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Last Approved	1/8/2024	Area	Laboratory-Point of Care
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Point of Care Testing Approval Process

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. This document describes the steps for obtaining approval to implement point of care (POC) testing and for requesting additional POC devices within Corewell Health, including both hospital and outpatient sites without their own Clinical Laboratory Improvement Amendments (CLIA) certificate. POC testing is subject to state and federal regulatory requirements; therefore, such testing will undergo a thorough approval process. Prior to sending the Request for Point of Care Testing form to a requesting department, efforts will be made to work with the department to improve their current process or flow for laboratory testing.

B. When used appropriately, POC testing may improve patient outcomes by providing laboratory results in a shorter time frame than main laboratory testing. However, overused or incorrectly performed POC testing poses a risk to patient care and safety. POC testing may not be appropriate for all patient areas. Efforts should be made, prior to POC testing implementation, to utilize main laboratory testing.

C. This document is only applicable to areas that are approved for testing under one of the laboratory's CLIA certificates or Certificate of Waiver (COW) documents.

II. POLICY STATEMENT:

A. Before POC testing is implemented or additional POC devices are placed into use, the requesting clinical service or department shall obtain approval by following the steps outlined in this policy. If the request is granted, the requesting department commits to maintain compliance with regulatory guidelines, which includes, but is not limited to the following items:

1. Performance of POC testing and device maintenance according to approved procedures and manufacturer guidelines

2. Operator training and competency assessment by qualified individuals
3. Submission of degree or diploma for non-waived testing
4. Participation in proficiency testing
5. Quality control (QC) performance, documentation, and additional quality assurance (QA) measures
6. Recording of expiration dates on controls and reagents
7. Maintaining complete and accurate QC, patient logs, and temperature logs and delivery of logs to the appropriate POC department in a timely manner for review, where applicable
8. Notifying POC staff in the event of an instrument malfunction or if repair is needed
9. Proper documentation of maintenance and corrective actions
10. Compliance with applicable POC policies and procedures
11. Participation in additional tasks as requested by POC personnel in accordance with regulatory agency compliance standards, quality assurance, proficiency testing, safety, troubleshooting, etc.

B. POC departments at each site will monitor performance of each clinical department performing POC testing. Laboratory Medical Directors reserve the right to revoke POC testing privileges should the performing department demonstrate continued non-compliance with regulatory requirements.

C. The requesting department shall complete Part A of the Request for Point of Care Testing form and submit it to the site-specific POC department.

III. DEFINITIONS:

A. **POC Testing:** Any clinical laboratory test performed outside the laboratory, at or near the patient's bedside or place of medical evaluation or treatment.

B. **Bedside Testing Review (BTR):** A multi-disciplinary group of Corewell Health employees, including laboratory and direct patient care professionals, which meets to review a specific POC test request and offer varied perspectives and recommendations regarding the proposed POC test system and its implementation, if needed.

1. **Required attendees**: Physician leader, Manager, or other representative from the requesting department, POC Manager/designee for requesting site, key members of the system POC Best Practices Committee, POC System Medical Director, POC System Technical Director, POC System Manager.
2. ***Ad hoc* attendees**: discipline-specific laboratory Medical Director appropriate for the requested POC test, CLIA laboratory Medical Director, laboratory Operations Director(s), system laboratory contracts coordinator, billing, legal, epidemiology, phlebotomy, information technology, etc.

IV. PROCEDURE:

A. When a request is received for a new POC test or device, the appropriate POC department will

be notified. The POC Manager/designee:

1. Contacts the requester to evaluate the need for POC testing
2. Reviews the following items with the requesting department:
    a. Current processes or workflow for laboratory testing
    b. Potential changes or improvements that would meet clinical needs without POC test implementation
3. Requests relevant data for main laboratory testing (e.g., current turn around times).

B. If the request appears valid after this initial review, the POC Manager/designee sends the requester a Request for Point of Care Testing form.

C. The Request for Point of Care Testing Form – Part A is completed by the Manager of the requesting department. This form is used to review the clinical and financial considerations that justify the need to perform the POC test. To allow adequate time for review, this form should be submitted a minimum of three (3) months in advance of the requested implementation date.

D. The POC Manager/designee evaluates Part A, completes Part B, and distributes the completed form to the POC System Manager.

E. The POC System Manager, in consultation with the POC System Medical Director, perform an initial review of the request. If needed, the POC System Manager and POC System Medical Director may determine if a formal BTR meeting is needed and which key individuals should be present. The meeting is scheduled and conducted by the POC System Manager.

F. All requests will be reviewed at the monthly POC Best Practice Committee meetings.

G. The College of American Pathologists (CAP) and Center for Medicare and Medicaid Services (CMS) hold each laboratory medical director responsible for POC testing performed within the scope of the laboratory's CLIA certification. Therefore, the decision of the appropriate Corewell Health laboratory Medical Director(s), as listed on the relevant CLIA license(s), in consultation with the System POC Medical Director, regarding all POC test requests is final.

H. All approvals and denials will be submitted via email by the System POC Manager to the site-specific POC department and site-specific laboratory Medical Director.

I. If the request is approved, POC testing staff will work directly with the appropriate non-laboratory professional staff in the requesting department to set up training, policy, procedure, QC, ongoing competency assessment, and other required QA measures.

J. If no consensus is reached during the BTR meeting, any member of this group may request additional data collection, review of hospital variances, or inclusion of other members. Once additional information is studied by BTR members, a follow-up meeting is scheduled with all involved parties in order to reach a consensus, and either approve or decline the program request. The BTR will present the requesting department with alternative laboratory solutions if the request is declined.

Attachments

Request for POC Testing Part A .pdf

Request for POC Testing Part B.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	1/8/2024
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	1/3/2024
CLIA Medical Directors	John Pui: Chief, Pathology	12/26/2023
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	12/26/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	12/19/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	12/19/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	12/19/2023
	Caitlin Schein: Staff Physician	11/30/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	11/27/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	11/27/2023
	Jessica Czinder: Mgr, Division Laboratory	11/27/2023

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne