COLLEGE of AMERICAN PATHOLOGISTS

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Urinalysis Checklist

CAP Accreditation Program

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Urinalysis 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
Urinalysis 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
None

REVISED Checklist Requirements
None

DELETED/MOVED/MERGED Checklist Requirements
None

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a urinalysis 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).*

QUALITY MANAGEMENT

SPECIMEN COLLECTION AND HANDLING

URN.22000 Urine Specimen Collection **Phase II**

Written instructions are provided to patients and personnel for the proper collection of clean voided urine specimens (ie, in nursing procedure manual or in specimen collection area).

NOTE: Proper collection of urine specimens is important to avoid contamination, or deterioration of constituents. Instructions must be available to all personnel that collect urine specimens to outline proper specimen collection. While not required, the CAP suggests having instructions in foreign languages common to the population served by the laboratory.

URN.22300 Urine Specimen Examination **Phase II**

Urine specimens without chemical preservative or refrigeration are examined within two hours of collection.

Evidence of Compliance:

- ✓ Records of time of collection and examination

URN.22400 Urine Preservation **Phase II**

The laboratory uses defined methods for urine preservation (refrigeration or specified preservative) for all tests when analysis will be delayed.

NOTE: If testing is unavoidably delayed (night collection, etc.), the laboratory must define the method for appropriate preservation of specimens to maintain integrity of cells and formed elements.

- *Refrigeration of urine may be acceptable because it inhibits bacterial growth; however, it does not prevent the lytic effects of low specific gravity or alkaline pH and may induce urine crystal formation.*
- *Preparations that contain boric acid/sorbitol or release formaldehyde may be effective preservatives for some, but not all, urine tests. If preservatives are used, the procedure must include instructions to indicate which preservative was added. In addition, the testing procedure must also identify any pre-analytic errors attributable to such preservatives.*

CONTROLS AND STANDARDS – WAIVED TESTS

URN.24320 QC - Waived Tests **Phase II**

The laboratory follows manufacturer's instructions for quality control, reviews results, and records acceptability prior to reporting patient results.

NOTE: Quality control must be performed according to manufacturer's instructions. To detect problems and evaluate trends, testing personnel or supervisory staff must review quality control data on days when controls are run prior to reporting patient results. The laboratory director or designee must review QC data at least monthly or more frequently if specified in the laboratory QC policy.

*With respect to internal controls, acceptable control results must be recorded, at a minimum, once per day of patient testing for each device.**

**Acceptable internal control results need not be recorded, if (and only if) an unacceptable instrument control automatically locks the instrument and prevents release of patient results.*

Evidence of Compliance:

- ✓ Records showing confirmation of acceptable QC results

URN.24330 QC Corrective Action - Waived Tests **Phase II**

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

URN.24342 Calibration, Calibration Verification - Waived Tests **Phase II**

For waived tests, the laboratory follows manufacturer's instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:

- ✓ Records for calibration/calibration verification/related functions documented as required by the manufacturer **AND**
- ✓ Records of recalibration or other appropriate corrective action when calibration verification is unacceptable

CONTROLS AND STANDARDS – NONWAIVED TESTS

CALIBRATION

NOTE: Explanatory notes on calibration may be found in the Chemistry checklist.

URN.24345 Calibration Procedure **Phase II**

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

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

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.

URN.24355 Calibration/Calibration Verification Criteria **Phase II**

Criteria for the frequency and the acceptability of calibration 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 of acceptable limits, and the system cannot be corrected to bring control values into the acceptable range*
3. *After major maintenance or service*
4. *When recommended by the manufacturer*

Evidence of Compliance:

- ✓ Records of calibration verification at defined frequency

URN.24365 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

CONTROLS FOR NONWAIVED TESTS

URN.24370 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 for each test performed. 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 controls must be run as follows:
- *Quantitative tests - two controls at different concentrations at least daily*
- *Qualitative tests - a negative control and a positive control (when applicable) at least daily*

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

URN.25280 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

URN.25287 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

URN.25300 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 test results obtained in an analytically unacceptable test run or since the last acceptable test run must be evaluated to determine if there is a significant clinical difference in patient results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

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

URN.25350 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient 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 performed by the same personnel performing patient testing

URN.25400 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient results.

Evidence of Compliance:
- ✓ Records of control result approval

URN.25750 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

PROCEDURES AND TEST SYSTEMS

URINALYSIS PARAMETERS

The elements of a macroscopic urinalysis vary according to the patient population served by a laboratory and the needs of clinicians. A complete routine urinalysis should include at least the following: glucose, protein, blood/hemoglobin, leukocyte esterase, specific gravity, and nitrite. Other analytes (eg, color, clarity, turbidity, bilirubin, ketones, pH and urobilinogen) are optional for CAP accreditation, but their utility should be reviewed with the medical staff served by the laboratory. There are few occasions when the color, clarity, and odor of urine are of clinical significance.

URN.30425 Microscopic Exam Correlation **Phase II**

The laboratory correlates microscopic sediment findings (such as casts, RBC or WBC) with macroscopic results (presence of protein, positive occult blood, positive leukocyte esterase, etc.).

URINALYSIS - MANUAL MICROSCOPY

URN.30750 Reference Materials **Phase I**

Reference materials (atlases, charts or photomicrographs) are available to assist in the microscopic identification of urine sediment.

URN.30800 Morphologic Observation Evaluation **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing urine sediment microscopy at least annually.

NOTE: The laboratory must ensure the identification of urine sediment constituents is reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:

1. *Circulation of a pre-graded set of preserved urine sediments with defined abnormalities involving leukocytes, erythrocytes, casts, bacteria, yeast, etc.*
2. *Multi-headed microscopy*
3. *Use of urine sediment photomicrographs with referee and consensus identifications (eg, former CAP surveys clinical microscopy photomicrographs)*
4. *Digital images*
5. *Enrollment and participation of all personnel in an external assessment program for morphologic observation for urine sediment microscopy.*

The laboratory director or designee must determine acceptability criteria for agreement. The laboratory must maintain records of performance and record corrective actions taken for personnel demonstrating significant discrepancies from the group consensus.

Evidence of Compliance:

- ✓ Records of evaluation **AND/OR**
- ✓ Records of enrollment/participation of staff in an external assessment program

AUTOMATED AND SEMI-AUTOMATED SYSTEMS

AUTOMATED MICROSCOPY SYSTEMS

URN.31400 Erroneous Morphology Results **Phase II**

The laboratory follows written criteria for identifying urine specimens that may give clinically relevant erroneous results.

NOTE: Excessively turbid urine samples may block aperture flow or interfere with visual detection of pertinent microscopic elements. Manual microscopic examination must be performed if problems are noted with accurate identification or classification of clinically important urine structures, such as casts.

URN.31425 Carryover Detection **Phase II**

The laboratory has a process to detect and evaluate potential carryover for the automated microscopy system.

NOTE: The laboratory must have records of carryover studies performed as part of the initial evaluation of an instrument and after major maintenance or repair of the pipetting assembly of the instrument.

If carryover is detected or cannot be evaluated (eg, spermatozoa), the test procedure must include criteria for identifying results that may be affected and define actions to be taken to prevent the release of incorrect results (eg, run blank samples after a turbid or bloody sample, reflex to manual microscopic review).

Evidence of Compliance:

- ✓ *Records of reassessment of samples with potential carryover*

URN.31600 Daily QC - Automated Microscopy Systems **Phase II**

The laboratory performs controls at two different levels each day of patient testing to detect instrument malfunction on automated microscopy systems.

NOTE: Accumulation of sediment can block the flow aperture, leading to spuriously low counts.

Evidence of Compliance:

- ✓ Records of daily QC results

URN.31700 Reportable Range **Phase II**

Upper and lower limits of all quantitative reportable parameters on automated microscopy systems are defined, and results that fall outside these limits are reported properly.

NOTE: The laboratory must initially establish or verify the reportable range for each parameter of its automated microscopy system. The laboratory may report counts that are lower or higher than the reportable range as "less than" the lower limit or "greater than" the higher limit. Alternatively, when clinically appropriate, the laboratory may dilute samples with results exceeding the higher limit to bring the value within the defined analytical measurement range, and apply the appropriate dilution factor.

Evidence of Compliance:

- ✓ Record of action taken when limits are exceeded, including the reporting of results