<table>
<thead>
<tr>
<th>Requirement Code</th>
<th>PT Title</th>
<th>Description</th>
<th>Management Plan/Action Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT-0001</td>
<td>PT Participation</td>
<td>The laboratory participates in the proficiency testing program.</td>
<td>The laboratory's result was implemented in a timely manner.</td>
</tr>
<tr>
<td>PT-0002</td>
<td>PT Education</td>
<td>Educational PT challenges that were intended to be graded, but were not, for reasons such as:</td>
<td>Professional training records AND PT education records in the personnel files of the individuals.</td>
</tr>
<tr>
<td>PT-0003</td>
<td>PT materials</td>
<td>When external proficiency testing is not available due to the unavailability of human specimens where patient-specific results are not reported for materials, the semiannual alternative performance assessment process must be followed:</td>
<td>Protocols and records AND the diagnosis, handling of PT specimens AND Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0004</td>
<td>PT demon 1</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0005</td>
<td>PT demon 2</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0006</td>
<td>PT demon 3</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0007</td>
<td>PT demon 4</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0008</td>
<td>PT demon 5</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0009</td>
<td>PT demon 6</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0010</td>
<td>PT demon 7</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0011</td>
<td>PT demon 8</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0012</td>
<td>PT demon 9</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
<tr>
<td>PT-0013</td>
<td>PT demon 10</td>
<td>The laboratory's result was implemented in a timely manner.</td>
<td>Written policy describing proper handling of PT specimens.</td>
</tr>
</tbody>
</table>

**NOTE:** The above table is a sample representation and is not exhaustive. The actual content might include more detailed information and specific requirements that are relevant to the proficiency testing program. The table is designed to illustrate the structure and typical content that might be included in a document related to proficiency testing regulations and requirements.
### PT and Alternative Performance Assessment

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Verify staff training on proficiency testing</strong></td>
<td>Proficiency testing staff must be trained on PT policies and procedures, including how to handle PT samples, how to assess results, and how to report results.</td>
</tr>
<tr>
<td><strong>Ensure PT samples are appropriately identified</strong></td>
<td>Each PT sample must be securely submitted in a container labeled with two identifiers. Identifiers may be in a machine readable format, such as a barcode.</td>
</tr>
<tr>
<td><strong>Manage PT sample handling</strong></td>
<td>PT samples must be handled in the same manner as patient specimens.</td>
</tr>
<tr>
<td><strong>Adhere to quality control standards</strong></td>
<td>Quality control standards must be maintained for PT samples.</td>
</tr>
<tr>
<td><strong>Implement alternative performance assessment</strong></td>
<td>Alternative performance assessment must be performed at least semiannually in lieu of PT.</td>
</tr>
</tbody>
</table>

### Quality Management

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Document quality management processes</strong></td>
<td>The laboratory must document its quality management processes, including its quality management system, policies, procedures, and processes.</td>
</tr>
<tr>
<td><strong>Establish quality objectives</strong></td>
<td>The laboratory must establish measurable quality objectives and monitor their achievement.</td>
</tr>
<tr>
<td><strong>Conduct internal audits</strong></td>
<td>The laboratory must conduct periodic internal audits to assess its quality management system.</td>
</tr>
</tbody>
</table>

### Specimen Collection and Handling

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proper specimen collection</strong></td>
<td>Proper specimen collection includes ensuring the specimen is collected and handled according to the test request.</td>
</tr>
<tr>
<td><strong>Correctly identify specimens</strong></td>
<td>Specimens must be correctly identified with evidence of review and action. Correct identification includes the use of a specimen collection system, if available.</td>
</tr>
</tbody>
</table>

### Comparability Criteria - Non-waived

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ensure comparability</strong></td>
<td>The laboratory must ensure comparability of tests performed in different laboratories.</td>
</tr>
<tr>
<td><strong>Implement comparability assessment</strong></td>
<td>The laboratory must implement a comparability assessment program.</td>
</tr>
</tbody>
</table>

### Comparison of Technological Methods

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conduct cross-comparisons</strong></td>
<td>The laboratory must conduct cross-comparisons to assess the comparability of methods.</td>
</tr>
<tr>
<td><strong>Review results</strong></td>
<td>Results must be reviewed for comparability.</td>
</tr>
</tbody>
</table>

### Delta Checks

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conduct delta checks</strong></td>
<td>Delta checks must be conducted periodically to ensure the accuracy of results.</td>
</tr>
<tr>
<td><strong>Record delta checks</strong></td>
<td>Results of delta checks must be recorded and reviewed.</td>
</tr>
</tbody>
</table>

### Quality Control

<table>
<thead>
<tr>
<th>Requirement</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Maintain quality control</strong></td>
<td>Quality control must be maintained for all tests.</td>
</tr>
<tr>
<td><strong>Conduct quality control checks</strong></td>
<td>Regular quality control checks must be conducted to assess the accuracy of results.</td>
</tr>
</tbody>
</table>

### Patient Safety

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implement patient safety protocols</strong></td>
<td>Patient safety protocols must be implemented to prevent errors and adverse events.</td>
</tr>
<tr>
<td><strong>Report adverse events</strong></td>
<td>Adverse events must be reported promptly.</td>
</tr>
</tbody>
</table>

### Confidentiality and Privacy

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protect patient confidentiality</strong></td>
<td>Patient confidentiality must be protected. Access to patient information must be restricted to authorized personnel.</td>
</tr>
<tr>
<td><strong>Maintain privacy controls</strong></td>
<td>Privacy controls must be maintained to protect patient confidentiality.</td>
</tr>
</tbody>
</table>

### Patient Rights

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Respect patient rights</strong></td>
<td>Patient rights must be respected.</td>
</tr>
<tr>
<td><strong>Informed consent</strong></td>
<td>Informed consent must be obtained for tests that may cause discomfort or risk.</td>
</tr>
</tbody>
</table>

### Summary

The laboratory must ensure compliance with all regulatory and accreditation requirements, including those related to proficiency testing, quality management, specimen collection, and patient safety. The laboratory must maintain comprehensive records and documentation to support its quality management system.
null
### Instrument and Equipment Records

- **Function Check Tolerance Limits**: Records of action when the limits are exceeded.
- **Verification**: Records confirming acceptability of results to the acceptability criteria (e.g., accuracy, precision, linearity, selectivity). The action related to tests that have an approved Individualized Quality Control Plan (IQCP) is performed as specified in the plan.
- **Troubleshooting and Repairs**: Records of troubleshooting and repairs of instruments, equipment, and computer systems.
- **Function Check**: Verification of the test method performance specifications within defined tolerance limits.
- **Manufacturer Instructions**: Appropriate maintenance and function checks. The procedure and schedule must be consistent with manufacturer instructions for each instrument.

### Instrument Troubleshooting

- **Trouble Codes**: For instruments, trouble codes are defined and instructions are provided for troubleshooting.
- **Technical Staff**: Technical staff operating the equipment and performing troubleshooting and repairs must be appropriately trained.

### Function Check Tolerance Limits

- **Verification Records**: Records of function check results of reagent kits only within the kit lot unless the laboratory uses components from other reagent lots.
- **Function Check Results**: Verification of the test method performance specifications also includes processes to verify that new lots and shipments, including different reagent lots, are acceptable for use.

### Reagent Kit Components

- **Expiration Dates**: Reagents may impact the calibration status of instruments and consistency of patient results.
- **Expiration Determination**: Expiration dates are assigned based on known stability, frequency of use, manufacturer instructions, and in-process controls. Laboratories must perform a function check on reagents before use.
- **Storage and Handling**: Reagents are stored and handled as defined by the manufacturer instructions.

### Reagent Expiration Date

- **Reagent Expiration**: If the laboratory identifies a problem with a reagent that was used for patient testing (e.g., microscopy), it may use the reagent kit, the laboratory uses components from other reagent lots.
- **Expiration Date**: The remaining checklist requirements in the REAGENTS section do not apply to waived tests.

### Transmission of Critical Results

- **Electronic Means**: Electronic transmission of critical results is acceptable if the inspector is satisfied that the records can be promptly retrieved.

### Reagent Storage and Handling

- **Expiration Determination**: Expiration dates are assigned based on known stability, frequency of use, manufacturer instructions, and in-process controls. Laboratories must perform a function check on reagents before use.
- **Storage and Handling**: Reagents are stored and handled as defined by the manufacturer instructions.

### Reagent Expiration Date

- **Expiration Determination**: Expiration dates are assigned based on known stability, frequency of use, manufacturer instructions, and in-process controls. Laboratories must perform a function check on reagents before use.
- **Storage and Handling**: Reagents are stored and handled as defined by the manufacturer instructions.

### Waived Tests

- **Procedures**: For waived tests, the laboratory follows manufacturer instructions for handling and processing.
<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volumetric Glassware and Pipettes</td>
<td>Pipettes used for quantitative dispensing (i.e., single use or multiuse pipettes integrated with analytic instruments) are checked for accuracy and reproducibility initially and according to the manufacturer's instructions, at minimum and as defined in laboratory procedure. Such checks may be done by gravimetric, colorimetric or other validation procedures. Alternative approaches include determination of pipette carryover or direct plating of clinical specimens such as urine cultures. This requirement is not applicable for pre-calibrated inoculation loops that are used in the direct plating of clinical specimens such as urine cultures.</td>
</tr>
<tr>
<td>POLICY MANUAL: -∞HPO- Pathology DEPARTMENT OF PATHOLOGY GENERAL</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Method Validation (QM015)</strong></td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
</tbody>
</table>

**Method Validation (QM015)**

Method Validation (QM015) is a policy that outlines the procedures for validating medical laboratory methods. It is a critical component of the laboratory's quality assurance program, ensuring that all methods used for patient care are accurate, precise, and reliable.

### Validation Requirements

- **Method Evaluation:** Methods must be evaluated for accuracy, precision, and analytical specificity before they can be implemented.
- **Implementation:** Methods must be implemented following a valid protocol and according to the manufacturer's instructions.
- **Monitoring:** Methods must be monitored for performance on a regular basis, and corrective action must be taken if necessary.
- **Documentation:** All validation activities must be documented, and records must be maintained for at least two years.

### Validation Procedures

1. **Method Selection:** Methods must be selected based on the laboratory's needs and the availability of resources.
2. **Method Evaluation:** Methods must be evaluated for accuracy, precision, and analytical specificity.
3. **Method Implementation:** Methods must be implemented following a valid protocol and according to the manufacturer's instructions.
4. **Monitoring:** Methods must be monitored for performance on a regular basis, and corrective action must be taken if necessary.
5. **Documentation:** All validation activities must be documented, and records must be maintained for at least two years.

### Quality Assurance

- **Method Validation:** Methods must be validated to ensure that they meet the laboratory's performance criteria.
- **Performance Evaluation:** Methods must be evaluated on a regular basis to ensure that they continue to meet the laboratory's performance criteria.
- **Corrective Action:** Corrective action must be taken if methods do not meet the laboratory's performance criteria.

### References

- **Method Evaluation:** Methods must be evaluated for accuracy, precision, and analytical specificity before they can be implemented.
- **Implementation:** Methods must be implemented following a valid protocol and according to the manufacturer's instructions.
- **Monitoring:** Methods must be monitored for performance on a regular basis, and corrective action must be taken if necessary.
- **Documentation:** All validation activities must be documented, and records must be maintained for at least two years.

### Contact Information

For more information, please contact the laboratory director or the department manager.

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**Table of Method Validation (QM015) Requirements**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method Evaluation:</strong></td>
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**Monitoring:** Methods must be monitored for performance on a regular basis, and corrective action must be taken if necessary.

---

**Documentation:** All validation activities must be documented, and records must be maintained for at least two years.

---

**Contact Information:**

For more information, please contact the laboratory director or the department manager.
Body Fluid Analysis

Methods for body fluid analysis have been validated or verified and metrics for interpretation have been established. NOTE: This requirement applies directly to body fluid testing that the laboratory offers as a routine, orderable test. If the test is routinely performed on the fluid, there must be a written procedure. The requirement COM.40000 for a method validation or verification approval applies. Method performance specifications for blood specimens may be used for body fluids if the laboratory can reasonably exclude the existence of matrix interferences affecting the latter either by reference in the procedure manual to published literature or by evaluation for interferences due to matrix effects by performing an appropriate study (eg. a dilution study using admixtures of samples, spiking samples, further dilution). Alternative performance assessment is required (COM.01500) and may be performed using clinical assessment by chart review.

The reference intervals must be defined and reported with the results, unless the concentration of the analyte is reported in comparison to its concentration in a contemporaneously collected blood specimen. If the result is to be interpreted by comparison to the patient's blood, serum, or plasma, such results must be accompanied by an appropriate comment such as, “The reference intervals and other method performance specifications are unavailable for this body fluid. Comparison of this result with the concentration in the blood, serum, or plasma is recommended.” Reference intervals citations from the manufacturer’s insert or published literature citations may be used to determine the reference intervals (COM.40605). However, reference intervals have not been published for many body fluid analytes, and obtaining normal fluids to establish reference intervals may not be feasible.

Records of validation or verification studies with review and approval AND Records of reference interval study OR records of verification of manufacturer’s stated interval or published literature OR other methods approved by the laboratory/section director

A request for a test on a body fluid specimen that is not listed on the laboratory’s test menu that requires clearance by the section director or designee is considered a clinically unique specimen, rather than a routine, orderable test. Typically, these specimens are submitted due to an unusual clinical concern in a specific patient or situation (e.g. pathologic states where the analyte is not normally found in the fluid type) and it may not be possible to establish a comparative metric. In such cases, the result must be accompanied by a comment such as, “The reference intervals and other method performance specifications have not been established for this body fluid. The test result must be integrated into the clinical context for interpretation.”

Clinical Claims Validation

All clinical claims made by the laboratory are validated for the following types of tests:

* Laboratory-developed tests (LDTs)
* FDA-cleared/approved tests for which the laboratory makes a clinical claim(s) not included in manufacturer instructions
* In laboratories not subject to US regulations, tests approved by an internationally recognized regulatory authority (eg, CE marking) for which the laboratory makes a clinical claim(s) not included in the manufacturer’s instructions

NOTE: Clinical claims include statements about a test’s diagnostic sensitivity and specificity, ability to predict the risk of a disease or condition, clinical usefulness, or cost-effectiveness. Clinical claims may be found on the test report or in other information distributed by the laboratory (websites, test catalogues, newsletters, memoranda, advertisements, etc.). Laboratories are not required to make clinical claims about a test, but any claims made by the laboratory must be validated. The laboratory director must review and approve the validation of clinical claims for FDA-cleared/approved tests not included in manufacturer’s instructions and laboratory-developed tests, as applicable.

In order to adequately support a claim about diagnostic sensitivity and specificity and/or ability to predict risk of a disease or condition, the laboratory must perform a clinical validation study, unless the clinical validity of the test is documented in peer-reviewed literature or textbooks. The clinical validation study must include at least 20 samples and must include both positive and negative samples. If the laboratory uses fewer samples, the laboratory director must record the criteria used to determine the appropriateness of the sample size.

Records of clinical studies performed by the laboratory OR peer-reviewed literature that reasonably substantiates all claims made by the laboratory about a test
Note that IQCP requirements do not apply to waived testing. Nonwaived tests that employ an internal (electronic/procedural/built-in) quality control system must fulfill the following requirements:

- The laboratory must have its own IQCP approved by the laboratory director. There must be an evaluation performed if there are differences in testing personnel or in the process of conducting the risk assessment. It is not necessary for all personnel in the process of conducting the risk assessment to be involved in the evaluation.

- The laboratory director must consider the laboratory's clinical and legal responsibilities for accuracy and reliability of test results.

- The laboratory has a sample of local testing personnel to conduct the risk assessment and that laboratory-specific personnel must be represented in the sample.

- The IQCP for a test/device/instrument must be defined all aspects monitored based on the intended medical uses of the test and for the specific clinical use, unless the information is readily available on any of the package inserts or in the laboratory manual or other documentation. According to the CAP guidelines, IQCPs must be consistent with the laboratory manual or other documentation. The laboratory has a copy of the IQCP approved by the laboratory director. AND

- The laboratory maintains a list of laboratory-developed tests (LDTs) including those performed using microbiology media and reagents used for microbial identification and susceptibility testing is eligible for IQCP as defined in the Microbiology Checklist.

- The IQCP for a test/device/instrument must have performance specifications for each method, validated or previously used by the laboratory. The laboratory must involve a representative sample of testing personnel in the process of conducting the risk assessment and that laboratory-specific personnel must be represented in the sample.

- The laboratory director must consider the laboratory's clinical and legal responsibilities for accuracy and reliability of test results.

- The laboratory has a sample of local testing personnel to conduct the risk assessment and that laboratory-specific personnel must be represented in the sample.

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- The IQCP for a test/device/instrument must have performance specifications for each method, validated or previously used by the laboratory. The laboratory must involve a representative sample of testing personnel in the process of conducting the risk assessment and that laboratory-specific personnel must be represented in the sample.

- The laboratory director must consider the laboratory's clinical and legal responsibilities for accuracy and reliability of test results.

- The laboratory has a sample of local testing personnel to conduct the risk assessment and that laboratory-specific personnel must be represented in the sample.

- The IQCP for a test/device/instrument must be defined all aspects monitored based on the intended medical uses of the test and for the specific clinical use, unless the information is readily available on any of the package inserts or in the laboratory manual or other documentation. According to the CAP guidelines, IQCPs must be consistent with the laboratory manual or other documentation. The laboratory has a copy of the IQCP approved by the laboratory director. AND

- The laboratory maintains a list of laboratory-developed tests (LDTs) including those performed using microbiology media and reagents used for microbial identification and susceptibility testing is eligible for IQCP as defined in the Microbiology Checklist.

- The IQCP for a test/device/instrument must have performance specifications for each method, validated or previously used by the laboratory. The laboratory must involve a representative sample of testing personnel in the process of conducting the risk assessment and that laboratory-specific personnel must be represented in the sample.

- The laboratory director must consider the laboratory's clinical and legal responsibilities for accuracy and reliability of test results.

- The laboratory has a sample of local testing personnel to conduct the risk assessment and that laboratory-specific personnel must be represented in the sample.
Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes records of the following:

- Review of quality control and instrument/equipment maintenance and function check data at least monthly
- Evaluation of errors relating to preanalytic, analytic and post analytic phases of the testing process
- Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing
- Evaluation of corrective actions taken when problems are identified
- Re-evaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur
- Reapproval of the quality control plan by the laboratory director or designee at least biennially

NOTE: If ongoing assessments identify failures in one or more components of the quality control plan, the laboratory must investigate the cause and consider if modifications are needed to the quality control plan to mitigate potential risk. Common examples of failures include unacceptable proficiency testing results, recurrent out-of-range reagent storage or room temperatures, unacceptable quality control results, use of unvalidated specimen types, and the IQCP not being followed as written.

An example form is available on cap.org through e-LAB Solutions Suite under Checklist Resources IQCP Toolbox that may be used for recording ongoing assessments of the IQCP.
NOTE: This section does not apply to waived tests performed following manufacturer’s instructions.

ANALYTICAL VALIDATION/VERIFICATION

Analytical verification is the process by which a laboratory determines that an unmodified FDA-cleared/approved method is fit for use. Analytical validation is the process used to confirm with objective evidence that a laboratory-developed method is fit for use. See below for requirements for laboratories not subject to US regulations.

Laboratories are required to perform analytical validation or verification of each nonwaived test, method, including instruments of the same make and model and temporary replacement (loaner) instruments. The laboratory must have data for the validation or verification of the applicable method performance specifications.

If an FDA-cleared or approved method was verified by someone other than the laboratory’s personnel (e.g., manufacturer’s quality control), the laboratory must verify such information on accuracy, precision, reportable range, and reference intervals.

The method performance specifications (i.e., the applicable analytic performance characteristics of the test) must be established prior to first use, when an instrument is moved, or any time that the laboratory determines that the method performance specifications such as set-up limitations, environmental conditions, etc. must be changed. The laboratory must follow manufacturer’s instructions in the performance of instruments and equipment to confirm that they function according to expectations. See also Section (COM.30550, COM.30600).

QUALITATIVE TESTING

Not all method performance specifications apply to qualitative tests. For qualitative tests, the laboratory must:

LABORATORIES SUBJECT TO US REGULATIONS:

- For unmodified FDA-cleared or approved tests, the laboratory may use information from manufacturer’s literature on accuracy, precision, reportable range and reference intervals.
- For modified FDA-cleared or approved tests and laboratory-developed tests (LDTs), the laboratory must verify such outside information on specificity, (interferences), reportable range, and reference intervals, as applicable; data on interference must be established prior to first use or any time the method performance specification must be changed.

LABORATORIES NOT SUBJECT TO US REGULATIONS:

- For laboratories performing tests approved by an internationally recognized regulatory authority or published literature, but the laboratory must verify such outside information on accuracy, and local laws and regulations for approval and usage of such tests. These instruments and controls must be validated or verified as applicable; data on interference must be established prior to first use or any time the method performance specification must be changed.
- For tests not approved by an internationally recognized regulatory authority, the laboratory must perform validation or verification as applicable; data on interference must be established prior to first use or any time the method performance specification must be changed.

LABORATORY-DEVELOPED TESTS:

For the purposes of interpreting the checklist requirements, a laboratory-developed test (LDT) is defined as:

1. The test is performed by the clinical laboratory in which the test was developed wholly or in part AND
2. The test is neither FDA-cleared nor FDA-approved (or, for laboratories not subject to US regulations, an internationally recognized regulatory authority or published literature). See also Section (COM.30550, COM.30600).

EMERGENCY USE AUTHORIZATION (EUA)

For laboratories subject to US regulations, an emergency use authorization (EUA) is the legal mechanism of an approved medical product during an emergency to diagnose, treat, or prevent a serious or life th
A laboratory that uses an EUA assay may not be able to establish accuracy, precision, analytical sensitivity, or the assay or test system's protocol as authorized by the FDA without modification and document the alterations. Information on current EUA assays can be found on the FDA website at the following link:
WAIVED TESTS

An approved test performs according to the specifications set forth by the manufacturer when used as directed or modified. An FDA-cleared/approved test method or instrument system delivers reliable results for the intended use, regardless of when it was first introduced by the laboratory. There is no exception for analytical validation or verification of tests introduced prior to a specific date, although the manufacturer’s representative, manufacturer, or published literature, as applicable. A test used in patient management that has both of the following features:

1. Is not approved by an internationally recognized regulatory authority (e.g., the European Union’s Conformité Européenne (CE) Marking), the laboratory may use information from manufacturers, or published literature, but the laboratory must verify such outside information.

2. Analytical verifications may be obtained from manufacturers or published literature, as applicable.

As follows: A test used in patient management that has both of the following features:

1. Is used by the FDA to allow the use of an unapproved medical product (e.g., diagnostic device) or an unapproved medical product for non-labeled indications.

2. Causes a treatable disease condition caused by a chemical, biological, radiological, or nuclear agent (CBRN).
ity, interferences, analytical specificity, (interferences) reportable range and reference interval studies. An alternative mechanism employed to ensure accurate test results.

https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm
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refer to the manufacturer's manual regarding critical requirements,
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Laboratories using an EUA assay must follow