



COLLEGE of AMERICAN
PATHOLOGISTS

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Chemistry and Toxicology Checklist

CAP Accreditation Program



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Chemistry and Toxicology Checklist



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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES

Chemistry and Toxicology Checklist

12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
 - Modifications that may require a change in policy, procedure, or process for continued compliance; or
 - A change to the Phase
3. Deleted/Moved/Merged:
 - Deleted
 - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
 - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
CHM.12925	12/26/2024
CHM.15225	12/26/2024

REVISED Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
CHM.13550	08/24/2023
CHM.13600	08/24/2023
CHM.33900	12/26/2024

DELETED/MOVED/MERGED Checklist Requirements

<u>Requirement</u>	<u>Effective Date</u>
CHM.18800	08/23/2023
CHM.31100	12/25/2024
CHM.31200	12/25/2024
CHM.31300	12/25/2024
CHM.31400	12/25/2024
CHM.31500	12/25/2024
CHM.31550	12/25/2024
CHM.31600	12/25/2024
CHM.31650	12/25/2024
CHM.31700	12/25/2024
CHM.32100	12/25/2024

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a chemistry laboratory section or department.

Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>.



Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

CHEMISTRY & TOXICOLOGY GENERAL ISSUES

PROFICIENCY TESTING

****NEW** 12/26/2024**

CHM.12925 Hemoglobin A1C Testing

Phase I

For laboratories that use accuracy-based proficiency testing (PT) for hemoglobin A1C, the laboratory evaluates its results based on acceptable performance criteria of +/- 6% from the target value, with appropriate corrective action taken for each unacceptable result.

NOTE: The CAP recommends use of accuracy-based PT products, when possible, to evaluate the accuracy of hemoglobin A1C results. Due to limitations in product stability, this may not be available for laboratories outside of the US.

The Centers for Medicare and Medicaid Services (CMS) have established acceptable performance criteria for hemoglobin A1C as a regulated analyte at +/- 8% from the target value. The CAP and all CAP-accepted PT providers must use the +/- 8% criteria in the formal grading of the PT for reporting non-waived results to the CMS. For laboratories participating in the CAP's accuracy-based PT program for hemoglobin A1C, the CAP will also evaluate their results against the target value using +/- 6% performance criteria. This is provided in the participant evaluation and participant summary report. Laboratories must review their performance against the +/- 6% criteria and perform corrective action for each unacceptable result.

Evidence of Compliance:

- ✓ Records of accuracy-based PT evaluation using the +/- 6% performance criteria

QUALITY MANAGEMENT

CALIBRATION AND STANDARDS

CALIBRATION AND VERIFICATION PROCESSES – NONWAIVED TESTS

The remaining requirements in this checklist on CALIBRATION, CALIBRATION VERIFICATION, and ANALYTIC MEASUREMENT RANGE (AMR) VERIFICATION do not apply to waived tests.

This introduction discusses the processes of calibration, calibration verification, and AMR verification.

CALIBRATION: *The process of adjusting an instrument or test system to establish a relationship between the measurement response and the concentration or amount of the analyte that is being measured by the test procedure.*

CALIBRATION VERIFICATION: *The process of confirming that the current calibration settings for each analyte remain valid for a test system.*

Each laboratory must define limits for accepting or rejecting results of the calibration verification process. Calibration verification can be accomplished in several ways. If the manufacturer provides a calibration validation or verification process, it must be followed. Other techniques include (1) assay of the current calibration materials as unknown specimens, and (2) assay of matrix-appropriate materials with target values that are specific for the method.

ANALYTICAL MEASUREMENT RANGE (AMR): *The range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment that is not part of the usual assay process.*

LINEARITY AND THE AMR

Linearity is a fundamental characteristic of many analytic measurement methods, whereby there is a straight-line relationship between “true” analyte concentrations and measured concentrations. In this context, linearity refers to the relationship between the predicted and observed measurement results and not to the relationship between instrument signal output and analyte concentration. For most assays, this relationship is linear within the AMR.

AMR VERIFICATION

Laboratories are required to verify that the appropriate relationship is maintained over the AMR. Laboratories may verify and use an AMR that is narrower than the range defined by the manufacturer. This may be appropriate when materials available for method validation and/or AMR verification are not available to verify the full range claimed by the manufacturer, or reporting values across the full range defined by the manufacturer is not clinically relevant. For many assays, results beyond the AMR can be reported through dilution or concentration studies (see CHM.13710 & CHM.13720). AMR verification is not required for calculated test results (refer to the Definition of Terms in the All Common Checklist) as long as the individual results contributing to the calculation have AMR verification.

Minimum requirements for AMR verification can be met by using matrix appropriate materials, which include low, mid and high concentration or activity range of the AMR with recovery of results that fall within a defined range of the target value. Records of AMR verification must be available.

CLOSENESS OF SAMPLE CONCENTRATIONS OR ACTIVITIES TO THE UPPER AND LOWER LIMITS OF THE AMR

When verifying the AMR, it is required that materials used are near the upper and lower limits of the AMR. Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available. The laboratory director must define limits for accepting or rejecting verification tests of the AMR.

CHM.13000 Calibration Procedure

Phase II



The laboratory calibrates each test system as defined and reviews the calibration records for acceptability.

NOTE: Calibration of FDA-cleared/approved methods must be performed following the manufacturer's instructions, at minimum, including the number, type, and concentration of calibration materials, frequency of calibration, and criteria for acceptable performance. Calibration procedures are typically specified in the manufacturer's instructions but may also be established by the laboratory.

CHM.13100 Calibration and Calibration Verification Materials

Phase II

High quality materials with test system and matrix-appropriate target values are used for calibration and calibration verification whenever possible.

NOTE: Calibration and calibration verification must have defined analyte target values and appropriate matrix characteristics for the clinical specimens and specific assay method. Many instrument systems require calibration materials with system-specific target values to produce accurate results for clinical specimens.

Suitable materials for calibration verification include, but are not limited to:

1. Calibrators used to calibrate the analytical system
2. Materials provided by the manufacturer for the purpose of calibration verification
3. Previously tested unaltered patient/client specimens
4. Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method
5. Third party general purpose reference materials that are suitable for verification

In general, routine control materials and proficiency testing materials are not suitable for calibration verification, except in situations where the material has been shown to be suitable (eg, specifically designated by the method manufacturer) or no other materials are available.

Evidence of Compliance:

- ✓ Records of calibration and calibration verification

CHM.13125 Calibration Materials - Non-FDA Cleared/Approved Assays

Phase II

The quality of all calibration materials used for non-FDA cleared or approved assays is evaluated and recorded.

NOTE: Commercial standards used to prepare calibrators require certificates of quality from the manufacturer, or a quality check as part of the initial assay validation process. The laboratory must ensure the accuracy of a new lot of calibrators by checking the new lot against the current lot.

CHM.13175 Pure Controlled Substances Phase II

If the laboratory uses chemicals (for standards, controls, etc.) covered by the Controlled Substances Act, it maintains appropriate licenses.

NOTE: The intent is to be compliant with national, federal, state (or provincial), and local laws and regulations.

For US laboratories, a DEA license, and in some states, a state license is required for controlled substances. A DEA license is not required for certain commercial solutions of controlled substances.

CHM.13400 Recalibration/Calibration Verification Criteria Phase II



Criteria for the frequency and acceptability of recalibration or calibration verification are defined and followed.

NOTE: Laboratories must either recalibrate or perform calibration verification at least every six months and if any of the following occur:

1. At changes of reagent lots unless the laboratory can demonstrate that the use of different lots does not affect the accuracy of patient/client results
2. If QC shows an unusual trend or shift or is outside acceptable limits and the system cannot be corrected to bring control values into the acceptable range
3. After major preventive maintenance or change of a critical instrument component
4. When recommended by the manufacturer

Single use devices, and other test devices that do not allow user calibration, do not require calibration verification.

Evidence of Compliance:

- ✓ Records of calibration verification at defined frequency

CHM.13500 Recalibration Phase II

The test system is recalibrated when calibration verification fails to meet the established criteria of the laboratory.

Evidence of Compliance:

- ✓ Records of recalibration, if calibration or calibration verification has failed

****REVISED** 08/24/2023**

CHM.13550 AMR Verification Materials Phase II



Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials which, at a minimum, include the low, mid and high range of the AMR, and appropriate acceptance criteria are defined.

NOTE: The matrix of the sample (ie, the environment in which the sample is suspended or dissolved) may influence the measurement of the analyte. In many cases, the method manufacturer will recommend suitable materials. Other suitable materials for AMR verification include the following:

1. Linearity material of appropriate matrix, eg, CAP CVL Survey-based or other suitable linearity verification material
2. Previously tested patient/client specimens, that may be altered by admixture with other specimens, dilution, spiking in known amounts of an analyte, or other technique
3. Primary or secondary standards or reference materials with matrix characteristics and target values appropriate for the method
4. Patient samples that have reference method assigned target values
5. Control materials, if they adequately span the AMR and have method-specific target values

Factors to consider in verifying the AMR are the expected analytic imprecision near the limits, the clinical impact of errors near the limits, and the availability of test specimens near the limits. It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations and activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion.

Evidence of Compliance:

- ✓ Records of AMR verification

****REVISED** 08/24/2023**

CHM.13600 AMR Verification

Phase II



Verification of the analytical measurement range (AMR) is performed at least every six months and following defined criteria. Records are retained.

NOTE: The AMR must be verified at least every six months after a method is initially placed in service and if any of the following occur:

1. At changes of reagent lots unless the laboratory can demonstrate that the use of different lots does not affect the accuracy of patient/client results, and the range used to report patient/client test data
2. If QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range
3. After major preventive maintenance or change of a critical instrument component
4. When recommended by the manufacturer

It is not necessary to independently verify the AMR if the calibration of an assay includes calibrators that span the full range of the AMR, with low, midpoint and high values represented (ie, three points) and if the system is calibrated at least every six months. A one-point or two-point calibration does not include all of the necessary points to verify the AMR.

AMR verification is not required for calculated test results as long as the individual results contributing to the calculation have AMR verification.

AMR verification is not required for methods that measure an analyte quantitatively or semi-quantitatively yet report a qualitative value based on concentration threshold. For such methods, eg, drugs of abuse, refer to checklist requirement CHM.13750.

Evidence of Compliance:

- ✓ Records of AMR verification, as required, at least every six months

CHM.13710 Diluted or Concentrated Samples

Phase II



If a result is greater than or less than the AMR, a numeric result is not reported unless the sample is processed by dilution, a mixing procedure or concentration so that the result falls within the AMR.

NOTE:

1. A measured value that is outside the AMR may be unreliable and should not be reported in routine practice. Dilution, a mixing procedure* or concentration of a sample may be required to achieve a measured analyte activity or concentration that falls within the AMR. The result must be within the AMR before it is mathematically corrected by the concentration or dilution factor to obtain a reportable numeric result.
2. For each analyte, the composition of the diluent solution and the appropriate volumes of sample and diluent must be specified in the procedure manual. Specifying acceptable volumes is intended to ensure that the volumes pipetted are large enough to be accurate without introducing errors in the dilution ratio.

3. All dilutions, whether automatic or manual, should be performed in a way that ensures that the diluted specimen reacts similarly to the original specimen in the assay system. For some analytes, demonstrating that more than one dilution ratio similarly recovers the elevated concentration may be helpful.
4. This checklist requirement does not apply if the concentration or activity of the analyte that is outside the AMR is reported as "greater than" or "less than" the limits of the AMR.

*This procedure is termed the "method of standard additions." In this procedure, a known quantity (such as a control) is mixed with the unknown, and the concentration of the mixture is measured. If equal volumes of the two samples are used, then the result is multiplied by two, the concentration of the known subtracted, and the concentration of the unknown is the difference.

Evidence of Compliance:

- ✓ Patient reports or worksheets

CHM.13720 Maximum Dilution

Phase II



For analytes that may have results falling outside the limits of the AMR, the laboratory defines the maximum dilution that may be performed to obtain a reportable numeric result.

NOTE:

1. For each analyte, the laboratory procedure defines the maximum dilution that falls within the AMR and that can be subsequently corrected by the dilution factor to obtain a reportable numeric result. Note that for some analytes, an acceptable dilution procedure may not exist because dilution would alter the analyte or the matrix causing erroneous results, eg, free drugs or free hormones. Also note that, for some analytes, there may be no clinical relevance to reporting a numeric result greater than a stated value.
2. Analytes for which a dilution procedure is unable to bring the activity or concentration into the AMR should be reported as "greater than" the highest estimated values.
3. Establishment of allowable dilutions is performed when a method is first placed into service. The laboratory director is responsible for establishing the maximum allowable dilution of samples that will yield a credible laboratory result for clinical use.

Evidence of Compliance:

- ✓ Patient reports or worksheets

CHM.13730 Concentration Techniques

Phase I



Concentration techniques for quantitative tests are verified.

NOTE: Techniques used to concentrate specimens for analysis must be verified at specified, periodic intervals (not to exceed one year or manufacturer's recommendations).

Evidence of Compliance:

- ✓ Records of concentration technique verification at defined frequency

CHM.13750 Cut-Off Values for Qualitative Tests

Phase II



For qualitative tests that use a quantitative cut-off value to distinguish positive from negative results, the analytic performance around the cut-off value is verified or established initially, and reverified at least every six months thereafter.

NOTE: This requirement applies to tests that report qualitative results based on a quantitative measurement using a threshold (cut-off value) to discriminate between positive and negative results for clinical interpretation. It does not apply to methods where the laboratory is not able to access the actual numerical value from the instrument.

Appropriate materials for establishment and verification of the cut-off are identical to those recommended for calibration verification. The requirement can be satisfied by the process of calibration or calibration verification using calibrators or calibration verification materials with values near the cut-off. It may also be satisfied by the use of QC materials that are near the cut-off value if those materials are claimed by the method manufacturer to be suitable for verification of the method's calibration process.

Verification of the cut-off should also be performed at changes of lots of analytically critical reagents (unless the laboratory director has determined that such changes do not affect the cut-off); after replacement of major instrument components; after major service to the instrument; and when QC materials reflect an unusual trend or shift or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

For FDA-cleared or approved tests, the clinical appropriateness of the cut-off value is evaluated as part of the clinical validation performed by the manufacturer. For laboratory-developed tests and modified FDA-cleared or approved tests, refer to COM.40640 for validation of clinical claims.

Evidence of Compliance:

- ✓ Records of initial establishment and verification of the cut-off value at defined frequency

CONTROLS

Controls are used to ensure that a test system is performing correctly. Traditionally, controls are samples that act as surrogates for patient/client specimens, periodically processed like a patient/client sample to monitor the ongoing performance of the entire analytic process. Under certain circumstances, other types of controls (electronic, procedural, built-in) may be used. (Details are in the checklist requirements in this section, below.)

CONTROLS – NONWAIVED TESTS

CHM.13900 Daily QC - Nonwaived Tests

Phase II



The laboratory performs controls for quantitative and qualitative tests each day of testing, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, and when changes occur that may impact patient results.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed.

Controls must be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate. Daily quality control must be run as follows:

1. Quantitative tests - two controls at different concentrations at least daily
2. Qualitative tests - a negative control and a positive control (when applicable) at least daily
3. Tests producing a graded or tiered result - a negative control and a control material with graded or tiered reactivity, as applicable, at least daily (serially diluted positive controls are not required)

Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria.

If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have

an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

Evidence of Compliance:

- ✓ Records of QC results including external and internal control processes **AND**
- ✓ Manufacturer product insert or manual

CHM.13950 Fluorescent Antibody Stain QC

Phase II

Positive and negative controls are included with each patient run for all fluorescent antibody stains (eg, ANA IFA).

Evidence of Compliance:

- ✓ Records of fluorescent antibody stain QC at defined frequency

CHM.14000 Control Range Establishment or Verification

Phase II



The laboratory establishes or verifies an acceptable control range for each lot of control material.

NOTE: For unassayed control materials, the laboratory must establish an acceptable control range by repetitive analysis in runs that include previously tested control material. For assayed control materials, the laboratory must verify control ranges supplied by the manufacturer.

Control values supplied by the manufacturer may be used without verification for qualitative (eg, positive or negative) testing.

Evidence of Compliance:

- ✓ Records for control range establishment or verification of each lot

CHM.14125 Calibrator Preparation

Phase II



If the laboratory prepares calibrators and controls in-house, these materials are prepared separately.

NOTE: In general, calibrators should not be used as QC materials. If calibrators are used as controls, then different preparations should be used for these two functions.

CHM.14150 Calibrators as Controls

Phase I



If a calibrator obtained from an outside supplier is used as a control, it is a different lot number from that used to calibrate the method.

NOTE: In general, calibrators should not be used as QC materials. However, this practice may be necessary for some methods when a separate control product is not available. In such cases, the calibrator used as a control must be from a different lot number than that used to calibrate the method.

Evidence of Compliance:

- ✓ QC/calibrator records

CHM.14200 Alternative Control Procedures

Phase II



If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:

- ✓ Records of alternative control procedures

CHM.14300 QC Data

Phase II

Quality control data are organized and presented so they can be evaluated daily by the technical staff to detect problems, trends, etc.

NOTE: Results of controls must be recorded or plotted to readily detect a malfunction in the instrument or in the analytic system. These control records must be readily available to the person performing the test.

CHM.14500 Numeric QC Data

Phase II

For numeric QC data, quality control statistics (eg, SD and CV) are calculated monthly to define and monitor analytic imprecision.

NOTE: The laboratory must evaluate the imprecision statistics (eg, SD and CV, or other appropriate statistics) monthly to confirm that the test system is performing within acceptable limits. For whole blood methods, where stabilized whole blood or other suitable material is not available for QC, such statistics may be generated from previous patient/client samples using the SD of duplicate pairs or other patient data based statistical procedures.

This checklist requirement does not apply to external controls run only to verify new lots/shipments of test materials. However the laboratory should have defined acceptable limits for such controls (either from the manufacturer, or developed by the laboratory).

Evidence of Compliance:

- ✓ QC records showing monthly monitoring for imprecision

CHM.14600 QC Corrective Action

Phase II

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

NOTE: The actions taken must be consistent with the laboratory's quality control program (GEN.30000). Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results. For example, evaluation could include comparison of patient means for the run in question to historical patient means, and/or review of selected patient results against previous results to see if there are consistent biases (all results higher or lower currently than previously) for the test(s) in question.

The corrective action for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:

- ✓ Records of corrective action for unacceptable control results

CHM.14800 QC Handling

Phase II



The laboratory tests control specimens in the same manner and by the same personnel as patient/client samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:

- ✓ Records reflecting that QC is run by the same personnel performing patient testing

CHM.14900 QC Confirmation of Acceptability

Phase II

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:

- ✓ Records of control result approval

CHM.14916 Monthly QC Review

Phase II

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:

- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

RESULTS REPORTING

****NEW** 12/26/2024**

CHM.15225 eGFR and LDL Cholesterol Calculated Test Results

Phase I

Clinicians have access to information regarding the equation used to calculate results for estimated glomerular filtration rates (eGFR) and low-density lipoprotein (LDL) cholesterol.

NOTE: Calculated results may differ based on which equation is used. This may limit clinical assessment of results and/or comparability of calculated results across laboratories, particularly when the source equation is not readily available to providers.

The information can be made available to clinicians using different approaches, such as on the patient report, test reference guide, or inclusion of the equation name in the test name.

Evidence of Compliance:

- ✓ Patient reports with information on the calculation used **OR**
- ✓ Test reference guide or other mechanism for providing calculation information

GENERAL CHEMISTRY

CHEMISTRY

THERAPEUTIC DRUG MONITORING

CHM.28900	Specimen Collection/Drug Dosing	Phase I
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As applicable, information is available to clinical personnel for the optimal specimen collection time in relation to drug dosing.

Evidence of Compliance:

- ✓ Test reference guide **OR** other mechanism for providing guidance for specimen collection for therapeutic drug testing

CHM.29000	TDM Results	Phase II
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Where applicable, TDM results are reported in relation to patient dosing and/or timing information.

NOTE: The intent is to have a mechanism whereby the clinician can easily and accurately link TDM results from the laboratory to the dosage and time of drug administration. Ideally, the test result, dose and administration time would be reported in juxtaposition on the patient chart. This may be the responsibility of the laboratory, or an integrating function of reported laboratory analytic data with clinical information from other sources.

CHM.29025	Immunosuppressive Drug Result Reporting	Phase II
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For the reporting of immunosuppressive drug results, the patient report contains all of the following:

1. Appropriate therapeutic ranges based on the test method used
2. Analytical method (all tests) and method platform (immunoassays only)
3. Elements required in GEN.41096

NOTE: For immunosuppressive drugs (eg, cyclosporine, sirolimus, tacrolimus, mycophenolic acid, everolimus), the therapeutic range may depend upon the test method, type of transplant, and length of time since the transplant procedure. Results from different types of samples and different methods are not interchangeable.

Evidence of Compliance:

- ✓ Patient results showing required report elements

TUMOR MARKER TESTING

CHM.29050 Tumor Marker Result Reporting

Phase I

The following information is available to clinicians for the reporting of tumor marker results:

- **Manufacturer and methodology of the tumor marker assay**
- **A statement indicating that patient results determined by assays using different manufacturers or methods may not be comparable.**

NOTE: As used in this checklist, a tumor marker is defined as any analyte that is serially measured over time primarily as an indicator of tumor burden.

Tumor marker results obtained can vary due to differences in assay methods and reagent specificity. If there is an assay change while monitoring a patient, the CAP recommends (but does not require) that the laboratory run parallel measurements with both assays.

The required information does not need to be reported with the test result if it is readily available elsewhere (eg, test reference guide).

Evidence of Compliance:

- ✓ Patient reports with required elements **OR**
- ✓ Test reference guide or other mechanism for providing ordering and interpretation information

BLOOD GAS ANALYSIS

The Chemistry and Toxicology Checklist is intended for inspection of laboratory sections performing testing in a dedicated space (eg, main laboratory, respiratory therapy). Laboratories performing testing at or near the patient bedside (eg, portable instruments) must use the Point-of-Care Testing Checklist.

The number of checklists needed for test sites under the same CLIA number and CAP number is determined as follows:

- *Blood gas testing performed in more than one area under the **same supervision** use one Chemistry and Toxicology Checklist (eg, main laboratory and stat lab);*
- *Blood gas testing performed in more than one area under **different supervision** use separate Chemistry and Toxicology Checklists for each separately supervised site (eg, main laboratory and respiratory therapy department);*

Testing sites within an institution with different CLIA and CAP numbers must submit separate applications and have separate full inspections.

SPECIMEN COLLECTION AND HANDLING

CHM.33800 Arterial Puncture Complications

Phase II

Personnel performing arterial punctures are trained in the recognition and management of possible complications of this procedure.

Evidence of Compliance:

- ✓ Records of training in personnel files

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CHM.33900 Collateral Circulation

Phase II



For radial artery sampling, a test for collateral circulation is performed before arterial puncture if clinically indicated, with results recorded.

NOTE: Any of the various technologies evaluated in the published literature are acceptable. Consensus should be established between the laboratory and involved clinicians to define situations that require testing for collateral circulation, if any, to potentially avert patient injury.

Evidence of Compliance:

- ✓ Records of collection site and results of applicable collateral circulation testing

CHM.34000 Ambient Air Contamination

Phase II



The laboratory has a process to prevent ambient air contamination of blood gas samples before analysis.

BLOOD GAS INSTRUMENTS

CHM.34200 Calibration Materials

Phase II

The materials used for calibration of the pH, CO₂, and O₂ sensors are either in conformance with the instrument manufacturer's specifications or traceable to NIST Standard Reference Materials.

CHM.34300 Calibration - Blood Gas Instruments

Phase II



Blood gas instruments are calibrated according to manufacturer's specifications and at least as frequently as recommended by the manufacturer.

NOTE: Some instruments have built in calibration that is performed automatically by the instrument; however, there must be some defined procedure for verifying the reliability of this process. If appropriate, the calibration must compensate for the influence of barometric pressure.

Evidence of Compliance:

- ✓ Records for calibration at defined frequency

CHM.34400 Daily QC - Blood Gas Instruments

Phase II



A minimum of one level of quality control for pH, pCO₂ and pO₂ is analyzed at least every eight hours of operation when patient specimens are tested, or more frequently if specified in the manufacturer's instructions or laboratory procedure, and when changes occur that may impact patient results.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed. Controls must be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, or change of a critical instrument component, or with software changes, as appropriate.

If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the

control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.

Evidence of Compliance:

- ✓ Records of QC results including external and internal control processes **AND**
- ✓ Manufacturer product insert or manual

CHM.34500 Daily QC - Blood Gas Instruments

Phase II

The control materials for pH, pCO₂ and pO₂ represent both high and low values on each day of patient testing.

NOTE: If using internal controls, the electronic simulators should challenge at high and low values.

Evidence of Compliance:

- ✓ QC records reflecting the appropriate use of controls

CHM.34600 QC - Blood Gas Instruments

Phase II

At least one level of quality control material for pH, pCO₂ and pO₂ is included each time patient specimens are tested, except for automated instruments that internally calibrate at least once every 30 minutes of use.

NOTE: An internal quality control process (eg, electronic/procedural/built-in) may be used to meet this requirement if an individualized quality control plan (IQCP) has been approved by the laboratory director.

Evidence of Compliance:

- ✓ QC results **OR** record of internal calibrator