White Paper

Point of Care Testing for Infectious Diseases:

Navigating CLIA Compliance and Ensuring Quality

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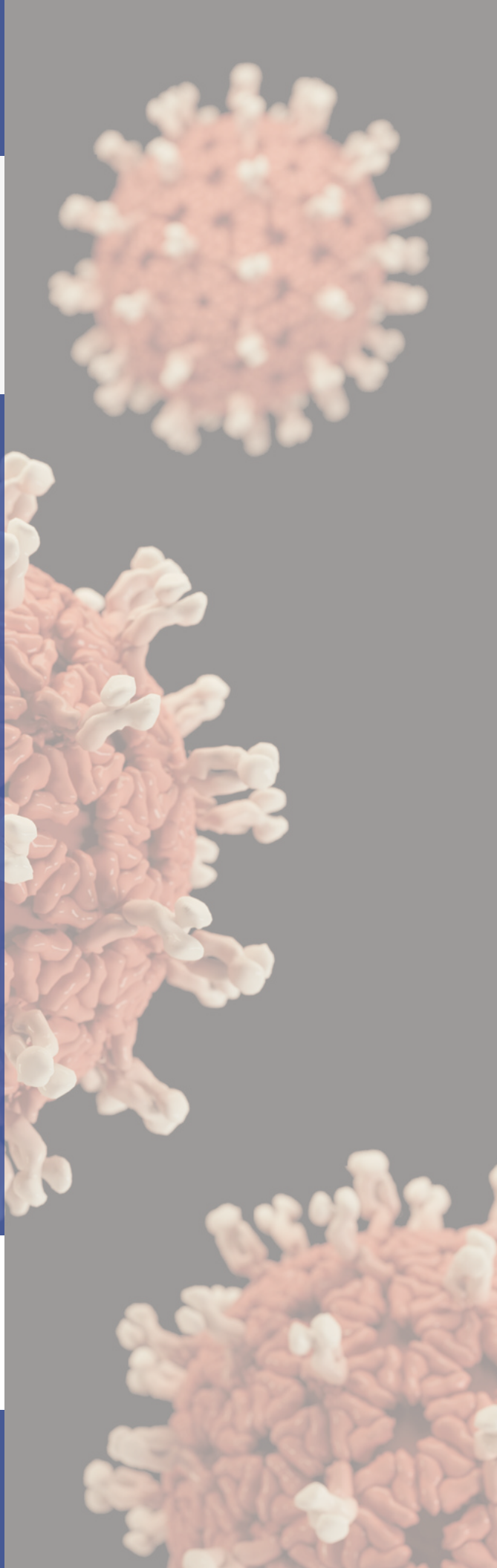

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INTRODUCTION

Assess Your POCT Team for Gaps in Training, Competency, and POC Test Knowledge

The utilization of high-quality point-of-care testing (POCT) for infectious diseases in community healthcare settings holds great potential for improving public health. However, the successful implementation of POCT in physician offices, outpatient clinics, and urgent care facilities necessitates adequate operator training, demonstration of competency, and vigilant monitoring of the performance of each POCT assay and testing platform. This is crucial to ensure the accuracy of results.

Introducing new POCT tests often reveals knowledge gaps, particularly among clinical staff with no laboratory background, which is common in community healthcare environments. As the demand for POC infectious disease testing continues to grow, it is imperative that POCT coordinators and laboratory directors remain proactive in achieving and maintaining the quality management standards required for their testing activities.

This white paper serves as a practical guide to enhance the understanding of the POCT team regarding critical success factors and essential functions needed to sustain compliance and produce reliable results. It focuses on the tangible aspects of good laboratory practice and regulatory compliance in routine and urgent patient care settings. This resource will be particularly beneficial to nursing and other clinical staff involved in patient testing.

While the approaches and solutions outlined in this white paper form a robust quality management program, it is crucial to adapt them carefully to the specific realities of your unique POCT environment and healthcare setting. Healthcare leaders should also consider variations in compliance applicability, certification, test complexity, safety frameworks, and the specific needs of patients, healthcare providers, and healthcare partners in their communities.

Build the POC testing team's understanding of your clinic's duties and responsibilities when implementing and maintaining standards for low-complexity diagnostic tests.

CHAPTER 1

The Technical Complexity of POCT Devices: Potential for Error and System Failures

POCT may appear deceptively simple, but it conceals a certain degree of complexity. While the Clinical Laboratory Improvement Amendments (CLIA) regulations deem waived tests to have a low risk of producing incorrect results, sites exclusively conducting waived testing are still obligated to hold a CLIA certificate (How to Apply for a CLIA Certificate) and diligently adhere to the manufacturer's instructions to ensure result accuracy.

For some POC testing operations, a self-defined quality system is necessary for ensuring safety and satisfaction in infectious disease testing.

One of the primary distinctions between POC waived testing and non-waived moderate- to high-complexity testing is the complexity of the testing process. POC devices can be likened to highly sophisticated "black boxes" that streamline the testing process, involving specimen collection, sample insertion into the device, and the receipt of qualitative and/or quantitative results. However, despite minimizing operator involvement, POCT methods still have some room for preanalytical and analytical error.

To ensure compliance and safety in infectious disease testing, a self-defined quality management system becomes necessary. Stringent procedures, routine checks of operator competency, and the implementation of quality control (QC) protocols remain essential for effective device management, operator oversight, competency management, and inventory control. QC procedures represent crucial measures for detecting errors that may arise at any stage of the testing process.

Recognizing the need for vigilance, the College of American Pathologists (CAP) has identified the Top 10 deficiencies in point of care testing that POC coordinators should be mindful of when introducing testing in physician office labs and urgent care clinics. Staying current with the CAP point of care checklist, maintaining thorough documentation, and conducting regular self-inspections are key practices for identifying and rectifying potential deficiencies proactively, well before an inspection is scheduled.

Most Commonly-Cited Deficiencies

CAP Wide – 2020	Description	CAP Checklist
1	Activity Menu	COM.01200
2	Competency Assessment – Non-waived Testing	GEN.55500
3	Procedure Manual	COM.10000
4	Maintenance and Function Checks	COM.30600
5	Comparisons of Instruments and Methods	COM.04250
6	PT/Alternative Assessment Result Evaluation	COM.01700
7	PT Attestation Statements	COM.01400
8	Instrument/Equipment Monthly Record Review	COM.04200
9	Reagent Labeling	COM.30300
10	Procedure Manual Review	COM.10100

CHAPTER 2

The Crucial Role of Proficiency Testing and Quality Control in POCT Results

Maintaining the quality of infectious disease results in a POC setting hinges on proficiency testing (PT) and quality control (QC). Both play distinct roles in ensuring the quality and accuracy of results. Proficiency testing provides an excellent indication of the accuracy and reliability of your waived POCT results and methods. It is performed several times a year, validating method performance and operator competency by mimicking patient sample analysis.

A robust proficiency testing program can ensure operator competency while satisfying CLIA compliance requirements.

QC procedures, on the other hand, are designed to detect errors arising from test system failure, adverse environmental conditions, sample collection errors, and variations in operator performance. They are conducted daily, weekly, or monthly according to the manufacturer's recommendations and site protocols. Ongoing QC is crucial for identifying problematic trends that could compromise accuracy and lead to erroneous test results, potentially impacting treatment decisions and the reputation of healthcare providers and laboratories.

Regardless of participation in QC and/or PT programs, expect certificate of waiver inspections at your testing site. Surveyors will scrutinize quality documentation and protocols to verify the appropriateness of testing and the use of sound laboratory practices.

A CLIA certification is required for all types of laboratory testing — even if labs are CLIA waived. There are different types of CLIA certifications based on the diagnostic tests laboratories perform.

And though it's true that laboratories holding a Certificate of Waiver (CoW) and running CLIA waived laboratory procedures aren't routinely inspected, inspectors can still make unannounced visits to investigate any possible complaints.*

**How to Prepare for a CLIA Inspection*, www.mckesson.com/resources

CHAPTER 3

The Benefits of Third-Party Controls in Validating Test Accuracy

Quality controls for POC test methods can come from two sources – the test manufacturer and a third-party vendor. While manufacturers' controls validate test performance, third-party quality controls for infectious disease testing offer several benefits that enhance the reliability and accuracy of testing procedures.

The recent SARS-CoV-2 (COVID) pandemic highlighted the underappreciated value of third-party controls. Throughout 2020, as the demand for COVID testing increased in the community setting, many new POC test devices were quickly brought to market. These devices had significantly lower sensitivity and specificity than lab-based polymerase-chain reaction (PCR) methods but were deemed accurate enough to use for screening purposes providing all negative results were confirmed by PCR. These devices used manufacturer-developed controls to validate system performance, but as reports of invalid test results began to appear, these devices came under increased scrutiny, and some were pulled from the market. The use of an independent third-party control may have helped uncover issues with these devices much earlier, reducing the need for repeat testing and more accurately identifying positive and negative COVID patients.

The COVID testing story underscores how third-party controls provide an independent and objective assessment of a testing system's accuracy, ensuring that the results obtained from the testing process are reliable. This is essential for maintaining the quality of patient care and ensuring that the testing methods meet predefined standards.

Some of the other advantages of third-party controls include:

- **Improved Patient Care**: False negative results can delay treatment, a potential disaster for patients with COVID or any other infectious disease with high morbidity and mortality rates. Accurate test results are essential for making informed clinical decisions and delivering effective patient care. The use of third-party controls enhances the overall quality of patient care by minimizing the risk of incorrect or inaccurate test results.

- **Compliance with Regulatory Requirements**: Many regulatory agencies, including CLIA, require the analysis of two levels of external quality control per day, and the analysis of third-party controls is one option for ensuring compliance with quality standards. Each individual laboratory must determine their own control plan, whether that be alignment with CLIA requirements OR their own Individualized Quality Control Plan (IQCP).

- **Minimizing Risk**: By implementing third-party quality controls, laboratories can reduce the potential triple threat of releasing inaccurate test results, being found non-compliant with regulatory standards, and failing proficiency testing. Several of the POC testing devices launched during the pandemic were later pulled from the market by the FDA due to the inaccuracy of their results. Implementation of a third-party control could have flagged the quality issues earlier, allowing manufacturers the chance to improve method specificity and sensitivity.

Regardless of the QC plan, third-party controls can play a key role in helping organizations to meet regulatory requirements.

CHAPTER 4

Quality Assurance and POC Testing

Even in high-paced and staff-constrained lab testing situations, QC measures are crucial in various scenarios - for instance, when a method is introduced or when method or reagent changes occur.

To detect issues that lead to testing problems, CLIA regulations require verification of the manufacturer's stated performance specifications (refer to all information provided by the test manufacturer, including the manufacturer's Instructions for Use (IFU)) for accuracy, precision, reportable range, and patient reference range for all tests before reporting patient results.

For validation of the point-of-care testing methods, it may be necessary to compare test results with a reference or hospital laboratory where testing is also performed on their patients—for verification to assure the comparable method. The validation should take place before implementing the test and should be in a written policy so it is not overlooked.

Regardless of the quality assurance methods used, POCT coordinators and administrators must ensure that all policies and procedures are documented and that quality system records are complete and up to date, including user training, user competency, quality control testing, proficiency testing, and corrective actions taken for any quality or accuracy issues that arise.

CHAPTER 5

Quality Challenges in Point of Care Waived Testing: Insights from CLIAC Discussions

Clinical Laboratory Improvement Advisory Committee (CLIAC) workgroups have emphasized their concerns regarding quality in physician office laboratories and the need to ensure testing integrity. Changes in test complexity may occur, often without proper oversight, leading to discrepancies between waived and non-waived tests. CLIAC discussions have shown a concern for errors in certificate of waiver test results.

Errors can occur anywhere in point of care testing process, particularly when the manufacturer's instructions are not followed. Errors can also occur when testing personnel are not familiar with all aspects of the test system. The Centers for Disease Control and Prevention's (CDC) Division of Laboratory Systems develops and revises CLIA technical standards in collaboration with CMS and performs regulatory impact analysis to address new and evolving testing, such as rapid point of care PCR diagnostics for infectious disease testing, and information technologies used in laboratories.

CHAPTER 6

Mastering Point of Care Testing: Understanding QA Fundamentals, QC Techniques, and Effective QC Material Management

The CDC's Laboratory Quality Assurance and Standardization Programs offer invaluable guidance to point of care testing coordinators and professionals working with POC testing platforms in settings like urgent care facilities and physician office laboratories.

To ensure the success of your point of care testing program, it's crucial to have a firm grasp of the core elements of Quality Assurance (QA) and Quality Control (QC):

1. **Establishing Standard Operating Procedures (SOPs)**: SOPs are the foundation of a well-organized testing process. They should comprehensively cover every aspect of the laboratory testing process, from the proper handling of specimens to the validation of instrument performance.

2. **Defining Administrative Requirements**: Administrative tasks are central to maintaining high testing standards. This involves mandatory recordkeeping, systematic data evaluation, and conducting regular internal audits to ensure strict adherence to established SOPs.

3. **Specifying Corrective Actions**: When problems or discrepancies arise, it's crucial to have a well-defined protocol for addressing these issues. The protocol should include clear documentation of the problem, the steps to rectify it, and assign responsibility to specific individuals for carrying out corrective actions.

4. **Sustaining High-Quality Employee Performance**: Quality assurance relies on the competence and consistency of personnel. Ongoing training, competency assessments, and continued professional development are essential to maintain a high standard of employee performance. This is particularly critical for those involved in point of care testing, where reliability and precision are paramount.

CONCLUSION

Point of care testing (POCT) for infectious diseases offers significant potential to enhance public health outcomes in community healthcare settings. It enables rapid testing and quick decision-making, making it an invaluable resource in environments like physician offices, urgent care clinics, and outpatient facilities. However, the implementation of POCT does come with a set of critical responsibilities and challenges.

POC test methods and devices are often more complex than anticipated, requiring rigorous quality control and quality assurance measures. POC coordinators must implement a quality assurance program to ensure the accuracy, reliability, and quality of infectious disease testing used in their POC settings. Proficiency testing (PT) and third-party quality controls play a vital role in infectious disease testing by safeguarding the accuracy, reliability, and quality of diagnostic procedures. Both are essential for meeting regulatory requirements, ensuring patient safety, and delivering high-quality healthcare services.

The discussion has underscored the responsibilities of those overseeing and conducting POCT, as well as the necessity for regular checks to maintain rigorous standards and avoid the potential for errors. The core elements of QA, including the establishment of standard operating procedures (SOPs), administrative requirements, and effective corrective actions, are vital in maintaining the quality and accuracy of testing.

In the dynamic landscape of infectious disease testing, adherence to these fundamental principles is essential to provide reliable and high-quality patient care. As POCT continues to evolve, the adoption of best practices and quality control measures will be instrumental in improving public health outcomes in communities.

This white paper was sponsored by LGC Diagnostics

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