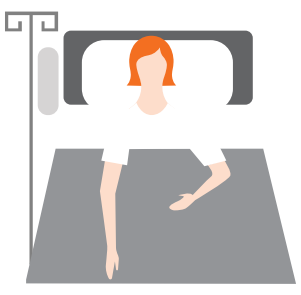
Identifying and Mitigating Potential Variables in Point-of-care Testing

Point-of-care testing (POCT) enables testing at or near the site of patient care, providing fast and actionable results that can lead to better patient outcomes. Point-of-care instruments are generally designed to provide convenient, user-friendly, portable testing platforms to clinicians across a variety of care settings, including critical care settings, clinics, and physician office labs, and require minimal sample volume, operator training, and maintenance.[1]



Although POCT provides many benefits across the continuum of patient care, successful implementation of POCT, like all diagnostic testing, requires that facilities understand and control test variables that have the potential to affect the accuracy of patient results.

The total testing process, from ordering a test through delivering a result, is divided into the pre-analytical, analytical, and post-analytical stages.

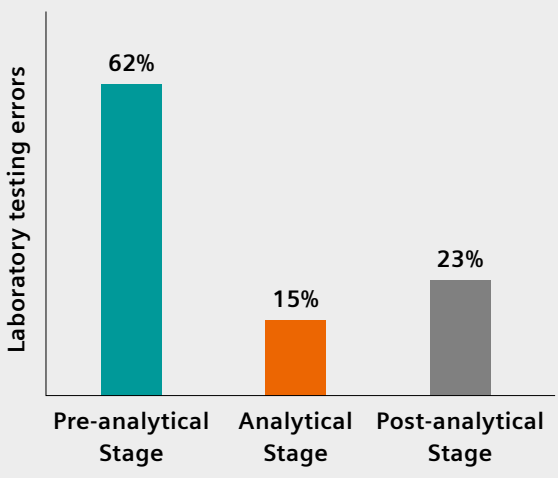
Pre-analytical stage:
All processes performed prior to testing a specimen

Analytical stage:
All processes performed during the testing of a specimen

Post-analytical stage:
All processes performed after test analysis

Laboratory testing errors

The literature reports that most laboratory testing errors occur in the pre-analytical stage (62%), followed by the analytical stage (15%) and post-analytical stage (23%).[2] One of the major benefits of POCT is that patient-side/near-patient testing eliminates many of the variables associated with pre-analytical errors, including specimen collection, labeling, and transportation.[3]



Decreased errors

Other attributes of POCT that can lead to decreased errors and increased testing accuracy include innovative manufacturing design, where instruments are equipped with built-in mechanisms to help mitigate both instrument and operator error, as well as operator education and training, which generate procedural awareness that helps to optimize test performance.[4,5]

Consider the factors below when choosing a test system and training your staff to help ensure quality testing and accuracy of results:

Stage	Source of error	Mitigation
Pre-analytical All processes performed prior to testing a specimen	• Test system access by unauthorized/untrained users	• Configurable operator access • User ID/password requirements • Operator lockout
	• Patient identification • Specimen labeling	• Implementation of bar-code readers for positive patient identification and specimen labeling, which helps prevent diagnostic and medication errors
	• Specimen collection Example: air bubbles, clots, hemolysis	• Availability of specialized, easy-to-use companion collection devices • Blood collection training guides and videos • Ability to test samples immediately after drawing, which provides the most accurate picture of the patient's current status
	• Specimen integrity • Specimen storage and stability • Specimen transportation	• Bedside testing negates the need for specimen storage and transportation, eliminating time delays associated with the risk of sample degradation.
	• Specimen processing Example: appropriate mixing for specimen type and test	• Specimen processing education and training guides
Analytical All processes performed during testing of a specimen	• Reagent stability	• Implementing test systems that are stable at room temperature Or: • Implementing and training staff on quality processes for inventory storage and access
	• Reagent lot expiration	• Bar-coded reagents that enable automatic checks for lot expiration Or: • Implementing and training staff on quality processes for inventory storage and access
	• Test system calibration error	• Automatic calibration with failsafes and error messages to prevent testing when failures occur
	• Failed quality control	• Failsafes and error messages to prevent testing when failures occur
	• Internal system operating error	• Electronic internal QC monitoring throughout test process • External QC • Failsafes and error messages to prevent testing when failures occur • Development of IQCP for POCT instrument
	• Operator error	• Manufacturer training guides, videos, and competency assessment • Guided instructions on instrument display screen
	• Selection of correct sample type	• Sample type selection required by operator
	• Insufficient sample volume or incorrect sample introduction	• Automatic sensor with audible and visual messages • Failsafes and error messages to prevent testing when failures occur
	• Test result out of range	• Administrator rights to set analyte reference ranges • Analyzer that can flag out-of-range results
	• Test result in critical range	• Administrator rights to set critical results • Analyzer that can flag and document critical results in test record
Post-analytical All processes performed after test analysis	• Undocumented or incorrectly documented result Example: transcription error	• Results displayed on and stored in instrument with associated patient/QC information, plus ability to recall results • Instrument connectivity for secure transmission of results and associated information to data management system
	• Delayed reporting of critical results	• Instrument connectivity for secure transmission of results and associated information to data management system
	• Confirmation of result transmission	• Analyzer that can flag result transmission errors

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