1-Analytical Processes

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ANNUAL REVIEW:

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SUPERSEDES: Procedure titled _____

Purpose:

This SOP is about taking all measures involve or related to analytic phase of clinical laboratory processes ensuring accurate and reliable testing.

Scope:

Applies to the testing areas and activities of the laboratory.

Health and Safety:

Always be sure to wear proper PPE when handling hazardous waste.

Definitions and abbreviations

PPE-personal protective equipment
SOP- Standard Operating Procedure

Testing Environment

The environment in which patient specimens and testing materials are stored, in addition to the locations where testing is performed can have a profound impact on the accuracy of test results. Testing is performed in a designated area with adequate space and lighting. Inadequate lighting can negatively affect specimen collection, test performance, and interpretation of test results. The designated work space ensures patient confidentiality, and ease of specimen collection, test performance, and storage of supplies and records. Work surfaces will be clean, stable, level, and free of clutter or trash.

Each day the laboratory is open, environmental conditions, such as refrigerator, room temperature and humidity, are monitored and recorded. If the reading is outside of the acceptable range as noted on the temperature log, corrective action is taken and documented.

This laboratory maintains environmental logs for the following:

- ___Refrigerators
- ___Freezers
- ___Room temperature
- ___Incubators
- ___Water baths or heat blocks
- ___Temperature dependent equipment
- ___Humidity

Verification of Performance Specifications

Prior to using any nonwaived test system for patient testing, the laboratory verifies that the performance described in the manufacturer's package insert or operator's manual is capable of being reproduced in this facility by using laboratory employees.

In case laboratory seeks support from the test system manufacturer to provide guidance and help in procedures to verify accuracy, precision, reportable range and reference range, as well as samples to conduct this testing, it should be under laboratory present and observations. All results must be reviewed for acceptability by the Laboratory Director, prior to approving the test method for use to test patients and report results.

Copies of all materials, data, instructions, and results obtained when verifying performance specifications retain for the time period in which the method is being used for patient testing plus 2 years after.

Equipment Maintenance

Equipment maintenance and function checks are performed according to the manufacturer's instructions to ensure that the test system is ready for testing. Maintenance records, including any manufacturer-performed service records, are retained for two years.

Equipment Calibration

When applicable, calibrations for individual tests are performed:

- at the frequency identified by the manufacturer,
- using the number, type and concentration of calibration materials indicated by the manufacturer,
- according to the manufacturers step-by-step instructions.
- using a new reagent lot number
- when quality control shows shifts, trends, or is out of range
- when corrective actions are not able to correct the problem
- after maintenance to critical parts or subsystems or after service procedures have been performed.

Calibration Verification

- Quantitative tests, calibration verification is performed every 6 months unless the tests is calibrated at more frequent intervals.
- This to confirm that the instrument setting continues to provide accurate results throughout the reportable range for the individual test.
- Three samples or quality controls (low, mid-point, and high) that have known values are run as a patient specimen.
- The results obtained are then compared to the known values and must be within the acceptable limits identified on the calibration verification form.
- when a new lot number or complete change of reagents occurs.
- when major preventative maintenance is performed or a critical part is changed.

Should calibration or calibration verification fail, troubleshooting and corrective action are required prior to performing any patient testing. Notify the Laboratory Director to obtain further instructions.

All calibration and calibration verification records, including manufacturer package inserts, are retained for two years.

Quality Control

An essential element to ensure quality patient testing is to run quality control. This involves testing a control specimen, which has a known interpretive value or range of values. This should be tested the same way a patient specimen is tested. If the control results fall within the expected range of values, staff can be reasonably

certain that the test has been performed correctly and patient test results are accurate.

- Control material is ordered and obtained on a regular schedule to allow the laboratory sufficient time to verify the expected range of a new lot number of control material prior to the expiration of the previous lot number of control material.
- For qualitative assay, positive, negative or/and equivocal quality controls materials to be tested following the manufacturer instruction on the number and frequency of running quality controls
- Quality control material has an expiration date.
- Controls are not to be used beyond their expiration date before and after opening day.
- Quality control is performed at the frequency, number and type indicated by the manufacturer or as specified in the CLIA regulations, whichever is more stringent. At least 2 level of quality controls should be tested every day testing performed
- Controls are run in the same manner as patient specimens.
- Quality control logs electronically or manual are maintained. The log includes the date tested, identify the individual that performed, the result obtained, an indication of whether the result was acceptable or not, and if not acceptable - corrective actions taken.
- The acceptable range for control materials is provided in the package insert, this will be used as guide, the laboratory director or designee will identify the acceptable limit of performance. Package inserts from control materials are retained with quality control records.
- If assayed controls materials used, verify the accuracy of the new lot of quality controls by running 5-3 times, compare the achieved mean with the manufacturer provide mean or/and peer group mean to establish accuracy
- If using non-assayed control materials, a minimum of 20 data points is required to set the mean and standard deviation to determine the acceptable range. All documentation used in setting the acceptable range is maintained.
- Staff review and confirm that control results are within acceptable range prior to reporting patient results.
    - If control results are unacceptable, an investigation into the cause of the unacceptable result is conducted. Corrective actions are taken to resolve the problem, and recorded before resuming patient testing.
    - If patient specimens were tested at the same time as unacceptable controls, the patient specimens will be re-tested once acceptable control results are obtained.
- Quantitative control results are plotted electronically/manual on a Levy-Jennings chart on a daily basis. These charts are reviewed every 5-7 data points for shifts and trends. If a shift or trend is identified during the review, corrective action is taken and document.
- All quality control records are retained for two years.

Quality Control is also performed whenever:

- There is a change in reagent lot numbers, as directed by the manufacturer.

- Instrument service or calibration is performed.
- Patient results are questionable.

Director Review of Quality Control Results:

NOTE: If the Laboratory Directory chooses to delegate this responsibility, this should be indicated in the delegation statement. This person should be qualified to hold the CLIA position of Technical Consultant/Technical Supervisor or General Supervisor.

On a monthly basis, the Laboratory Director/or designee reviews the quality control logs and Levey-Jennings charts to ensure:

- The appropriate number and type of controls are being performed.
- Controls are being performed at the appropriate frequency.
- Control results are within the acceptable range.
- If controls are outside of the acceptable range, there is a record of the actions taken to resolve the problem, and controls were repeated with acceptable results.

Upon completion of review, the Laboratory Director/ designee signs and dates the control logs.

Performing Testing

In performing any testing, all procedural instructions must be followed exactly.

- Get ready to test. This may include calibration or function checks and bringing refrigerated items to room temperature before testing. Assemble any supplies that will be needed.
- Perform quality control per the procedure and record the results.
- Ensure steps are timed properly and results are read at the correct time.
- Confirm that quality control results are acceptable prior to testing patients. If quality control results are unacceptable, take corrective action and document this action.
- Once the problem is resolved and acceptable results are obtained for quality control, patient testing may begin.
- Maintain the identification of each patient specimen throughout each step of testing.
- If all steps mentioned pass, then patients' samples can be performed and reported

References

CAP all common checklist 2023
COLA accreditation manual 2022