Creating an Individualized Quality Control Plan (IQCP) Procedure

1. **PRINCIPLE**
   1. The laboratory’s Individualized Quality Control Plan (IQCP) is the alternative to the CLIA quality control (QC) option. It will provide an equivalent QC program for the laboratory that will meet the CLIA regulations for all non-waived testing. IQCP looks at the entire testing process (pre-analytical, analytical and post-analytical) and uses a risk assessment to apply an appropriate and through quality control program for individual tests. Each IQCP requires three elements: Risk Assessment (RA), Quality Control Plan (QCP) and Quality Assessment (QA).
2. **MATERIALS**
   1. Evaluate the need to create an IQCP for each existing and new test
      1. All non-waived qualitative tests must either:
         1. Perform two levels of external controls on each test system for each day of testing or
         2. Follow an IQCP
   2. Historical QC data (6 months prior testing or from verification studies)
   3. Package inserts
   4. All relevant procedures
   5. Verification/Validation
   6. Risk Assessment chart (Appendix A)
3. **PROCEDURE**
   1. Risk Assessment (RA)
      1. Identify and evaluate potential problems and errors that may occur for this test.
      2. The risk assessment must include the pre-analytic, analytic and post-analytic times of the testing process.
      3. Each RA must consider 5 aspects: Specimen, Testing personnel, Reagents, Environment, and Test system
      4. Sources of error may include but are not limited these **PRE-ANALYTIC** considerations:
         1. Specimen
            1. Specimen Collection
            2. Specimen Labelling
            3. Specimen Storage and stability
            4. Specimen transport
            5. Specimen processing
            6. Specimen acceptability requirements and rejection
      5. Sources of error may include but are not limited to these **ANALYTIC** considerations:
         1. Test System
            1. Inadequate sampling of specimen
            2. Capabilities of detecting interfering substances
            3. Calibration issues
            4. Mechanical failures
            5. Optics
            6. Pipette malfunction
            7. Barcode readers
            8. Failure of system controls/ function checks
            9. Temperature monitors and controls
            10. Software/hardware malfunction
         2. Reagents
            1. Shipping/receiving conditions
            2. Storage conditions
            3. Expiration dates
            4. Specimen and reagent preparation
         3. Environment
            1. Temperature
            2. Airflow/ventilation
            3. Noise/vibration
            4. Humidity
            5. Light intensity
            6. Dust
            7. Power failure/surge
            8. Space
         4. Testing personnel
            1. Training
            2. Competency
            3. Education/experience
            4. Staffing
      6. Sources of error may include but are not limited to these **POST-ANALYTIC** considerations:
         1. Test System
            1. LIS transmission
            2. Result reporting
         2. Testing personnel
            1. Test result interpretation
            2. Post reporting result review
            3. Error resolution / Doctor complaints
   2. Quality Control PLAN (QCP)
      1. At minimum, the QCP must include control guidelines as stringent as suggested in the manufacturer’s instructions. It is never acceptable that the QCP is less stringent than what is suggested in the package insert instructions.
      2. The QCP must define all aspects monitored based on the potential errors identified during the risk assessment, including the following if applicable:
         1. The number, type (internal and external) and frequency of controls that are to be run
         2. The criteria for control acceptance of quality control results
         3. The procedure for controls that are not acceptable
         4. Monitoring the testing environment and reagents
         5. Specimen quality
         6. Instrument calibration, maintenance, and function checks
         7. Training and competency of testing personnel
   3. Quality Assessment (QA)
      1. Ongoing monitoring is performed by the laboratory to ensure that the QCP I effective in mitigating the identified risks for the IQCP and includes records of the following:
         1. Review of quality control and instrument/equipment maintenance and function check data at least monthly.
         2. Evaluation of errors relating to preanalytic, analytic and post analytic phases of the testing process
         3. Review of complaints from clinicians and other health care providers regarding the quality of testing to confirm the clinical efficacy of the testing
         4. Evaluation of corrective actions taken when problems are identified
         5. 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
         6. Re-approval of the quality control plan by the laboratory director or designee at least biennially (Every 24 months)
4. **REFERENCES**
   1. CLIA IQCP Introduction documents – released July 2013
   2. Developing an IQCP – A Step-By-Step Guide. CDC/ CMS literature
   3. CAP requirement checklist and requirement

Appendix A – IQCP Risk Chart

