Every patient deserves the GOLD STANDARD ...

Urinalysis Checklist

CAP Accreditation Program

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- 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.

SUMMARY OF CHECKLIST EDITION CHANGES
Urinalysis Checklist
04/21/2014 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 listing of requirements below is 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

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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.

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

QUALITY MANAGEMENT AND QUALITY CONTROL

SPECIMEN COLLECTION AND HANDLING

Inspector Instructions:

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

REFERENCES

Urine specimens are examined within 1-2 hours of collection.

NOTE: If testing is unavoidably delayed (night collection, etc.) provisions must be made for appropriate preservation of specimens to maintain integrity of cells and formed elements. Refrigeration of urine may be acceptable since it inhibits bacterial growth, but it does not prevent the lytic effects of low specific gravity or alkaline pH. Urine crystal formation may be induced by refrigeration. Preparations that contain boric acid/sorbitol or release formaldehyde may be effective preservatives for some, but not all, urine tests. There should be a method of indicating whether preservative has been added to the sample, and the laboratory should have specified any pre-analytic errors attributable to such preservatives.

Evidence of Compliance:
✓ Written procedure defining criteria for urine specimen handling AND
✓ Records of time of collection and examination

REFERENCES
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?

- Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action

URN.24320 Documented QC Results - Waived Tests

The laboratory follows manufacturer instructions for quality control and documents and reviews results for acceptability prior to reporting results.

NOTE: Quality control must be performed according to manufacturer 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 documented, at a minimum, once per day of patient testing for each device.*

*Acceptable internal control results need not be documented, 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 instructions for each waived test AND
- Records showing confirmation of acceptable of QC results

URN.24330 QC Corrective Action - Waived Tests

There is evidence of corrective action when control results exceed defined acceptability limits.
For waived tests, the laboratory follows manufacturer 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 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

Documented calibration procedures for each test system are adequate, and calibration is recorded.

NOTE: Calibration is the process of testing and adjusting a test system to provide a known relationship between the response measurement and the value of a substance measured by the procedure. Calibration is mandated to be in accordance with and with at least the frequency of manufacturer's instructions. Calibration must also be performed when calibration verification fails to meet acceptable limits.

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

NOTE: Criteria typically include:

1. At changes of reagent lots for chemically or physically active or critical components, unless the laboratory can demonstrate that the use of different lots does not affect the accuracy of patient test results and the range used to report patient test data.
2. If 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.
3. After major maintenance or service.
4. When recommended by the manufacturer.
5. At least every 6 months.

Evidence of Compliance:
- ✓ Written procedure defining the method, frequency and limits of acceptability of calibration verification for each instrument/test system AND
- ✓ Records of calibration verification documented at defined frequency.

REFERENCES

Recalibration

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

Evidence of Compliance:
- ✓ Written procedure defining criteria for recalibration AND
- ✓ Records of recalibration, if calibration or calibration verification has failed.

REFERENCES

CONTROLS FOR NONWAIVED TESTS

Inspector Instructions:
- ✔ Sampling of quality control policies and procedures
- ✔ Sampling of QC records

- ✔ How have you validated the adequacy of limiting daily QC to electronic/procedural/built-in QC?
- ✔ 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?
Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action.

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

**Controls are run daily for quantitative and qualitative tests.**

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

**NOTE 1:** Except for tests meeting the criteria in Note 2, below, daily external surrogate sample* controls must be run as follows:

a. For quantitative tests, 2 controls at 2 different concentrations must be run daily or with each batch of samples/reagents, or unless a different requirement is specifically required by this checklist.

b. For qualitative tests, a negative control and a positive control (when available) must be run daily.

Control testing is not necessary on days when patient testing is not performed.

**NOTE 2:** Daily controls may be limited to electronic/procedural/built-in (e.g. internal, including built-in liquid) controls for tests meeting the following criteria:

1. For quantitative tests, the test system includes 2 levels of electronic/procedural/built-in internal controls that are run daily.
2. For qualitative tests, the test system includes an electronic/procedural/built-in internal control run daily.
3. For laboratories subject to US regulations, the system is FDA-cleared or approved, and not modified by the laboratory.
4. The laboratory has performed studies to validate the adequacy of limiting daily QC to the electronic/procedural/built-in controls. Validation studies must include daily comparison of external controls to built-in controls for at least 20 consecutive days when patient samples are tested. For validation of multiple identical devices, the minimum of 20 consecutive daily comparisons applies to the initial device; the laboratory director is responsible for determining the extent of the validation studies for the other devices. Acceptable validation is required before daily quality control can be limited to built-in controls. The laboratory director is responsible for determining criteria for acceptability, and other details of the validation. Validation records must be retained while an instrument is in service, and for 2 years afterwards. The requirement for 20 consecutive daily comparisons is effective for validation studies performed after 1/31/2012. Corrective action must be taken if either the internal or external control is out of acceptable range during or after the evaluation process. Repeating controls or re-evaluation of the internal control system may be necessary to achieve acceptable results.
5. External surrogate sample controls are run for each new lot number or shipment of test materials; after major system maintenance; and after software upgrades.*** Regarding the external control for qualitative tests, best practice is to run a weak positive control, and in the case of drug testing, also a high negative control (e.g. 25% below cutoff) to maximize detection of problems with the test system.
6. External surrogate sample controls are run as frequently as recommended by the test manufacturer, or every 30 days, whichever is more frequent.

*A “surrogate sample” is a specimen designed to simulate a patient sample for quality control purposes. Traditional external liquid control materials are considered surrogate external surrogate sample controls. Some surrogate sample controls may not be external, but may be contained within...
an instrument (e.g. in a cartridge); systems using these built-in controls must meet the requirements in Note 2, above.

***Repetition of the initial validation study is not required when running external surrogate sample controls with new lots/shipments of test materials, after system maintenance or software upgrades, or in accordance with paragraph 6 in the Note.

Evidence of Compliance:
✓ Records of QC results including external and electronic/procedural/built-in control systems AND
✓ Records documenting in-house verification of electronic/procedural/built-in control systems, if used

REFERENCES

Phase II Target Range Verification

For quantitative tests, a statistically valid target range (e.g. mean, SD, CV) is verified or established for each lot of control material by repetitive analysis in runs that include previously tested control materials.

Evidence of Compliance:
✓ Written procedure defining method used to establish target range AND
✓ Records of target range determination or verification, as applicable

Phase II QC Corrective Action

There is documentation 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.

REFERENCES

Phase II QC Handling

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, recognizing that pre-analytic and post-analytic variables may differ from those encountered with patients.

Evidence of Compliance:
✓ Records reflecting that QC is run by the same personnel performing patient testing

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

Evidence of Compliance:
✓ Written policy/procedure stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Evidence of corrective action taken when QC results are not acceptable

REFERENCES

**REVISED** 04/21/2014
URN.25750 Monthly QC Review

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 documented 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.

Evidence of Compliance:
✓ Records of QC review with documented 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
- Sampling of pipette/dilutor checks
- Microscope maintenance records

- Microscope (proper working condition)

- How do you verify the function of the refractometer?

**REVISED** 07/29/2013
URN.26100 Refractometer Calibration Check

Refractometers with specific gravity capability are checked at least annually with appropriate solutions of known specific gravity and/or refractive concentration index.
NOTE: Distilled water (sp. gr. = 1.000) and 5% NaCl (sp. gr. = 1.025) can conveniently verify total solids (T.S.) meter calibration. For specific gravity determination by dipstick, manufacturers’ recommendations must be followed.

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

REFERENCES

Phase II

URN.26700 Pipette Accuracy

Pipettors and dilutors (fixed volume or adjustable) are checked before being placed in service and at least annually for volumetric accuracy and reproducibility, and results recorded.

Evidence of Compliance:
✓ Written procedure detailing method for checking the accuracy and reproducibility of pipettes

REFERENCES

URN.26800 Glassware Accuracy

Volumetric glassware is of certified accuracy (Class A) or checked by the laboratory to verify accuracy.

Evidence of Compliance:
✓ Glassware marked Class A OR NIST certificate OR validation study of accuracy for non-certified glassware

REFERENCES
5) Johnson B. Calibration to dye for: Artel’s new pipette calibration system. Scientist. 1999;13(12):14

**REVISED** 04/21/2014

URN.26850 Microscope Maintenance

Microscopes are clean, adequate (i.e. low, high dry and oil immersion lens), and properly maintained with documentation of preventive maintenance on an annual basis and as deemed necessary.

REFERENCES
1) Vetter JP. Solving problems with illumination, focus, and detail in color photomicrography. Lab Med. 1997;28:719-723
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 (e.g. 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.30200  Dipstick UA  Phase I**

The routine dipstick urinalysis (whether read manually or by electronic reader) includes, as clinically applicable:

1. Glucose
2. Protein
3. Blood or hemoglobin
4. Nitrite
5. Leukocyte esterase
6. Specific gravity

REFERENCES

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

There is a documented 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
URINALYSIS - MANUAL MICROSCOPY

Inspector Instructions:

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

**REVISED** 07/29/2013

Phase IMicroscopic Exam

Manual microscopic examinations of urine sediment are performed as part of complete urinalysis testing, or there are specific, documented 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


**REVISED** 07/29/2013

Phase IAzospermic Specimen Result Reporting

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)

Phase I

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

REFERENCES

Phase II

Morphologic Observation Assessment - UA
The urinalysis section of the laboratory at least annually assesses morphologic observations among personnel performing urine sediment microscopy, to ensure consistency.

NOTE: Suggested methods to accomplish this include:

1. Circulation 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 (e.g. former CAP surveys clinical microscopy photomicrographs)
4. Digital images

The procedure manual should include definitions of semiquantitative measurements such as 1+, 2+, 3+, etc.

Evidence of Compliance:
✓ Written procedure defining the method and criteria used for evaluation of consistency AND
✓ Employee records documenting annual assessment

REFERENCES

AUTOMATED AND SEMI-AUTOMATED SYSTEMS

DIPSTICK READERS

Inspector Instructions:

- Sampling of urinalysis policies and procedures

URN.31250  Dipstick Reader  Phase I

There are criteria for identifying urine samples that may give erroneous results by the dipstick reader and thus require evaluation by alternate means (visual examination or other confirmatory method).

NOTE: Criteria should be given for identifying urine samples that may give erroneous results by the dipstick reader, and thus require confirmation by other means, such as visual examination. Intensely colored urine samples may result in false positive dipstick reactions with automated reflectance readers. However, the anomalous color will be apparent when visual evaluation is performed.

REFERENCES

MORPHOLOGY SYSTEMS

Inspector Instructions:

- Sampling of urinalysis policies and procedures
- Sampling of automated morphology QC results, if applicable
- How did your laboratory establish reportable range limits for your particle counting instrument?

**REVISED** 07/29/2013
URN.31400  Erroneous Morphology Results  Phase II
Based on any limitations detected in the initial evaluation, criteria are established 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 should be performed if problems are noted with accurate identification or classification of clinically important urine structures, such as casts.

REFERENCES

**REVISED** 07/29/2013

URN.31600 Daily QC - Automated Morphology Phase II

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

NOTE: Controls should 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

URN.31700 Reportable Range Phase II

Upper and lower limits of all reportable parameters on particle counting instruments are defined, so results that fall outside these limits are verified before reporting.

NOTE: The laboratory must initially establish or verify the reportable range for each parameter of its automated or semi-automated particle counter. Apparent counts that are lower or higher than the reportable range may be reported as "less than" the lower limit or "greater than" the higher limit. Alternatively, when clinically appropriate, samples with results exceeding the higher limit may be diluted so that the value falls within the established analytic range, and appropriate multipliers applied.

Evidence of Compliance:
 ✓ Written procedure defining the upper and lower instrument reporting limits AND
 ✓ Record of action taken when limits are exceeded, including the reporting of results

REFERENCES

PERSONNEL

Inspector Instructions:

• Documentation of education and experience

URN.40000 Bench Testing Supervision Phase II
The person in charge of bench testing/section supervisor in urinalysis has education equivalent to an associate’s degree (or beyond) in a chemical, physical or biological science or medical technology and at least 4 years experience (one of which is in urinalysis) under a qualified section director.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field