

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

Human Resources	Name of Employee	Interview	Review of Training and Competency
Collection	_____	_____	_____
Accessioning	_____	_____	_____
Examination	_____	_____	_____
Supervision	_____	_____	_____

Resource Management

- ___ Reagent Inventory
- ___ Equipment Maintenance
- ___ Environmental Controls (temperatures, etc.)