# POLICY
# Corewell Health East - Laboratory Individualized Quality Control Plan (IQCP) - All Beaumont Hospitals

**This Policy is Applicable to the following Corewell Health sites:**
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

| | |
|---|---|
| **Reference #:** | 33453 |
| **Version #:** | 2 |
| **Effective Date:** | 07/29/2025 |
| **Functional Area:** | Clinical Operations, Laboratory |
| **Department Area:** | Lab - General, Laboratory Policies |

1. **Purpose**
   This document describes the required components of Corewell Health East Laboratories Individualized Quality Control Plan (IQCP).

2. **Definitions/Abbreviations**
   - **A. IQCP: Individualized Quality Control Plan:** "The IQCP process includes Risk Assessment, a Quality Control Plan, and Quality Assessment. It must address the potential failures and errors identified in the entire testing process: pre-analytic, analytic and post-analytic phases of testing"
   - B. **CLIA (Clinical Laboratory Improvement Act):** This act contains amendments passed by Congress (in 1988) in response to public concerns about the quality of laboratory testing. This legislation brought all U.S. clinical laboratories, including physician's office laboratories, under uniform regulations. Standards apply to laboratory personnel and procedures and are based on test complexity and potential harm to the patient. For tests of moderate or high complexity, the laboratory must participate in a continuing proficiency testing program.
   - C. **CMS: Centers for Medicare and Medicaid Services:** The federal agency that runs the Medicare program. In addition, CMS works with the States to run the Medicaid program. CMS works to make sure that the beneficiaries in these programs are able to get high quality health care.
   - D. **Risk Assessment**: A means of identifying and evaluating potential problems or errors that may occur along the continuum of the testing process.
   - E. **Risk Assessment Components:** These components must be evaluated in the risk assessment.
     1. Specimens
     2. Test System
     3. Reagents
     4. Environment
     5. Testing Personnel
   - F. **Laboratory Environment:** Examples of potential environmental hazards are dust, temperature, airflow/ ventilation. Light intensity, noise and vibration, humidity, electrical or water quality, and

adequate space. Assess these conditions specific to the laboratory to determine if/how they could affect the test system performance.

G. **Quality Control Plan**: A written plan which describes the practices and procedures which the laboratory uses to reduce the chance of failures/errors in the testing process. This includes but is not limited to: Internal/External controls, proficiency testing, calibration, maintenance, personnel training, competency testing. "The components of the quality control plan must meet regulatory and CAP accreditation requirements and be in compliance with the manufacturer instructions, at a minimum. The quality control plan must control the quality of the test process and ensure accurate and reliable test results. External control material samples must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions."

H. **Quality Assessment**: The continuous process of monitoring the effectiveness of the Quality Control plan.

I. **Test System**: A system which includes all steps (across the laboratory continuum: pre-analytic through post-analytic) used to produce a result; includes all instrumentation, equipment, reagents and supplies used to produce results. A test system may be manual or automated, single-use or multi-channel.

## 3. Responsibilities

The IQCP will be developed by the individual departments by the Manager, Supervisor, Lead Technologist or Designee. The Lab Medical Director must approve prior to implementation.

## 4. Policy Statement

A. Each laboratory section performing IQCP has developed written procedures for the implementation of the specific tests for which IQCP is used. These procedures, specific to IQCP, are maintained by the individual IQCP testing sections. Each IQCP section of the laboratory "performs ongoing quality assessment monitoring to ensure that the QC plan is effective in mitigating the identified risks for the IQCP".

B. For non-waived testing, each section of this laboratory either follows the minimum daily QC requirements as defined by CLIA and by the College of American Pathologists (CAP) or follows an IQCP plan.

C. Following CAP guidelines, this laboratory has identified all tests using an IQCP and has completed the CAP's forms (see template and forms in Attachment section) for laboratories using an IQCP. The use of the CAP form is required, even if standardized forms and templates are used by the laboratory. The laboratory is responsible for maintaining the accuracy of the data on the form and for providing a current copy to the inspector during an on-site CAP inspection. The IQCP forms and written plans/procedures are maintained by each lab section participating in IQCP.

## 5. Procedure

A. An IQCP must:
   1. Provide immediate detection of errors for each phase of testing.
   2. Specify the number, type and frequency of QC testing.
   3. Contain criteria to determine acceptable QC.

B. An IQCP requires:
   1. **Risk Assessment**: The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include the following:
      a. Pre-analytic, analytic, and post-analytic phases of the testing process.
      b. Intended medical uses of the test and impact if inaccurate results are reported (clinical risk).
      c. Components of the tests including reagents, environment, specimen, testing personnel, and test system.
      d. Variations in the components based on use of the tests (eg, use in different

environments, by different personnel, or multiple identical devices).
   e. Data from the laboratory's own environment, instrument/equipment performance, and testing personnel demonstrating acceptable performance over the maximum time interval between external quality control runs defined in the IQCP.
   f. Manufacturer's instructions and recommendations.
2. **Quality Control Plan:** The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:
   a. The number, type (external and internal quality control systems), and frequency of quality control.
   b. Criteria for acceptable performance.
   c. Monitoring of the testing environment and reagents.
   d. Specimen quality.
   e. Instrument calibration, maintenance, and function checks.
   f. Training and competency of testing personnel.
   g. Provisions for multiple identical devices and variation for uses covered under one IQCP.
3. **Quality Control Plan Approva**l: The IQCP includes a written quality control plan approved by the laboratory director prior to implementation.
4. **Ongoing Quality Assessment:** Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes records of the following:
   a. Review of quality control and instrument/equipment maintenance and function check data at least monthly.
   b. Evaluation of errors relating to pre-analytic, analytic and post analytic phases of the testing process.
   c. Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing.
   d. Evaluation of corrective actions taken when problems are identified.
   e. Re-evaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur.
   f. Reapproval of the quality control plan by the laboratory director or designee at least biennially.

**C. List of Individualized Quality Control Plans:** The laboratory has identified all tests using an IQCP on the CAP's List of Individualized Quality Control Plans form. The use of the CAP form is **required**, even if standardized forms and templates are used by the laboratory. **See Attachment: List of Individualized Quality Control Plans**

**6. General Information**

A. The Centers for Medicare and Medicaid Services (CMS) implemented a risk assessment-based Quality Control (QC) option, Individualized Quality Control Plan (IQCP), to monitor the accuracy and precision of the entire testing process.2 The use of IQCP is voluntary. However, if not implementing IQCP, laboratories must follow the minimum Clinical Laboratory Improvement Amendments (CLIA) daily QC requirements for non- waived testing (i.e. Labs must run at **least two levels of external QC** [or more frequent, as defined] for a non-waived test each day of patient testing). IQCP is, in effect, required for tests, including single-use devices, where external QC is not performed. IQCP does **not** apply to waived testing. A laboratory may **not** implement an IQCP that allows for QC to be performed **less frequently** than indicated by the manufacturer

B. NOTE: "For affiliated laboratories (e.g. systems) with integrated procedures, each accredited laboratory must have its own IQCP approved by the laboratory director. There must be records

demonstrating that risks specific to the site were evaluated involving a representative sample of local testing personnel to conduct the risk assessment and that the laboratory-specific QC data were used in the study to support the defined frequency of quality control. Laboratories may use data from other sites to supplement risk assessments and to support their findings."

**7. Revisions**

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

**8. References**

A. All Common Checklist, CAP, Northfield, IL, current version
B. Individualized Quality Control Plan (IQCP) | CMS

**9. Policy Development and Approval**

**Document Owner:**

Laura Judd (Operations Specialist)

**Writer:**

Tracie Rusicka (Operations Specialist)

**Reviewer(s):**

Ashley Beesley (Mgr, Laboratory), Donna Cary (Mgr, Division Laboratory), Fatima Bazzi (Supv, Laboratory), Helga Groat (Mgr, Laboratory), Jamie Pert (Mgr, Division Laboratory), Jennifer Burke (Mgr, Laboratory), Jennifer Yaker (Mgr, Laboratory), Kelly Sartor (Mgr, Division Laboratory), Kelly Walewski (Mgr, Laboratory), Kristen DiCicco (Mgr, Laboratory), Kristin Russell (Mgr, Laboratory), Lauren Hingst (Mgr, Division Laboratory), Leah Korodan (Mgr, Division Laboratory), Lynn Vanderlaan (Mgr, Division Laboratory), Megan Masakowski (Mgr, Division Laboratory)

**Approver(s):**

Lab - EAST L3 Medical Directors, Amy Knaus (Dir, Pathology Service Line), Ann Marie Blenc (System Med Dir, Hematopath), Brittnie Berger (Dir Sr, Lab Operations), Christopher Ferguson (Dir, Laboratory Services), Elzbieta Wystepek (Dir, Laboratory Services), Hassan Kanaan (OUWB Clinical Faculty), Jeremy Powers (Chief, Pathology), John Pui (Chief, Pathology), Kurt Bernacki (System Med Dir, Surgical Path), Masood Siddiqui (Staff Pathologist), Muhammad Arshad (Chief, Pathology), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Subhashree Mallika Krishnan (Staff Physician)

**10. Keywords:**

COM.50200, COM.50300, COM.50400, COM.50500, COM.50600