Document Control & Process Verification

Patient Report Selection

Specialty(ies): ________________________________

The entrance interview will be used to identify those analytes and patient specimens to be selected for document control review. Criteria used to select examination procedure and patient report (check all that apply):

- [ ] Newly introduced test
- [ ] Newly hired or reassigned personnel
- [ ] Point-of-care tests
- [ ] High risk to patient management if erroneous results
- [ ] Proficiency testing poor performance
- [ ] Critical values
- [ ] Timely reporting required
- [ ] Specimen stability challenges
- [ ] Reportable to public health
- [ ] Consensus practice standards exist
- [ ] Examination platform encompasses multiple subspecialties

Examination Selection: ________________________________

Patient Accession Identified: ________________________

Report Date: ________________________________
Recreation of Test Process

Pre-Examination Procedures

- Instruction to clients / Specimen collection & handling procedures
- Test Requisition
- Accession Record
- Specimen rejection log
- Work list

Standard Operating Procedure Manual

- Version for period of specimen examination
- Bench excerpts
- Bench notes

Examination Procedures

- Worksheets
- Instrument report
- Calibration record
- Quality control record

Examination Procedure Verification

- Initial verification/validation
- Calibration verification record
- Quality control lot verification
- Reagents lot verification

Post-Examination Procedures

- Documentation of examination results approval for reporting
- Authorized release records
- Patient report
- Compilation of reported critical values for the examination procedure

Quality Assessment & Improvement

- Accuracy verification records (PT or PT alternative)
- Non-conformance reports (failed QC, audit findings, complaints)
- Investigation and corrective action reports
**Human Resources**

Identify all personnel engaged in the processing of the selected patient specimen and provide job descriptions and training and competency records. Indicate whether the employee is available for interview sometime during the inspection.

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<thead>
<tr>
<th>Task</th>
<th>Employee(s)</th>
<th>Interview (Yes/No)</th>
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**Resource Management**

Identify the resources used to process the selected patient specimen and provide all records pertinent to the verification and maintenance of performance specifications at the time. Resources may include environmental controls (general facility, refrigerators, freezers), instruments, centrifuges, pipets, analytical balances.

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