ASCLS Mission:

The mission of ASCLS is to make a positive impact in health care through leadership that will assure excellence in the practice of laboratory medicine.

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Your Safety and Service Experience Are Important To Us!

Laboratory Patient Safety Tips

Point of Care Testing Use and Limitations

Information For Providers

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What is Point of Care Testing?

Point of Care Testing (POCT) is defined as specimen analysis performed outside of the clinical laboratory setting. The testing is usually performed close to the patient chairside or bedside when rapid results are needed.

What are the advantages and disadvantages of performing POCT?

Advantages: POCT can be used by clinical staff to obtain test results for more efficient diagnosis or treatment decisions.

Disadvantages:

- POCT may be less precise, accurate, specific, or sensitive than testing performed in a clinical laboratory setting.
- POCT is usually performed by staff who are untrained in laboratory medicine. Operators may not be familiar with following test procedures, instrument maintenance and calibration, or quality control, increasing risk of error in the analytical phase of testing when compared to testing performed by laboratory professionals who practice in a clinical laboratory,
- The inability to detect interferences, such as hemolysis, icterus and lipemia in whole blood samples, can lead to inaccurate test results.
- Certain POCT methods are intended only for screening purposes and should not be utilized for diagnosis. Consult the manufacturer or a laboratory professional in the clinical laboratory to ask for advice and to determine if a specific test or device is approved for screening or diagnostic use.

Are there any regulatory requirements for POCT?

Yes. POCT is regulated by the Centers for Medicare and Medicaid Services through the Clinical Laboratory Improvement Amendments (CLIA). If testing is not covered under another accredited CLIA license and the clinical laboratory does not provide administrative oversight for your POC testing, you will need to obtain a CLIA certificate to perform testing.

Some states require professional licensure of individuals who perform moderate complexity POCT that do not have a degree in clinical laboratory science. For more information on licensure requirements and regulations applicable to your location, contact your state CLIA office.

What factors can affect POCT accuracy?

The following factors can affect the accuracy of POCT:

- Pre-analytical specimen collection errors
- Interfering substances including certain medications and over-the-counter supplements
- Altitude
- Temperature
- Humidity
- Failure to follow manufacturer instructions for calibration and quality control
- Failure to recognize and resolve instrument flags indicating an erroneous test result
- Improper instrument maintenance
- Inability to effectively troubleshoot failed instrument calibration, quality control, or error codes

Are the reference intervals identical for both POCT and traditional laboratory testing?

No. Point of care methodologies may have different reference intervals compared to testing performed in a clinical laboratory. When reference intervals differ, patients must be monitored for treatment and/or diagnosis with the same test method. This is critically important for a number of tests, including Troponin and B-hCG quantitative testing.

What is the difference between waived and non-waived testing?

The FDA determines complexity for all laboratory tests. Waived testing refers to testing that is simple to perform and demonstrates a low risk of obtaining erroneous results. Non-waived testing, including moderate and high-complexity tests and Provider Performed Microscopy (PPM), requires specialized training of individuals performing sample analysis. POCT that requires specific specimen preparation, precise timing or pipetting, calculations, or independent judgement and interpretation is categorized as non-waived complexity.

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How do POCT results compare to those from traditional clinical laboratory testing?

Testing performed on different analyzers (e.g. point-of-care vs. clinical laboratory) are ***not*** interchangeable. If a patient is admitted to the hospital, follow up laboratory testing may require baseline comparison to the testing method in the hospital. If feasible, testing the original sample is recommended.

Point of care testing may provide results that are not comparable with, or show bias in relation to, clinical laboratory testing, even if reference intervals are identical. Examples of testing where this may be observed: Hemoglobin, Hematocrit, Creatinine, Prothrombin Time/INR (PT/INR) and Activated Clotting Time.

POCT results may correlate well with laboratory methods in the normal/low range, but may diverge as the test values increase. A cut-off value is determined to identify when a venous specimen must be sent to the clinical laboratory for analysis. This is especially important with tests such as PT/INR.

Are there any specific concerns for patients performing POCT testing at home?

If patient performed POCT is used for clinical decisions, patients must be educated on the importance of home testing as it relates to their specific diagnosis. The following concerns should be addressed:

- Test strip or reagent storage and expiration
- Quality control purpose and frequency
- Test result interpretation, including recognition of error codes for test results above or below device linearity
- Device cleaning and disinfection
- Expected variance in results for specimens collected from alternative body sites

If you have questions regarding POCT use, quality requirements, federal regulations, testing comparison and/or interpretation, please contact your clinical laboratory for additional information.