Audit Date Initiated: **Audit Response Due:**	**Audit Reference #:** **Priority Audit**

Audit Objectives: Monitor effectiveness of multiple CAPA initiatives and assess the scope and activities template of this plan that will be implemented monthly.

Scope of Internal Audit: End to End Audit on 10 random patient samples in previous month

Department/Area & Participants: All technical areas.

IT (Zeqiang.Ma@PerkinElmer.com): Request randomized 10 patient specimens

COLOR representative: Scott Tupper (scott@color.com): Request requisitions and reports for the 10 patient samples.

Administrative Resource (Sean.Romigh@PerkinElmer.com) : Request an API Search Export for the 10 patient samples

Administrative Resource (Victor.Marrufo@PerkinElmer.com): Assist with the request for the name/site of the facility where specimens originated.

(Obtained through OptumServe and/or Color) Michael Knudtson mknudtson@Logisticshealth.com
Gina Schaller gschaller@Logisticshealth.com
Amy Lockwood Amy.Lockwood@color.com.

As needed: Accessioning Supervisor(s), Wet Lab Manager(s), SignOut Manager(s)

Assigned Auditor/Audit Team: Determined on a monthly basis

Schedule: Expected Start Date: Monday of the second full week of every month or random

Schedule: Expected Report Date: Monday of the third full week of every month or 7 days after the initiation of the audit

Sampling Plan: IT pulls the first 1000 released records on the 7th and 23rd of each month (or selected days as requested for random audit) then selects the first sample in each day with Negative, Positive, Presumptive positive (Inconclusive in LIMC), Invalid and Unsatisfactory.

Activities to be Audited: *Add agenda items and times if practical. Add any pertinent details, participants, and normative references if needed.*

1.Availability of specimen requisition replete with all required elements:

1. **Adequate patient identification information (eg, name, registration number and location, or a unique confidential specimen code if an alternative audit trail exists)**
2. **Patient sex**
3. **Patient date of birth or age**
4. **Name and address (if different than the receiving laboratory) of the physician, legally authorized person ordering the test, or name and address of the laboratory referring the specimen**
5. **Tests requested**
6. **Date of specimen collection, and if appropriate, time of collection**
7. **Source of specimen, when appropriate**

2. Availability of Receipt Manifest and Specimen Acceptability with appropriate documentation and timely resolution of any issues. Note: there is no direct download of specimen collection/transport facility into our LIMC. It will be necessary to obtain from OPTUM SERVE (or COLOR), were the samples originated from to obtain the following information. The manifests and spreadsheets are maintained on Accessioning One Drive (will need Operations Manager or Accessioning Supervisor to assist with review).

- Verify that manifest is scanned and date/time stamped.
- Verify that batch delivery is documented on the Specimen Delivery Log.

3. Review of all personnel qualification documents of employees involved in specimen receipt, accessioning, extraction, PCR, Analysis/Result Reporting.
   - Access Media Lab and verify CV, diploma and/or transcript, and international equivalency evaluation (if needed) and lab licensure documentation (if appropriate).
   - Note any Not Started Assignments and determine if they are applicable. Note those that are extraneous/in error and those that are overdue.
   - Access CAP.org Organization Profile and verify technical employees have been added.
   - Access Master Employee Database and verify all information is updated and correct.

4. Review of all applicable personnel training and competency documents of employees involved in specimen receipt, accessioning, extraction, PCR, Analysis/Results Reporting.
   - Access Media Lab and ensure that employee has been assigned to the appropriate Group in Media Lab.
   - Verify that completed technical training records are uploaded and approved in Media Lab.
   - Verify that the individual assessing competency is qualified (have delegated job responsibility form and completed GS and/or TS competency).
   - Verify that competency records for 6mo, 12 mo and/or yearly are uploaded and approved in Media Lab.
   - Note any *Not Started Assignments* and determine if they are applicable. Note those that are extraneous/in error and those that are overdue.

5. Review all equipment qualifications and maintenance records used in testing specimens.
   - Verify that instrument and equipment maintenance and function checks are reviewed and assessed at least monthly by Supervisor.
   - Verify that service and repair records, maintenance logs, performance verification records are readily available and usable by technical staff operating the instrumentation.
   - Verify that troubleshooting logs are present, used, resolution documented and documentation follow GDP.
   - Verify that comparability of results between instruments has been conducted in the last 6 months.

- Verify ambient temperature was maintained and corrective action taken if tolerance limits were exceeded.

6. Review of QC for each batch. Meet acceptability criteria and was there documented monthly review signed by Supervisor?
   - Verify that monthly QC (month specimens were tested) was reviewed by Supervisor

7. Result Reporting
   - Review the reports provided by COLOR to determine if reported accurately and have all of the required patient information that is on the patient requisition.
     - Date and time of specimen collection
     - Date and time of release of report
     - Specimen source
     - Test results – match the LIMC
     - Any conditions of suboptimal specimen
   - Determine if there were any report errors/corrected reports for these patients.
   - Determine if the test report was successfully transmitted (as indicated in the API search report)
   - Verify if TAT was within 48 hours
   - Verify that the result interpretations on the report MATCH the result interpretations in the Data Analysis and Result Reporting technical procedure (CA-RPT-SOP-002)

Reference Requirements: (*CAP Checklist Item or CLIA reference number)*

GEN.40700 All Specimens are accompanied by an adequate requisition, need not be paper; computerized acceptable.

GEN.40750 Elements in the requisition

GEN.40900 Specimen Date received

COM.06300 Specimen Rejection Criteria Accessioning SOP 001 and 002

GEN.54025 Lab Personnel Roster is Current

GEN.54750 Nonwaived Testing Personnel Qualifications

GEN.55450 Personnel Training records are satisfactorily completed

GEN.55500 Competency Assessments assessed at the required frequency

GEN.55510 Qualifications of Individuals Assessing Competency

GEN.55525 Competency/Performance Assessment of Supervisors

COM.30550 Instrument/Equipment Performance Verification – verified prior to use, after major maintenance, after relocation

COM.30600 Equipment Maintenance/Function Checks performed on defined schedule, logs GDP compliance

COM.30675 Instrument and Equipment Records readily available to technical staff

COM.30750 Temperature Checks recorded on day of use and evidence of corrective action if temperature range are exceeded.

GEN.30000 Regular review of QC and corrective actions taken based on establishment of tolerance limits.

GEN.41096 Report Elements

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Laboratory Director Signature/Date