (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolates or removes the bloodborne pathogens hazard from the workplace.
         4. Use of work practice controls e.g. reducing the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).
         5. Use of Personal Protective Equipment: specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.
         6. Exposure evaluations
7. Housekeeping: Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

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11. Employee Information and training: The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

b. Standard Precautions

1. In 1996, The CDC combined the requirements of Universal Precautions and those of Body Substance Isolation, using the term Standard Precautions. Standard Precautions are based on the assumption that “all blood, body fluids, secretions, excretions, except sweat, nonintact skin, and mucous membranes may contain transmissible infectious agents” and apply to all patients. Included are rules for hand hygiene, use of personal protective equipment, handling of potentially contaminated equipment/items, respiratory hygiene/cough etiquette, and safe injection practices.


c. Chemical safety: For most POCT hazardous chemical exposure is not a major issue. However, knowledge of the OSHA regulations, the chemicals used in each kit or device, and making provisions for any employee exposure where hazardous chemicals are present is important. Any Material Safety Data Sheets (MSDS) provided by the manufacturer should be available where the device or kit is being utilized.

3. Twenty-four states plus Puerto Rico and the Virgin Islands have OSHA approved safety programs. While many of these are similar to Federal
OSHA rules many have specific and/or more stringent requirements that the laboratory director must be aware of. Links to specific state programs can be found at: State OSHA’s.

D. **State regulations**
   1. There are currently two states that have more stringent laboratory regulations that CLIA88 and have been granted exemption from CLIA regulations: New York and Washington.
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   2. The following states have some form of laboratory regulation but they are highly variable in their content, requirements and applicability to point of care testing. Pathologists administering point of care testing programs within these states should familiarize themselves with any applicable regulations.
   3. The remaining states have no specific laboratory regulations and rely on CLIA88.

E. **International regulations**
   1. Various regulations and standards have been developed in other countries with regard to clinical laboratory testing. Many of these are based on the ISO standards; however, there may be significant variations between different countries and regions. Pathologists involved in point of care testing programs should familiarize themselves with the regulations and standards of the country and or region that they are operating in. Further editions of this Tool Kit will address international regulations in more detail.

F. **Center For Medicare & Medicaid Services & Office of the Inspector General**
   1. Medical necessity: Center For Medicare & Medicaid Services (CMS) via National Coverage Determinations (NCD’s) and Local Coverage Determinations (LCD’s) specify the medical conditions that demonstrate medical necessity for certain laboratory tests. Unless the medical necessity requirement is met the test may not be reimbursed by CMS.
   2. Medicare patients presenting with test orders where medical necessity cannot be demonstrated should be asked to sign and Advance Beneficiary Notice (ABN) and accept responsibility for payment. When a laboratory determines that, based on diagnostic information received with the test request, that Medicare is unlikely to reimburse for the test, the laboratory must provide the patient with an ABN that allows the patient to either accept responsibility for payment should Medicare deny reimbursement OR not have the testing performed. **Information on the requirements of the ABN**
      a. **NCD information**
      b. **LCD information** is dependent on the specific Fiscal intermediary (Part A) or Carrier (Part B) that Medicare patient testing is billed through. Knowledge of the LCD’s for your particular region and billing type is required to understand potential reimbursement for POCT. A listing of **Intermediaries and Carriers by state is available**.
3. **Common Procedural Terminology, 4th Ed (CPT-4) codes:** Most laboratory tests, including POCT, are billed via CPT-4 codes. The laboratory must select the most appropriate code for each test billed. CPT-4 codes are developed by the **American Medical Association** and are available annually in book form and via on-line subscription services.

4. **Office of the Inspector General (OIG) Model Compliance Plan for Laboratories:** In order to reduce laboratory fraud and abuse CMS via the OIG developed a billing compliance plan for laboratories. If a laboratory is reviewed with regard to billing practices, the presence of an OIG Compliant plan may mitigate (to some degree) the extent of the audit.

G. **Health Insurance Portability and Accountability Act (HIPAA)**

1. The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety.

2. In terms of POCT, the primary facets of HIPAA that may be relevant are safeguarding Protected Health Information (PHI), executing Business Associate Agreements, if applicable, and the electronic transmission of test results/PHI.

3. **Protected Health Information:** The Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)." "Individually identifiable health information" is information, including demographic data, that relates to:
   a. the individual's past, present or future physical or mental health or condition,
   b. the provision of health care to the individual, or
   c. the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

13 Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

4. **Business Associate (BA):** In general, BA status may not strictly apply to vendors who are contracted to provide POCT materials. However, it may be prudent to execute Business Associate Agreements (see below) with vendors who provide instrumentation that stores PHI and could be accessed during servicing or repair of the instrument.

   a. In general, a business associate is a person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information. Business associate functions or activities on behalf of a covered entity include claims processing, data analysis, utilization review, and billing. Business associate services to a covered entity are limited to legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services. However, persons or organizations are not considered business...
associates if their functions or services do not involve the use or disclosure of protected health information, and where any access to protected health information by such persons would be incidental, if at all. A covered entity can be the business associate of another covered entity.

b. Business Associate Agreement (BAA): When a covered entity uses a contractor or other non-workforce member to perform "business associate" services or activities, the Rule requires that the covered entity include certain protections for the information in a BAA. In the business associate contract, a covered entity must impose specified written safeguards on the individually identifiable health information used or disclosed by its business associates.

1. Sample language may be found at: DHHS Business Associate Contracts.

c. Electronic Transmission & Security Standards: The HIPAA Security Rule applies to POCT whenever PHI is stored in a test device or transmitted via electronic means from that device. The specifics of the regulations can be found here.

1. In terms of POCT, when testing is performed with an instrument, it is important to understand what information is entered and stored in the device, and how is it accessed (e.g., password or user code), and to ensure that such information is removed from the device if/when it is returned to the manufacturer for service, repair or replacement.

d. If the instruments are used to transmit results and PHI to an electronic medical record or other electronic repository, then the manner in which the data is transmitted (e.g., encryption, firewall security) and the security and integrity of the repository must be taken into account.
Pathologist’s Regulatory Role in Addition to CLIA

c. In addition to maintaining compliance with the regulations set forth in CLIA88 the Laboratory Director is also responsible for knowing, understanding and maintaining compliance with other Federal and State regulations that pertain to clinical laboratory testing. In the POCT environment, some of these regulations take on a different perspective and often require different solutions or accommodations than in the clinical laboratory. In this section we will briefly discuss the other agencies and regulations that the POCT Laboratory Director must be aware of and some information on how compliance may be achieved.

A. Food & Drug Administration (FDA): The FDA regulates all laboratory tests and devices used in testing human samples for clinical purposes.

1. The vast majority of POCT is performed using FDA approved kits and/or instruments. A listing of approved waived and moderately complex tests can be found at: FDA CLIA88 Test Database Search Page

2. Most FDA enforcement is aimed at tests/kits/reagents that are marketed for clinical use in the U.S. via the 510k Premarket Notification or Pre-Market Approval (PMA) processes.

3. An overview of Device Regulation and the process to receive FDA approval is available at: FDA Overview of Device Regulation.
   b. Pre-Market Approval (PMA) processes OR in the Code of Federal regulations: 21 CFR Part 814

4. In terms of POCT, the primary impact of the FDA Approval process is in the manufacturer’s instructions and specifications for the use of the test. Deviation from the manufacturer’s instructions typically will result in the test classification (waived or moderately complex) to immediately be considered ‘high complexity’ with all the ramifications of that classification. Items of particular importance to be cognizant of when initiating a POC test are:
   a. Sample types that are approved for use with the test
   b. Sample collection methods and devices
   c. Sample stability and maximum time from sample collection to testing
   d. Device, reagent, and, if applicable, control material storage conditions. Typically terms such as ‘room temperature’ or ‘refrigerator’ storage are no longer used and manufacturers must specify a temperature range for proper storage. This then, by extension, requires that the temperature of any storage area be monitored. Be sure to note any additional storage conditions such as humidity, light exposure, etc.
   e. Performance of Quality Control: How it is performed, at what frequency, etc.
   f. Reportable range for the test
   g. Requirements for follow-up or confirmatory testing
   h. The testing procedure itself

5. Analyte Specific Reagents (ASRs):
   NOTE: Although it is atypical for POC tests to use ASR’s we have included this section for completeness.
   a. Definition: ASRs are defined as “antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid
sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens.” Class I ASR’s may be purchased and used by laboratories to develop specific clinical tests (laboratory developed tests; LDTs) that may be used within the laboratory that developed the test for patient testing without specific FDA approval.

b. There are additional FDA requirements prior to marketing Class II and Class III ASR’s.

1. Class II ASR: reagent is used as a component in a blood banking test of a type that has been classified as a Class II device (e.g., certain cytomegalovirus serological and treponema pallidum nontreponemal test reagents). 21 CFR 864.4020(b)(2)

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      a. the individual’s past, present or future physical or mental health or condition,
      b. the provision of health care to the individual, or
      c. the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.13 Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).
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APPENDICES

1. Business Plan for a Point Of Care Testing Service (XLS, 50 KB)

2. Checklist (Gantt Chart) For Establishing And Maintaining A Point Of Care Testing Program (XLS, 48 KB)

3. Duties And Responsibilities Of The Point Of Care Testing Medical Director (XLS, 43 KB)

4. Communication Checklist (XLS, 49 KB)

5. Cost Analysis Tool (Excel, 53 KB)

6. Cost Analysis Tool Instructions (Word, 78 KB)

7. POCT Sample Policy (PDF, 6.3 MB)