



# TRACER METHODOLOGY 101

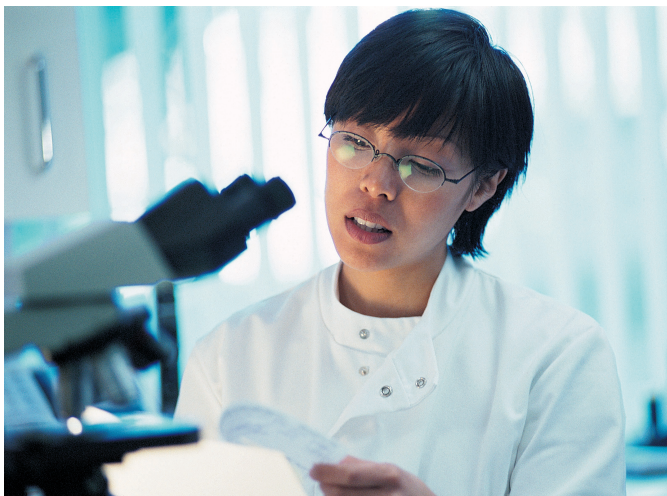
## Point-of-Care Testing and Laboratories

Point-of-care testing provides an essential component in modern health care. Although certain tests may appear run-of-the-mill or low risk to perform due to their frequency and the rise in technological devices to take these tests, such as monitoring glucose levels, they still require qualified skill and consistency to ensure patients' well-being and to accurately identify any unexpected shifts in health. This is particularly important in the hospital setting where patients are often acutely ill or recovering from complex surgeries or procedures, and where testing in all its forms provides an important measure of a patient's improvement or decline. When point-of-care testing works well, it can make a difference to high-quality, safe care, but when it doesn't then mistakes can happen, including delay in care or other unexpected outcomes.

Lab-related functions work best when overseen and supported by the laboratory-related expertise in the organization, explains John Gibson, MA MT(ASCP), DLM, associate director in the Standards Interpretation Group at The Joint Commission. This is evidenced in the growing number of inaccuracies in waived testing that are being noticed by and reported to regulators and accreditors, he adds. When the scientific expertise of laboratory-based colleagues is not well integrated into the testing-based work of a hospital, whether from the perspective of performing tests or from that of overseeing their function, then it can result in missed steps in a critical process, particularly if these tests are being performed by unqualified staff.

For the laboratory within a hospital or other type of health care organization, understanding and using the correct skilled qualifications at the right time is particularly important. This is particularly true in the case of point-of-care testing, especially from the perspective of waived or nonwaived testing. "If a health care organization does not understand who is qualified to perform either waived or nonwaived testing from the very get-go, it can put a patient and organization in harm's way," explains Gibson. This is particularly true in instances in which unqualified staff are performing tests without understanding their complexity.

Ideally, Gibson says, there should be no instances in which an unqualified staff member performs a nonwaived test. Yet this can sometimes happen due to the recent upsurge of devices that support a widening range of tests.



*Careful coordination among laboratory and hospital staff can help prevent errors and patient safety events related to diagnostic testing.*

"Part of the challenge has come from technology and a growing list of waived tests," adds Cherie Ulaskas, MT, MA, associate director in The Joint Commission's Standards Interpretation Group. "For quite some time health care organizations have been investing in waived testing devices that give the impression of simplicity and ease of collection. The challenge there, however, is that these devices have become increasingly complex, and unqualified staff may be using them without understanding their use from a scientific or technical point of view."

While it is good practice to conduct tests at the bedside for the benefit of patient care, the main concern is ensuring the right staff are involved in the process. This relates back to one of the core characteristics of a highly reliable organization, namely relying on the expertise of the correct staff for the correct situation. In the case of who should perform what tests, for both Gibson and Ulaskas, organizations need to check their Clinical Laboratory Improvement Amendments of 1988 (CLIA) qualification requirements against specific tests and ensure that there are no deviations from those regulations. This also needs to be competency tested and documented, stresses Gibson.

Ideally, he adds, a highly reliable organization will ensure that it uses the right staff expertise to perform

these tests. He has observed cases in which the expertise of laboratory staff has been underused. This can have an adverse effect on the collection and analysis of tests, at the very least delaying or nullifying results, and at the very worst producing mix-ups or missed results, which could result in patient harm.

Another way to ensure that point-of-care testing is handled appropriately is to have a reliable system in place to not only verify the qualifications of staff performing these tests, but to also embed an understanding of key laboratory practices throughout the organization during the orientation and ongoing education process. A key distinction in verifying a staff member's suitability to conduct specific tests, Ulaskas explains, is that with a great deal of laboratory testing the expectation is that the staff member is qualified to perform such tests. "There can be some confusion over qualifications in relation to licensure," she adds. "If nurses are conducting point-of-care testing, the organization must verify their qualifications to do so. Having a nursing license is not acceptable in these cases; for example, the organization must verify their higher education qualifications, such as through having a BSc [bachelor of science degree] in nursing, chemistry, or biomedical science."

During a survey, a laboratory surveyor is interested in understanding the dynamics of interaction between the laboratory itself and the outlying units and areas of the hospital. The surveyor will want to see how well laboratory leadership is integrated into the overall leadership in the hospital, and that leaders are enabled and relied on to provide expert input into the design of systems and processes that directly relate to testing in the hospital setting, explains Ulaskas.

Above all, adds Gibson, the surveyor will want to see what types of risk assessment the laboratory has conducted and any analysis of the types of staff and level of competency testing being monitored and provided. He or she will also be interested in such areas as the laboratory's procedures and expectations are related to nonwaived testing, whether documentation and daily review of patient results is taking place, how quality control is conducted, and any other requirements and procedures and policies that are in place. The surveyor will look to see how well the organization itself follows its own set procedures and will be looking for any inconsistencies or gaps in the process.

The ability to conduct point-of-care testing is a powerful tool, but only if it is managed correctly and performed by those with appropriate qualifications and training. When an organization uses its skills and expertise in laboratory-related testing to its maximum potential then it facilitates a reduction in errors and moves closer to the goal of being a highly reliable organization.

## The Scenario

This laboratory tracer took place in a large urban hospital in the Midwest, and occurred in both the laboratory and a hospital intensive care unit (ICU). During the tracer, the laboratory surveyor met with staff in the laboratory and later with staff in the ICU, where a test was conducted. The surveyor selected a 57-year-old female patient to trace who suffers from emphysema and was currently hospitalized in the ICU following bowel surgery. Although her surgery was not related to her emphysema, her physician had ordered an analysis of blood gasses to monitor her lung function during her recovery.

**Exploring processes for point-of-care testing.** The surveyor wanted to explore the process of waived testing and nonwaived testing during this tracer. [1] Before tracing the patient, the surveyor explored the laboratory's and hospital's processes for conducting point-of-care testing. He asked the staff to describe their process and related responsibilities. [2] After reviewing personnel records in the laboratory, the surveyor noticed that competencies were documented in the staff record of training. In addition, the laboratory had processes for hand hygiene guidelines, patient identification, documentation, communication, and quality control all documented. The surveyor reviewed a sample personnel record of one of the laboratory technicians who might ordinarily conduct a nonwaived test. [3]

**Following the point-of-care testing in the ICU.** The surveyor then went to the ICU to observe a point-of-care test. He observed a member of the nursing staff performing a blood gas analysis test on the selected patient. [4] He observed him adhering to appropriate hand hygiene guidelines before conducting the test and the correct use of patient identifiers. After the test he observed him performing a benchtop analysis and then correctly entering the test into the records. [5, 6] The surveyor then approached the nurse to ask him about his proficiency testing to conduct our nonwaived test and his last competency assessment. The nurse explained that he had not had a competency assessment since he began this new post several months before, but had undergone qualifications and training in his previous role at another hospital. [7] The surveyor then asked the nurse what procedures were in place for quality control and calibration verification for the analyzer, and the nurse explained that he was not familiar with the hospital's procedures but has been told training would be conducted in the next month or so. [8] A review of the nurse's employment record indicated that although his qualifications were verified, there was no competency assessment or training recorded for him.

**Going forward.** The surveyor discussed the laboratory's

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role in quality control and competency assessment with various types of point-of-care testing and discussed appropriate qualifications for nonwaived testing in particular. The laboratory director expressed concerns about inconsistency in practice and the fact that ordinarily a laboratory technician would have conducted such a test. The surveyor and staff discussed conducting an assessment of roles and responsibility in relation to lab functions in the hospital and to review the point-of-care testing process.

**Sample Questions**

The following represent some questions that could be asked during a tracer. Use them as a starting point to plan your own tracers.

1. Please describe your laboratory's and related health system's process to handle waived testing.
2. Please explain what types of waived testing are conducted at the point of care and who has responsibility for this.
3. Please describe situations in which where nonwaived testing takes place in the organization and who is responsible for this. What type of laboratory oversight is performed with nonwaived testing?
4. Please show me how you perform a point of care test at the bedside. What procedures do you follow?
5. How are tests transported to the lab? Who is responsible for them?
6. How are results communicated and documented?
7. How do you determine competency to conduct way testing and how was that documented? How is ongoing competency conducted and who is responsible for this? How is this documented?
8. What type of quality control do you perform on nonwaived testing and how often? **TS**

**Mock Tracer Tracking Worksheet**

Point-of-Care Testing and Laboratories

Use this worksheet to record notes and areas of concern that you identify while conducting your organization's mock tracers. This information can be used to highlight a good practice or to determine issues that may require further follow-up.

Tracer Team Members: \_\_\_\_\_ Tracer Patient or Medical Record: \_\_\_\_\_

Staff Interviewed: \_\_\_\_\_

Unit or Department Where Tracer Was Conducted: \_\_\_\_\_

TRACER PROMPTS	Correct Processes Observed	Areas of Concern	Follow-Up Needed	Required Written Documentation		Notes
				Required?	Present?	
1. Please describe your laboratory's and related health system's process to handle waived testing.						
2. Please explain what types of waived testing are conducted at the point of care and who has responsibility for this.						
3. Please describe situations in which nonwaived testing takes place in the organisation and who is responsible for this. What type of laboratory oversight is performed with nonwaived testing?						
4. Please show me how you perform a point-of-care test at the bedside. What procedures do you follow?						
5. How are tests transported to the lab? Who is responsible for them?						
6. How are results communicated and documented?						
7. How do you determine competency to conduct nonwaived testing and how was that documented? How is ongoing competency conducted and who is responsible for this? How is this documented?						
8. What type of quality control do you perform on nonwaived testing and how often?						