Compliance Tool: CLIA IQCP Risk Assessment (RA) Worksheet

Instead of the cookie-cutter quality control (QC) procedures CLIA regulations require, labs that perform nonwaived tests have the option of implementing an individualized quality control plan (IQCP) tailored to their unique testing environment and patients. In addition to supporting CLIA compliance, the IQCP helps you identify and eliminate issues in your testing systems that can lead to errors and compromise quality. There are three phases of IQCP implementation:

1. Risk Assessment (RA)
2. Quality Control Plan (QCP)
3. Quality Assessment (QA)

Here's a worksheet for the RA process based on the template and examples sketched out in the Centers for Medicare & Medicaid Services IQCP implementation guidelines.

IQCP Risk Assessment Worksheet

Laboratory Name: _____ Test System Name: _____

Instructions

In completing this worksheet:

- **Column 1:** List the risk component being assessed.
- **Column 2:** Use the manufacturer's instructions and other information on performing the test to identify potential sources of error in the process.
- **Column 3:** List Yes, No, or Not Applicable (NA) to indicate whether it's possible to mitigate each potential source of error.
- **Column 4:** Indicate approaches to mitigation, including via:
  - internal controls
  - laboratory actions
  - safeguards in the test system or laboratory practices

1	2	3	4
RA Component	**Potential Source of Error**	**Can Source of Error Be Reduced**	**Way(s) to Identify Potential Source of Error**
Specimen	*Documentation of collection or re-collection *Testing time frame *Specimen stability *Labeling *Other		

Test System	*Specimen volume *Limitations followed *LIS accuracy *Means of patient identification *Other		
Reagent	*Storage *Transfer *Degradation *Integrity checking *Preparation *Testing external and abnormal controls *Other		
Testing Environment	*Room temperature *Humidity *Ventilation *Lighting *Dust, debris, clutter *Other		
Testing Personnel	*Improper training *Improper verification of competency *Transcription errors in reporting results *Other		

Source: Adapted from U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, and Centers for Disease Control and Prevention, *Developing an IQCP: A Step-by-Step Guide*.