COLLEGE of AMERICAN PATHOLOGISTS

IQCP INSPECTOR TIPSHEET

Processes/Areas for Observation	• Risk Assessment • Quality Control Plan • Quality Assessment Monitoring
Key Documents to Review	1. Policies and procedures for the implementation of an IQCP 2. Completed CAP List of Individualized Quality Control Plan(s) Form from the laboratory to sample records 3. Review a sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years. Must include: a. Risk Assessment 1) All three phases of the testing process: preanalytic, analytic, and post analytic 2) All five required components: Specimen, Test System, Reagent, Environment, Testing Personnel 3) Data from the laboratory's own environment, instrument/equipment performance, and testing personnel, including variations in use 4) Review of the manufacturer's instructions and recommendations to identify potential risks and processes to mitigate risk b. Quality Control Plan 1) Approval of the plan with signature of laboratory director and date before implementation 2) Number, type (external and internal quality control systems), and frequency of quality control defined 3) Quality control performed at least as frequent as required in manufacturer's instructions 4) External control materials run with new lots and shipments 5) Additional processes for monitoring the quality of the specimen, test system, reagents, environment and testing personnel defined based on risk assessment 6) Customization of quality control plan for variations in use, including multiple identical devices, different personnel or different testing locations 7) Quality control plan followed as written c. Quality Assessment Monitoring 1) Monthly review of quality control and instrument/equipment maintenance and function check data 2) Evaluation of errors relating to all phases of the testing process 3) Separate monitoring for variations in testing 4) Evaluation of complaints on the quality of testing 5) Evaluation of corrective actions taken if problems are identified 6) Reevaluation of the risk assessment when failures are identified 7) Annual reapproval of the quality control plan