



# **Basic Guide to Laboratory Individualized Quality Control Plan (IQCP)**

## **I. Introduction to IQCP**

- IQCP (Individualized Quality Control Plan) is a risk-based approach to quality control.
- It provides flexibility in meeting CLIA quality control requirements.
- Applicable to non-waived testing that does not have QC performed on it daily under CLIA regulations.

## **II. Components of an IQCP consists of three main components**

### **A. Risk Assessment**

- Identify potential sources of error in the testing process.
- Evaluate risks associated with:
  - Specimen collection and handling.
  - Reagents and materials.
  - Environment and equipment.
  - Testing personnel.
  - Analytical process.

### **B. Quality Control Plan (QCP)**

- Establish customized QC practices based on the risk assessment.
- Define the frequency and type of QC checks.
- Include manufacturer recommendations and regulatory guidelines.
- Ensure ongoing monitoring and corrective action procedures.
- C. Quality Assessment (QA) & Monitoring
- Continuously assess and improve the IQCP.
- Regularly review QC and test performance data.
- Document corrective actions taken for identified issues.
- Modify the IQCP as needed based on new risks or regulatory changes.

### **III. Implementing an IQCP**

- Conduct a thorough risk assessment.
- Develop a written IQCP document.
- Train laboratory staff on IQCP procedures.
- Monitor and reassess periodically for effectiveness.

### **IV. Documentation & Compliance**

- Maintain complete IQCP documentation.
- Ensure compliance with CLIA and accrediting bodies.
- Keep records of risk assessments, QC plans, and QA reviews.

By implementing an IQCP, laboratories can optimize quality control while maintaining regulatory compliance and ensuring accurate patient test results.