Recreation of the Test Process:

Specialty(ies):__________________________________________

Examination Selection:___________________________________

Patient Accession Identified:_______________________________

Report Date:____________________________________________

Recreation of Test Process

Pre-Examination Procedures
_____ Instructions to Clients/ Specimen Collection & Handling Procedures
_____ Test Requisition
_____ Accession Record
_____ Specimen Rejection Log

Standard Operating Procedure Manual
_____ SOPM for Test, Analyzer, Critical Value, Reporting, Turnaround Time
_____ Bench Excerpts

Examination Procedures
_____ Worksheet
_____ Instrument Report
_____ Calibration Record
_____ Quality Control Record of Day of Testing & 3 Months Prior

Individual Quality Control Plan
_____ Risk Assessment done
_____ Address 5 Elements Over 3 Phases of Testing
  • Sample
  • Testing
  • Reagent
  • Environment
  • Personnel
_____ Empirical Data Supports IQCP
_____ Quality Plan Signed by Director

Examination Verification
_____ Method Verification/ Validation
_____ Calibration Verification Record (x2/year)
_____ Quality Control Lot Verification
_____ Reagent Lot Verification
_____ Multisystem Agreement
Post-Examination Procedures
_____Documentation of Review of Results
_____Critical Values Reporting
_____Patient Report, Reference Ranges/Interpretive Data
_____Reference Laboratory

Quality Assessment & Improvement
_____Proficiency Test
  • Enrollment Verification
  • Review of PT Documentation for 3 Events
_____Non-Conformance Reports (Failed Quality Control, Other Issues)
_____Corrected Report

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Resource Management
_____Reagent Inventory
_____Equipment Maintenance
_____Environmental Controls (temperatures, etc.)