COLLEGE of AMERICAN PATHOLOGISTS

Master

Urinalysis Checklist

CAP Accreditation Program

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Urinalysis Checklist

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ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

Participants of the CAP accreditation programs may download the checklists from the CAP website (cap.org) by logging into e-*LAB* Solutions Suite. 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.

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES
Urinalysis Checklist
09/22/2021 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 on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements
None

REVISED Checklist Requirements

Requirement	Effective Date
URN.22000	09/22/2021
URN.22300	06/04/2020
URN.22400	06/04/2020
URN.24370	09/22/2021
URN.31250	09/22/2021
URN.31400	09/22/2021
URN.31700	09/22/2021

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.

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

Inspector Instructions:

	• Sampling of urinalysis specimen collection and handling policies and procedures
	• Urine collection instructions for patients
	• What is your course of action when you receive unacceptable urine specimens?

*****REVISED** 09/22/2021***

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.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Urinalysis; Approved Guideline - Third Edition.* CLSI Document GP16-A3. (ISBN 1-56238-687-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 2009.

***REVISED** 06/04/2020*

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

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

Evidence of Compliance:

- ✓ Written procedure defining criteria for urine specimen handling **AND**
- ✓ Records of time of collection and examination

REFERENCES

1) Haber MH. Quality assurance in urinalysis. *Clinics in Lab Med.* 1998;8:432-436
2) Clinical and Laboratory Standards Institute (CLSI). *Urinalysis; Approved Guideline - Third Edition.* CLSI Document GP16-A3. (ISBN 1-56238-687-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 2009.
3) Howanitz PJ, *et al.* Timeliness of urinalysis. A College of American Pathologists Q-Probes study of 346 small hospitals. *Arch Pathol Lab Med.* 1997;121:667-672
4) Semeniuk H, *et al.* Evaluation of the leukocyte esterase and nitrite urine dipstick screening tests for detection of bacteriuria in women with suspected uncomplicated urinary tract infections. *J Clin Microbiol*. 1999;37:3051-3052

***REVISED** 06/04/2020*

URN.22400 Urine Preservation **Phase II**

There is a written procedure defining the method for urine preservation (refrigeration or specified preservative) within the laboratory for all tests when analysis is to 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.*

Evidence of Compliance:

- ✓ Written procedure for urine specimen preservation

REFERENCES

1) Delanghe JR, Speeckaert MM. Preanalytics in urinalysis. *Clin Biochem.* 2016;49(18):1346-50.
2) Clinical and Laboratory Standards Institute (CLSI). *Urinalysis; Approved Guideline - Third Edition.* CLSI Document GP16-A3. (ISBN 1-56238-687-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA, 2009.
3) Howanitz PJ, *et al.* Timeliness of urinalysis. A College of American Pathologists Q-Probes study of 346 small hospitals. *Arch Pathol Lab Med.* 1997;121:667-672

CONTROLS AND STANDARDS – WAIVED TESTS

Inspector Instructions:

	• Sampling of quality control policies and procedures • Sampling of QC records
	• Sampling of QC materials (labeling, storage)
	• How do you determine when quality control is unacceptable and when corrective actions are needed?
	• Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

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

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

✓ Written procedure consistent with manufacturer's instructions for each waived test **AND**
✓ Records showing confirmation of acceptable QC results

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

There is evidence of 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:

- ✓ Written procedure consistent with manufacturer's instructions for each waived test **AND**
- ✓ 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.

Inspector Instructions:

	• Sampling of calibration policies and procedures • Sampling of calibration/calibration verification records
	• What is your course of action when calibration is unacceptable? • When was the last time you performed a calibration procedure and how did you verify the calibration?
	• Further evaluate the responses, corrective actions and resolutions for unacceptable calibration results

URN.24345 Calibration Procedure **Phase II**

Calibration procedures for each test system are appropriate, and the calibration records are reviewed 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 must be performed following manufacturer's instructions, at minimum, including the number, type, and concentration of calibration materials, frequency of calibration, and criteria for acceptable performance.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1255]

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

Criteria are established for frequency of calibration or calibration verification, and the acceptability of results.

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:

- ✓ Written policy defining the method, frequency and limits of acceptability of calibration verification for each instrument/test system **AND**
- ✓ Records of calibration verification at defined frequency

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7165 [42CFR493.1255]
2) Miller WG. Quality control. In: Henry's Clinical Diagnostic and Management by Laboratory Methods, 21st Edition, ed McPherson RA, Pincus MR, Saunders Elsevier, 2007:99-111.

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:

- ✓ Written policy defining criteria for recalibration **AND**
- ✓ Records of recalibration, if calibration or calibration verification has failed

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7165 [42CFR493.1255]

CONTROLS FOR NONWAIVED TESTS

Inspector Instructions:

READ	• Sampling of quality control policies and procedures • Sampling of QC records, including external and internal quality control processes
ASK	• How do you determine when QC is unacceptable and when corrective actions are needed? • How does your laboratory verify or establish acceptable quality control ranges?
DISCOVER	• Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

- Use QC data to identify tests that utilize internal quality control processes to confirm that any individualized quality control plan (IQCP) is used as approved by the laboratory director

***REVISED** 09/22/2021*

URN.24370 Daily QC - Nonwaived Tests **Phase II**

Controls are run at least each day testing is performed, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, for quantitative and qualitative tests, 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 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**
✓ Written quality control procedures **AND**
✓ Manufacturer product insert or manual

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3708 [42CFR493.1256(d)(3)(ii)], [42CFR493.1256(d)(6)].
2) Clinical and Laboratory Standards Institute (CLSI). *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI document EP12-A2 (ISBN 1-56238-654-9). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2008.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.

URN.25280 Control Range Establishment or Verification **Phase II**

An acceptable control range is established or verified for each lot of control material.

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

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

Evidence of Compliance:

✓ Written procedure to establish or verify control ranges **AND**

- ✓ 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, there are written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. Examples of alternative procedures may include 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:

- ✓ Written procedures for alternative quality control **AND**
- ✓ Records of alternative control procedures

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1256(h)].

URN.25300 QC Corrective Action **Phase II**

There are records of corrective actions taken when control results exceed defined acceptability limits.

NOTE: 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.).

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1046[42CFR493.1282(b)(2)]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):[42CFR493.1282(b)(1)(i)].

URN.25350 QC Handling **Phase II**

Control specimens are tested in the same manner and by the same personnel as patient samples.

NOTE: QC specimens must be analyzed by personnel who routinely perform patient testing--this does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysts 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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7166 [42CFR493.1256(d)(7) and (8)].

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

The results of controls are reviewed for acceptability before reporting results.

Evidence of Compliance:

- ✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results **AND**
- ✓ Records of control result approval

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7166 [42CFR493.1256(f)]

URN.25750 Monthly QC Review **Phase II**

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should 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 including follow-up for outliers, trends or omissions

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

	• Refractometer calibration check records
	• How do you verify the function of the refractometer?

URN.26100 Refractometer Calibration Check **Phase I**

Refractometers with specific gravity capability are checked at least annually with appropriate solutions of known specific gravity and/or refractive concentration index.

NOTE: This annual calibration check is required in addition to the daily QC requirement for non-waived testing.

REFERENCES

1) Haber MH. Quality assurance in urinalysis. *Clinics in Lab Med.* 1988;8:432-436
2) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.

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.

Inspector Instructions:

- Sampling of urinalysis policies and procedures
- Sampling of patient reports with appropriate reportable parameters

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

There is a written procedure for correlation of microscopic sediment findings (such as casts, RBC or WBC) with macroscopic results (presence of protein, positive occult blood, positive leukocyte esterase, etc.).

REFERENCES
1) van Nostrand JD, *et al.* Poor predictive ability of urinalysis and microscopic examination to detect urinary tract infection. *Am J Clin Pathol.* 2000;113:709-713
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1281(b)]

URN.30700 Microscopic Exam **Phase II**

Microscopic examination of urine sediment is performed as part of complete urinalysis testing, or there are specific, written criteria defining the circumstances under which the microscopic examination may be omitted/abbreviated.

NOTE: There is evidence that in random urinalysis screening (hospital admissions, insurance physicals), urines that are yellow and clear and have negative chemical reactions have a markedly low yield on microscopic examination. Optimal service may entail protocols defining when microscopic examination of urine sediment should or should not be done.

Evidence of Compliance:

- ✓ Written procedure defining criteria for performance of manual microscopic examinations **AND**
- ✓ Patient reports with microscopic results **OR** records reflecting procedure for abbreviated testing

REFERENCES
1) Wenz B, Lampasso JA. Eliminating unnecessary urine microscopy. Results and performance characteristics of an algorithm based on chemical reagent strip testing. *Am J Clin Pathol.* 1989;92:78-81
2) Schumann GB, Friedman SK. Comparing slide systems for microscopic urinalysis. *Lab Med.* 1996;27:270-277
3) Hooper DW. Detecting GD and preeclampsia: effectiveness of routine urine screening for glucose and protein. *J Reprod Med.* 1996;41:885-888
4) Jou WW, Powers RD. Utility of dipstick analysis as a guide to management of adults with suspected infection or hematuria. *South Med J.* 1998;91:266-269
5) van Nostrand JD, *et al.* Poor predictive ability of urinalysis and microscopic examination to detect urinary tract infection. *Am J Clin Pathol.* 2000;113:709-713
6) Ringsrud KM. Cells in the urine sediment. *Lab Med.* 2001;32:153-155

7) Roggeman S, Zaman Z. Safely reducing manual urine microscopy analyses by combining urine flow cytometer and strip results. *Am J Clin Pathol*. 2001;116:872-878
8) Clinical and Laboratory Standards Institute. *Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline* 2nd ed. CLSI document POCT10-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2011.

URINALYSIS - MANUAL MICROSCOPY

Inspector Instructions:

	• Sampling of urinalysis policies and procedures • Sampling of records of morphologic observation consistency evaluation
	• Reference materials (atlas, photomicrograph, chart available)
	• How does your laboratory ensure consistency among personnel performing urine sediment morphology?

URN.30725 Azoospermic Specimen Result Reporting **Phase I**

For azoospermic and post-vasectomy seminal fluid specimens, the laboratory clearly communicates the findings of the assay and either employs a concentrating technique on seminal fluid or includes a comment in the patient report indicating that a concentrating technique was not performed.

NOTE: Without a concentration technique, the presence of both motile and non-motile sperm may not be detected. The method for detection of motile and non-motile sperm and the laboratory findings must be clearly communicated on the patient report so that the clinician can interpret the results in context to the method performed. The decision on the method used and extent of testing to be performed should be made in consultation with the medical staff served.

The American Urological Association (AUA) Vasectomy Guideline recommends a careful evaluation of an uncentrifuged specimen and does not recommend centrifugation of the specimen for further assessment. The AUA Guideline also recommends reporting both the presence and absence of sperm and presence or absence of sperm motility on the patient report. If no sperm are seen in the uncentrifuged specimen, the guideline recommends reporting that the presence of sperm is below the limit of detection.

Evidence of Compliance:

✓ Patient report with concentration findings or appropriate comment indicating that concentration was not performed

REFERENCES
1) Evaluation of the Azoospermic Male. *Fertil Steril.* 2008; 90 (S74-7)
2) Diagnostic Evaluation of the Infertile Male: A Committee Opinion. *Fertil Steril*. 2012; 98:294-301
3) American Urological Association (AUA) Guideline. American Urological Association Education and Research, Inc. 2012; amended 2015. https://www.auanet.org/guidelines/vasectomy-(2012-amended-2015)
4) Vasectomy Update 2010. *Can Urol Assoc J.* 2012 October; 4(5):306-309

URN.30750 Reference Materials **Phase I**

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

REFERENCES
1) Haber MH, Blomberg D, Galagan K, Glassy EF, Ward PCJ. Color Atlas of the Urinary Sediment: An Illustrated Field Guide Based on Proficiency Testing. Northfield, IL: College of American Pathologists; 2010.
2) Etzell JE, Bradley KT, Keren DF, et al. Urinalysis Benchtop Reference Guide: An Illustrated Guide for Cell Morphology. Northfield, IL: College of American Pathologists; 2014.
3) Graff L. A handbook of routine urinalysis. Philadelphia, PA: JB Lippincott, 1983
4) Brunzel NA. Fundamentals of urine and body fluid analysis.3rd ed. Philadelphia, PA: *Elsevier Health Sciences*, 2012
5) King C. Comparison of methods for detecting indinavir crystals in urine. *Am J Clin Pathol.* 1998;110:540
6) Hortin GL, *et al.* Detection of indinavir crystals in urine. Dependence on method of analysis. *Arch Pathol Lab Med.* 2000;124:246-250

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*

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

Evidence of Compliance:
- ✓ Written policy defining the method and criteria used for evaluation of consistency **AND**
- ✓ Records of evaluation

REFERENCES
1) Haber MH, Blomberg D, Galagan K, Glassy EF, Ward PCJ. Color Atlas of the Urinary Sediment: An Illustrated Field Guide Based on Proficiency Testing. Northfield, IL: College of American Pathologists; 2010.
2) Etzell JE, Bradley KT, Keren DF, et al. Urinalysis Benchtop Reference Guide: An Illustrated Guide for Cell Morphology. Northfield, IL: College of American Pathologists; 2014.
3) Astion ML, *et al.* A web-based system for assessing competency in microscopic urinalysis. *Clin Chem*. 2000;46:A36
4) Kim A, *et al*. Web-based competency assessment system for microscopic urinalysis. *Clin Chem.* 2002;48:1608-1611

AUTOMATED AND SEMI-AUTOMATED SYSTEMS

DIPSTICK READERS

Inspector Instructions:

- Sampling of urinalysis policies and procedures

***REVISED** 09/22/2021*

URN.31250 Erroneous Dipstick Reader Results **Phase I**

The laboratory follows written criteria for identifying urine specimens that may give erroneous results by the dipstick reader and evaluates those specimens by alternate means (visual examination or other confirmatory method).

NOTE: Intensely colored urine specimens may result in false positive dipstick reactions with automated reflectance readers. However, the anomalous color will be apparent when visual evaluation is performed.

REFERENCES
1) De Buys Roessingh AS, *et al*. Dipstick measurements of urine specific gravity are unreliable. *Arch Dis Child.* 2001;85:155-157

AUTOMATED MICROSCOPY SYSTEMS

Inspector Instructions:

READ	• Sampling of urinalysis policies and procedures • Sampling of automated microscopy QC results, if applicable
ASK	• How did your laboratory establish reportable range limits for your instrument?

***REVISED** 09/22/2021*

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.

REFERENCES
1) Elin RJ, *et al.* Comparison of automated and manual methods for urinalysis. *Am J Clin Pathol.* 1986;86:731-737
2) Wargotz ES, *et al.* Urine sediment analysis by the Yellow Iris automated urinalysis workstation. *Am J Clin Pathol.* 1987;88:746-748
3) Carlson DA, Statland BE. Automated urinalysis, In Haber MH, Corwin HL (eds). Urinalysis. *Clinics in Lab Med.* 1988;8:449-461

URN.31425 Carryover Detection **Phase II**

There is a written procedure for detection and evaluation of potential carryover for the automated microscopy system.

NOTE: Carryover studies must be performed as part of the initial evaluation of an instrument. Carryover studies should be repeated after major maintenance or repair of the pipetting assembly of the instrument.

If carryover is detected or cannot be evaluated (eg, spermatozoa), the written 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

REFERENCES

1) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.
2) Clinical and Laboratory Standards Institute. *Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline.* 3rd ed. CLSI Document EP10-A3-AMD. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

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

Controls at two different levels are run each day of patient testing on automated microscopy systems used for microscopic urinalysis.

NOTE: Controls must be analyzed no less frequently than each day of patient testing to detect instrument malfunction. Accumulation of sediment can block the flow aperture, leading to spuriously low counts.

Evidence of Compliance:

- ✓ Records of daily QC results

*****REVISED** 09/22/2021***

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:

- ✓ Written policy defining the upper and lower instrument reporting limits **AND**
- ✓ Record of action taken when limits are exceeded, including the reporting of results

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7164 [42CFR493.1253]