**Recreation of the Test Process**

**PFI:** Click or tap here to enter text. **Event *(CLEP use only)*:** Click or tap here to enter text.

**Date:** Click or tap to enter a date.

**Category(ies):** Click or tap here to enter text.

**Test Selection:** Click or tap here to enter text.

**Instrument/Test kit:** Click or tap here to enter text.

***Sample Information***

**Patient specimen accession number or other unique identifier:** Click or tap here to enter text.

**Collection Date:** Click or tap to enter a date. **Collection Time:** Click or tap here to enter text.

**Receipt Date:** Click or tap to enter a date. **Receipt Time:** Click or tap here to enter text.

**Report Date:** Click or tap to enter a date. **Report Time:** Click or tap here to enter text.

If records are stored electronically, they may be viewed in electronic format when more convenient

**The “radio buttons” (●Acceptable ●Unacceptable ●Not applicable) are for CLEP use and Laboratory self-assessment.**

**Pre-Analytic Systems**

Specimen Submission Instructions (instructions for specimen identification, collection, handling and transportation provided to your clients)

Test Request Form or an electronic equivalent (provider’s order for this specific specimen)

Accession Documentation (manual or electronic)

Specimen Rejection, example of documentation process (manual or trackable through LIS)

Reference Laboratory

**Analytic Systems**

Test Procedure

Document title:Click or tap here to enter text.

Procedure Excerpts (“cheat sheets, job aides, and/or procedural subsections, etc. used for quick reference at the bench)  Worksheet (if applicable)

Instrument Report (if applicable)

Method Performance Specification(s) Documentation (for test selected if new or changed since last on-site survey and any new methods/instruments/analyzers implemented since the last on-site survey)

Calibration Record (that was valid at the time test selected was performed)

Calibration Verification Record (x2/year)

Multisystem Agreement/Comparability studies (x2/year)

**Quality Control**

Quality Control Record for day of testing

Quality Control Review for month test was performed, current month, and 2 months prior (in the format reviewed for shifts and trends (Levey Jennings/QAP etc.))

Quality Control Lot Verification for lot(s) used on test date and current lot (Assayed value verification or Unassayed acceptability criteria documentation)

**Individualized Quality Control Plan** (If applicable to examination selection or any testing in this specialty)

Risk Assessment done

Addresses 5 Elements Over 3 Phases of Testing

●Sample ●Testing ●Reagent ●Environment ● Personnel

Empirical Data Supports IQCP

Approved by Director

Annual review

**Post-Analytic Systems**

Result Review Documentation (exception report or other documentation of supervisory review of results)

Alert Value(s) Notification Documentation & Documentation of Public Health Reporting (if applicable)

Test Report (printed or faxed version that would be sent if requested)

Reference or Contract Laboratory Report (if sent for confirmatory or additional testing, send-out form or manifest, received patient report, incidents (e.g., lost specimens))

Corrected Report (an example of a corrected and /or amended report for each module of the laboratory’s information system)

Non-Conformance Reports (failed quality control, other issues)

**Proficiency Testing**

Proficiency Test or Alternative­­­­­­ (CAP, API, WSLH, AAB, in-house, etc.)

* Enrollment Verification
* Documentation for last 3 events (performance review, attestations, submission forms, original test data)

**Resource Management**

Consumable Inventory (recording of the dates of receipt, lot numbers, expiration dates, dates of performance verification and the dates material is placed in service for all relevant reagents, control materials, and calibrators)

Consumables Verification (reagents, solutions, stains, etc.)

Instrument Maintenance & Preventative Maintenance (for each piece of equipment involved in this specimen; routine and preventive maintenance)

Equipment Function Checks and Performance Verification (thermometers, pipettes, centrifuges, timers etc.)

Environmental Controls (temperatures, etc.) (temperatures, humidity, etc.)

**Human Resources Name of Employee Interview Training and Competency**

**(new employee or new test: initial training**

**everyone (including new) competency performed since last on-site survey)**

Collection Click or tap here to enter text. Choose an item. Choose an item.

Accessioning Click or tap here to enter text. Choose an item. Choose an item.

Testing Click or tap here to enter text. Choose an item. Choose an item.

Supervision Click or tap here to enter text. Choose an item. Choose an item.

(on-site during testing)

***Continuing education of all technical employees involved in selected test for last 2 years***

**Physical survey of space: surveyor will observe testing & safety processes, interview staff, observe in-use and stored resources and specimens, assess for adequate space and separation of tasks**

***Notes:***