

# Beaumont

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Applicability All Beaumont Hospitals

## Point of Care Testing Internal Inspection

Document Type: Procedure

### I. PURPOSE AND OBJECTIVE:

- A. To describe the process for internal inspection of clinical areas that perform Point of Care (POC) testing and to outline procedures for documentation of inspections.
- B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

### II. PRINCIPLE:

- A. Point of Care (POC) staff trained in medical laboratory science perform random internal inspections of clinical areas authorized to perform POC testing for the purpose of verifying compliance with regulatory guidelines and providing quality assurance. This process is designed to be mutually beneficial between testing areas and POC. Rounding in testing areas conveys visibility of lab personnel and facilitates communication about issues related to testing, quality control (QC), inventory, and training.
- B. POC testing areas are inspected based on evaluation criteria provided in College of American Pathologists (CAP) inspection checklists.

### III. PROCEDURE:

- A. Each site-specific POC department will inspect as many POC testing areas as possible annually. If any areas are not inspected in a given year, those areas will be prioritized for the following year.
- B. Print a POC Internal Inspection form for the POC testing area to be inspected.
- C. Inspect each area in person. Directly observe and inquire with managers/supervisors and other

- POC device operators regarding the applicable items on the POC Internal Inspection form.
- D. Document findings on the POC Internal Inspection form.
  - E. The completed POC Internal Inspection form will be sent to the unit manager of the POC testing area via e-mail. If items of non-compliance are observed, send the unit manager the POC Internal Inspection Deficiency form. The unit manager will document corrective action taken or the process improvement plan to resolve the problem. The completed POC Internal Inspection Deficiency form will be returned to the site-specific POC department via e-mail within 1 week.
  - F. POC staff will review the completed POC Internal Inspection Deficiency form and re-inspect the POC testing area to verify appropriate corrective action has been taken.
  - G. POC staff will date, sign, and retain the inspection, deficiency forms, and documentation of corrective action for 2 years.
  - H. If POC testing areas are found to be non-compliant on repeated inspections, the POC staff provide documentation to the site-specific Clinical Laboratory Improvement Amendments (CLIA) medical director, who may choose to confer with system POC Medical and Technical Directors and the POC Best Practices committee on whether to revoke authorization to perform POC testing.

## IV. REFERENCES:

- A. Lab General Checklist, College of American Pathologists, Northfield, IL, current version.
- B. Lab All Common Checklist, College of American Pathologists, Northfield, IL, current version.
- C. Lab Point of Care Checklist, College of American Pathologists, Northfield, IL, current version.
- D. CLSI Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition. CLSI guideline POCT04, Wayne, PA Clinical and Laboratory Standards Institute 2016.

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## Attachments

[POC Internal Inspection Checklist.pdf](#)

[POC Internal Inspection Deficiency Plan.pdf](#)

## Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	4/17/2023

CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	3/23/2023
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	3/22/2023
CLIA Medical Directors	John Pui: Chief, Pathology	3/22/2023
CLIA Medical Directors	Muhammad Arshad: Physician	3/22/2023
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Mgr, Division Laboratory	3/22/2023
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	3/22/2023
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	3/22/2023
	Caitlin Schein: Staff Physician	3/22/2023
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	3/21/2023
POC Best Practices	Jessica Czinder: Mgr, Division Laboratory	3/21/2023
	Jessica Czinder: Mgr, Division Laboratory	3/7/2023

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## Applicability

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