

# Management Bulletin

North Carolina State Laboratory of Public Health | Laboratory Improvement Unit

## Selection Criteria for New In-House Testing

### Introduction

A clinician walks into the laboratory and states, “*I want you to start performing (fill in the blank) testing...*” As laboratorians, we have all heard these words or some variation of this statement. Whether you have a CLIA waived or moderate complexity certificate, choosing the right test for your laboratory is important for you and your patients; however, there are currently no consensus guidelines available for assessing the appropriateness of adding a new test.

This article will offer some guidance the laboratory should consider before making the decision to add any new test to its current waived or moderate complexity test menu. This includes but is not limited to the following:

- **Needs Assessment:** How will the care offered at the site benefit by the addition of a new test?
- **Cost Assessment:** What will be the cost associated with implementing a new test?
- **Physical Requirements:** What are the physical and environmental requirements for testing?
- **Test Characteristics:** What are the considerations in choosing the right test kit or system for your site?
- **Staffing:** How will introduction of new testing affect the current work flow, are there sufficient personnel to conduct testing, and how will they be trained? For moderate complexity tests, how will testing competency be maintained?

### Needs Assessment

To determine whether a new test is appropriate for your laboratory, an assessment of the test’s fit with the current or expected future patient population is essential. The viability of a new test can be

determined by the added value it may bring to patient care, better operation, or the cost benefit. Some useful questions to ask in determining the need to add a test include:

- What is the patient population for whom this test is currently ordered?
- What portion of this population might benefit from the test implementation onsite, and how will this affect test volume?
- What are the key clinical drivers for the demand for the test? Examples include urgency of testing and benefits of rapid turnaround time.
- Are there specific criteria for the patients that can be tested, such as age or predisposed conditions? This information is often available in the manufacturer’s package insert.

### Cost Assessment

Before any new test is implemented, an analysis of the cost to the laboratory as well as the patient should be considered. Many factors can contribute to the cost of a new test. They include:

- **Consumables:** test kits or instruments, supplies not provided with the test, control and calibration materials, inventory requirements for anticipated test volume (including seasonal testing), and the shelf life of test components and supplies.
- **Equipment maintenance:** repairs or preventive maintenance contracts.
- **Safety:** additional safety and biohazard equipment.
- **Personnel:** training, competency assessment, and the potential need for additional personnel.
- **Recordkeeping and information systems.**
- **Required supplemental/confirmatory testing.**

- **Regulatory compliance:** proficiency testing, CLIA regulations.
- **Additional Resources:** any needs to manage public health reporting, if required nationally or by the state.

## Physical Requirements

Assuring the appropriate physical environment for performing testing is important for evaluating potential new tests. In general, the testing environment should be performed in a clean work area with adequate space for patient privacy while allowing for the safe collection of samples and test performance.

In addition, some tests have specific environmental requirements described in the manufacturer's product insert that need to be met to ensure reliable test results. These requirements may include:

- **Humidity:** Unusually high, low, or extreme fluctuations in humidity can cause deterioration of reagents and test components, affect the rate of chemical reactions and specimen interaction, or make test endpoints blurred and difficult to read.
- **Temperature:** Temperature ranges for storage of test components and controls and for test performance are defined by the manufacturer to maintain test integrity. Extreme temperatures can degrade reagents and test components, affect reaction times, cause premature expiration of test kits and reagents and affect test results.
- **Lighting:** Inadequate lighting can negatively affect specimen collection, test performance, and interpretation of test results.
- **Work space:** Work surfaces should be stable and level and be able to be adequately disinfected; work space should be adequate in size for patient confidentiality, ease of specimen collection, test performance, and storage of supplies and records.

## Test Characteristics

After considering the need, cost, and physical requirements of a new test, an evaluation of the potential test system, its intended use, performance characteristics, and the population to be tested should be made. Information for this evaluation can be obtained from the test manufacturer's product insert or by speaking with the manufacturer's technical representatives. Specific considerations include:

- **Intended use:** This describes what is being measured by the test, the type of sample that the test is approved for, and whether the final result is quantitative (number) or qualitative (e.g., positive or negative).
- **Performance characteristics:** Review the data from the manufacturer on the test's accuracy, precision, sensitivity, specificity, and interferences.
- **Patient population:** Certain tests may not have been evaluated for all patient populations such as pediatric patients. In addition, the predictive value of results can vary in different populations.
- **Supplemental testing or patient follow-up:** Assess the potential need for additional time, documentation, and staffing and a mechanism to refer additional testing to another laboratory when offering a certain test. Some tests are used for screening and need follow up testing before a final result can be reported.
- **Test system considerations:** Consider the simplicity of operating the test system, length of time to obtain a result, and the level of technical support provided by the manufacturer or distributor.

## Staffing

Personnel competency and turnover are important factors affecting the quality and reliability of test results. No CLIA requirements exist for waived testing personnel qualifications; however, moderate complexity certificates must meet more stringent CLIA requirements as well as applicable

state or local personnel regulations. Personnel questions to consider include:

- **Is staffing adequate?**
  - Determine whether employees have sufficient time and skills to reliably perform all activities needed for testing in addition to their other duties. More complex testing will require more staff time.
  - Be aware that temporary or part-time laboratory staff might be less proficient in performing testing.
  - Evaluate staff for color-blindness because this can limit their ability to interpret test results based on color endpoints.
- **How much training will be needed?**
  - Take into account the staff turnover rate and the ongoing need to provide training for new personnel.
  - Factor in the time and resources for adequate training. Be aware that moderately complex tests will, in general, require more training time and resources.
  - Consider how testing personnel will maintain competency, especially when testing volume is low.

## Conclusion

Although this article lists several important points when considering implementing a new test, the laboratory should not limit itself to only these criteria. As stated, there are no consensus guidelines for test selection; however with forethought, planning, and preparation, the next time you hear the statement, “I want you to begin performing (fill in the blank) testing...” the laboratory will be well on its way to initiating high-quality waived or moderately complex testing in any type of setting.

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