COLLEGE of AMERICAN PATHOLOGISTS

Al Hammadi Hospital Al Nuzha
Laboratory Department

Limited Service Laboratory Checklist

CAP Accreditation Program

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

CAP Number: 8341527
Section/Department: microbiology

12.26.2024

Disclaimer and Copyright Notice

CAP inspections are performed with the edition of the Checklists mailed to a facility at the completion of the application or reapplication process, not necessarily those currently posted on the website. The checklists undergo regular revision and a new edition may be published after the inspection materials are sent.

For questions about the use of the Checklists or Checklist interpretation, email accred@cap.org or call 800-323-4040 or 847-832-7000 (international customers, use country code 001).

The Checklists used for inspection by the College of American Pathologists' Accreditation Programs have been created by the CAP and are copyrighted works of the CAP. The CAP has authorized copying and use of the checklists by CAP inspectors in conducting laboratory inspections for the Council on Accreditation and by laboratories that are preparing for such inspections. Except as permitted by section 107 of the Copyright Act, 17 U.S.C. sec. 107, any other use of the Checklists constitutes infringement of the CAP's copyrights in the Checklists. The CAP will take appropriate legal action to protect these copyrights.

All Checklists are ©2024. College of American Pathologists. All rights reserved.

Limited Service Laboratory Checklist

TABLE OF CONTENTS

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
Limited Service Laboratory 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

Requirement	Effective Date
LSV.38667	12/26/2024
LSV.43804	08/24/2023

DELETED/MOVED/MERGED Checklist Requirements

Requirement	Effective Date
LSV.46003	08/23/2023
LSV.46066	08/23/2023

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a limited service laboratory.

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).*

DEFINITION AND USE

The Limited Service Laboratory (LSV) Checklist may be used for medical or clinical laboratories whose scope of offered services includes basic, commonly performed laboratory tests or procedures in multiple disciplines. The checklist is typically used for a satellite lab, stat lab, outpatient clinic, emergency service, or special function laboratory.

The use of the LSV Checklist is restricted to a subset of tests under the following disciplines: chemistry, hematology, urinalysis, immunology, and microbiology. If a scope of service in a particular discipline exceeds those addressed in this checklist, a separate section-specific checklist is required for that discipline. The CAP Accreditation Program makes the final determination regarding the use of this checklist. Common examples of services exceeding the use of this checklist include the following:

- *Coagulation factor assays and platelet function studies in hematology*
- *Culture/sensitivity and nonwaived molecular infectious disease testing in microbiology*
- *Chromatography, electrophoresis, and cystic fibrosis sweat testing in chemistry*
- *Western blot testing and pre-transfusion immunohematological testing in immunology*

The LSV Checklist CANNOT be used to inspect anatomic pathology, cytopathology, flow cytometry, molecular pathology, histocompatibility, cytogenetics, or point-of-care testing. Section-specific checklists must be used for each of those disciplines. Laboratories storing and issuing blood components must use the Transfusion Medicine Checklist.

The LSV Checklist utilizes requirements already in existing section-specific checklists (eg, hematology, chemistry, microbiology). Only slight editorial changes have been made for the sake of maintaining context. In summary, this checklist does not represent any compromise of CAP Standards for Accreditation or difference with respect to CLIA regulatory requirements.

Additional information on inspection of limited service laboratories can be found in the Laboratory Accreditation Manual.

ATTESTATION

This LSV Checklist is not valid for a CAP inspection unless it is used for the purpose intended. If there is any doubt, inspectors should contact the CAP to confirm appropriate usage of the checklist. The laboratory director and inspector's signatures on the Inspector's Summation Report confirm that they are in mutual agreement that the laboratory concerned meets the criteria for use of the LSV Checklist.

QUALITY MANAGEMENT AND QUALITY CONTROL

Checklist requirements under the Quality Management and Quality Control section apply to all areas of the limited service laboratory. Additional discipline-specific requirements are found in the other areas of the checklist and are to be used in conjunction with this section.

QUALITY CONTROL AND CALIBRATION – WAIVED TESTS

LSV.37064 **Calibration, Calibration/Verification - Waived Tests** **Phase II**

For waived tests, testing personnel follow manufacturer's instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:

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

LSV.37068 **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 the reporting of 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

LSV.37072 **QC Corrective Action - Waived Tests** **Phase II**

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

QUALITY CONTROL – NONWAIVED TESTS

LSV.37078 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 titered result - a negative control and a control material with graded or titered reactivity, as applicable, at least daily (serially diluted positive controls are not required)*

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

LSV.37082 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

LSV.37084 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

LSV.37086 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.

LSV.37088 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

LSV.37090 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

LSV.37092 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

LSV.37094 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

LSV.37095 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

HEMATOLOGY SECTION

RESULTS REPORTING - HEMATOLOGY

***REVISED** 12/26/2024*
LSV.38667 Reference Intervals **Phase II**

Patient results are reported with accompanying reference intervals or interpretive ranges.

NOTE: For WBC differential counts, the CAP recommends that laboratories report absolute cell counts, along with their corresponding reference intervals. The CAP discourages the reporting of percent cell counts without absolute counts on WBC differentials. Laboratories reporting only percent cell counts must provide laboratory established reference intervals.

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals (printed copies or electronic data) to users and sites where reports are received. The laboratory must ensure that such data is up to date.

Reference interval citations from the manufacturer's insert or published literature citations may be used to determine the reference interval. However, reference intervals have not been published for many body fluid analytes and obtaining normal fluids to establish reference intervals may not be feasible. If reference intervals are not available, results must be accompanied by an appropriate comment such as, "The reference interval(s) and other method performance specifications are unavailable for this body fluid. Comparison of the result with concentration in the blood, serum, or plasma is recommended."

Evidence of Compliance:
- ✓ Patient reports

URINALYSIS AND CLINICAL MICROSCOPY SECTION

SPECIMEN COLLECTION AND HANDLING - URINALYSIS

LSV.42050 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.

LSV.42290 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

LSV.42370 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.*

CALIBRATION AND STANDARDS - NONWAIVED TESTS - URINALYSIS

NOTE: Explanatory notes for calibration are found in the Chemistry section of the Limited Service Laboratory Checklist. The master version of the checklist may be downloaded using e-LAB Solutions on the CAP website.

LSV.42375 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 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.

LSV.42380 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

LSV.42385 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

PROCEDURES AND TEST SYSTEMS

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.

LSV.42650 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.).

LSV.43090 Microscopic Exam **Phase II**

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

NOTE: Random urinalysis screening (hospital admissions, insurance physicals) of urines that are yellow and clear and have normal chemical reactions have a markedly low yield on microscopic examination. The laboratory may define protocols for when microscopic examination of urine sediment should or should not be done.

Evidence of Compliance:

- ✓ Patient reports with microscopic results **OR** records reflecting procedure for abbreviated testing

URINALYSIS - MANUAL MICROSCOPY

LSV.43170 Reference Materials **Phase I**

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

LSV.43250 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

AUTOMATED AND SEMI-AUTOMATED SYSTEMS

DIPSTICK READERS

LSV.43650 **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.

AUTOMATED MICROSCOPY SYSTEMS

LSV.43656 **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 should be performed if problems are noted with accurate identification or classification or clinically important urine structures, such as casts.

LSV.43657 **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

LSV.43659 **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

LSV.43661 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

BODY FLUIDS SECTION

MANUAL CELL COUNT - BODY FLUID

LSV.43662 Diluting Equipment **Phase II**

Certified pipettes or commercial dilution systems are used when diluting body fluid samples.

LSV.43668 Background Checks - Manual Counts **Phase II**

The diluting fluid is checked for interfering background particulates and changed when indicated.

NOTE: Checking can be done by examining samples of these fluids under the microscope. The check must be performed each day of use for manual diluting methods. If commercial microdilution systems are used, daily checks are not required but each lot must be examined visually for uniformity of filling and clarity. If diluting fluids are prepared by the laboratory, they must be prepared aseptically; refrigeration is recommended to prevent contamination with microorganisms.

Evidence of Compliance:
- ✓ Records of background checks

LSV.43670 Manual Cell Count Controls **Phase II**

For manual body fluid cell counts, the laboratory analyzes at least one cell count control specimen in duplicate or uses a procedural control each eight hours of patient testing.

NOTE: This requirement can be met with assayed liquid control material, a previously assayed patient sample, or a procedural control. An example of a procedural control is correlation of the cell count with the cellularity of a stained slide prepared by a standard, validated method. Liquid control materials must be tested in duplicate.

Evidence of Compliance:
- ✓ Records of cell count or procedural controls at defined frequency

LSV.43671 Counting Chamber and Optical Grid Quality **Phase I**

The lines in all counting or motility chambers, ocular micrometers, and optical grids are bright and free from scratches, dirt, or debris.

LSV.43674 Body Fluid Analysis Procedure **Phase II**

For manual body fluid cell counts, each sample is counted in duplicate.

NOTE: Testing records must reflect the performance of the counts in duplicate for all counting chambers. Limits of agreement between replicate counts must be defined.

Evidence of Compliance:

- ✓ Records or worksheets reflecting duplicate counts and corrective action when limits of agreement are exceeded

LSV.43680 Cell Clumps/Debris - Manual Methods **Phase II**

The laboratory indicates (as part of the report) that results may be inaccurate if the fluid specimen is partially clotted or has cell clumps or debris on the counting chamber.

LSV.43692 Red Cell Confirmation Techniques **Phase I**

There is an additional procedure beyond unstained bright-field microscopic visualization of cells on the hemocytometer used when necessary to ensure the accurate distinction of erythrocytes from other cell types.

NOTE: Suggested techniques include acid rinsing of the fluid sample to lyse erythrocytes after initially counting all cells, the addition of a stain such as methylene blue to improve recognition of non-erythrocytes, correlation with the number and proportion of cells on the cytospin preparation or phase microscopy.

Evidence of Compliance:

- ✓ Records of confirmation testing

NUCLEATED CELL DIFFERENTIALS - BODY FLUID

LSV.43734 Body Fluid Cell Differentials **Phase I**

The method for differentiating body fluid cells is appropriate for the intended clinical use.

NOTE: The laboratory should use stained cytocentrifuge preparations to facilitate quantitative differentials and complete classification of nucleated cell types in body fluids, as opposed to performing differentials of unstained hemocytometer preparations. Differentials based on supravitally-stained hemocytometer preparations, wedge smears and drop preparations are considered suboptimal; their use should be limited to clinical circumstances requiring differentiation of polymorphonuclear from mononuclear cells (eg, bacterial meningitis). Further sub-classification of nucleated cells, particularly the detection of malignant cells, should be performed using slide preparation methods that provide optimal cell recovery and morphologic detail, such as cytocentrifugation. Cytocentrifuge preparations provide excellent morphologic detail, deliver a high yield of cells even when the concentration is low, and have a high rate of detection for malignant cells. In cases of leukemia or lymphoma, Romanowsky-stained cytospin slides show excellent morphologic correlation with blood and bone marrow smears. If the laboratory uses an alternate slide preparation method or stain for sub-classification of body fluid mononuclear cells and/or detection of malignant cells, it must demonstrate from literature or in-

house studies that this technique is equivalent in cell yield/recovery and morphologic detail to Romanowsky-stained cytocentrifuge preparations.

Evidence of Compliance:

- ✓ Records showing in-house or literature validation of techniques other than Romanowsky-stained cytocentrifuge preparations

LSV.43740 Body Fluid Smear Quality **Phase I**

The quality of body fluid smears is satisfactory (uniform cell distribution, appropriate dilution so cells are not crowded, properly stained, adequate cell yield, ready recognition of cell types that are reported).

LSV.43746 Morphologic Observation Evaluation - Body Fluid **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing body fluid cell differentials at least annually.

NOTE: The laboratory must ensure the identification of body fluid cells is reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:

1. *Circulation of a pre-graded set of body fluid smears with defined nucleated cell differential distributions*
2. *Multi-headed microscopy*
3. *Use of body fluid photomicrographs with referee and consensus identifications (eg, former CAP Surveys photomicrographs)*
4. *Use of digital images*
5. *Enrollment and participation of all personnel in an external assessment program for morphologic observation for body fluid differentials.*

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

RESULT REPORTING - BODY FLUID

LSV.43771 Body Fluid Result Reporting of Nucleated Cells **Phase I**

When absolute total cell counting methods cannot reliably distinguish white blood cells from other nucleated cells, body fluid cell counts and differential results are reported with the total nucleated cell count and a differential with all nucleated cell types observed.

NOTE: If the absolute total cell counting method in the laboratory cannot reliably distinguish white blood cells from other nucleated cells (eg, unstained bright-field visualization of cells in a hemocytometer chamber and certain automated counting technologies), the laboratory must report the absolute total cell count (cells/µL) as TNC (total nucleated cells) not WBC (total white blood cells). The relative differential (% of total cells counted) performed on a stained cytocentrifuge slide, which can reliably distinguish white blood cells from other nucleated cells, must include the percentage of all nucleated cell types (eg, lymphocyte, neutrophil, monocyte/macrophage, basophils, eosinophil, plasma cell, mesothelial cell, bronchial lining cell, synovial

lining cell, ventricular lining cell, endothelial cell, squamous epithelial, and other) when TNC is reported for the absolute total cell count.

Evidence of Compliance:

✓ Patient report with body fluid cell count and differential results

SEMEN ANALYSIS

The preceding requirements in the Body Fluid Cell Counting and Body Fluid Nucleated Cell Differentials sections are generally applicable to semen analysis. Additional items of importance to this specialized area are identified in this section.

LSV.43773 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.

NOTE: If the laboratory only performs post-vasectomy checks for presence or absence of sperm, LSV.43773 is the only applicable requirement in this section.

Evidence of Compliance:

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

REQUISITIONS, SPECIMEN RECEIPT AND RESULTS REPORTING

LSV.43776 Specimen Collection/Handling **Phase I**

There are written patient instructions for collection and prompt delivery of a semen sample to the laboratory.

NOTE: This should be written in simple terms in a language readily understood by the patient. Elements should include the need to abstain from ejaculation for 2-7 days before collection of the specimen, avoidance of lubricants and other contamination, completeness of collection, use of the supplied container, maintenance of sample temperature, and prompt delivery. Instructions must be readily available and distributed to patients and to off-site physician offices that refer specimens.

LSV.43782 Specimen Collection/Handling **Phase I**

Semen specimens are accompanied by the following collection information, and records are retained on the following.

1. **Method of collection**
2. **Type of specimen container**
3. **Days of abstinence**
4. **Collection or transport problems (eg, incomplete specimen, exposure to temperature extremes)**
5. **Time of specimen receipt and analysis**

LSV.43788 Liquefaction **Phase I**

All semen specimens are given sufficient time for liquefaction before testing.

LSV.43794 Specimen Handling - Pre-analytic **Phase I**

Semen specimens are mixed thoroughly before testing.

LSV.43800 Specimen Characteristics - Analytic **Phase I**

All characteristics of the semen specimens are noted and reported (eg, gelatinous clumps, viscosity, contaminants, erythrocytes, and abnormalities of liquefaction).

NOTE: Macroscopic and microscopic characteristics of the semen specimens must be noted and reported, in accordance with the WHO laboratory manual for the examination of human semen (ie, fifth or sixth edition).

Evidence of Compliance:
- ✓ Patient reports

SPERM MOTILITY

***REVISED** 08/24/2023*
LSV.43804 Motility Method Verification **Phase I**

The laboratory verifies the sperm motility method used (eg, video tapes/digital images of specimens with known percent motility and/or specific motion quality) at least semiannually.

NOTE: This requirement applies to both automated and manual sperm motility methods.

Evidence of Compliance:
- ✓ Records of method verification

LSV.43807 Motility Quantification **Phase II**

Manual measures of percent sperm motility are quantified in a standardized manner.

NOTE: The laboratory must have a written method for determining and reporting sperm motility that describes how sperm are assessed and counted (percent motility) and is based on a reference method, such as the World Health Organization (WHO) Standards (ie, fourth or fifth edition).

LSV.43809 Forward Progression **Phase II**

Forward progression of sperm is evaluated.

Evidence of Compliance:
- ✓ Patient reports or worksheets with results of forward progression

LSV.43812 Motility/Progression Evaluation **Phase II**

Sperm motility percent and progression are routinely evaluated within one hour of collection.

Evidence of Compliance:
- ✓ Records indicating time of collection and evaluation **AND**
- ✓ Patient reports noting exceptions, when appropriate

LSV.43818 Standard Temperature Range **Phase II**

The laboratory has established a standard temperature range for semen analysis assessment, and deviations from this temperature are noted on the report.

NOTE: Sperm motility is temperature-dependent. Temperature ranges must be defined.

Evidence of Compliance:
- ✓ Records showing monitoring of temperatures

LSV.43824 Motility Microscopic Examination **Phase II**

The laboratory has written instructions for evaluating a sufficient number of separate and randomly chosen microscopic fields and sperm cells.

LSV.43833 Viability Testing Criteria **Phase I**

The laboratory performs viability testing on specimens with low percent motility (eg, less than 30%), or includes a comment that the decreased motility may be the result of non-viable or non-motile sperm.

NOTE: Non-motile sperm may represent forms that were originally non-viable in the ejaculate, or previously motile forms that have subsequently lost motility. Thus, viability assessment is useful in making the distinction, and is commonly performed with a dye-exclusion method such as eosin-nigrosin.

Evidence of Compliance:
- ✓ Patient records or worksheet with results of viability testing **OR** patient report with cautionary verbiage

STAINED SMEAR - SPERM DIFFERENTIAL

LSV.43842 Sperm Morphology Classification **Phase I**

The sperm morphology classification method used is indicated on the report.

NOTE: Different classification systems have different reference intervals for normality. To improve the consistency and usefulness of reporting, CAP recommends the use of the WHO Standards (ie, fourth, fifth, or sixth edition), and the Kruger classification system, and discontinuing the use of older classification systems.

LSV.43848 Morphologic Observation Evaluation - Sperm **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing microscopic morphologic classification of sperm and other cells at least annually.

NOTE: The laboratory must ensure the identification of sperm and other cells is reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:

1. *Circulation of a pre-graded set of stained semen smears with defined specific qualitative abnormalities of sperm*
2. *Multi-headed microscopy*
3. *Use of current published references*
4. *Digital images*
5. *Enrollment and participation of all personnel in an external assessment program for morphologic observation of semen smears.*

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

LSV.43854 Consultation **Phase II**

An individual with expertise in sperm morphology (the pathologist, laboratory director, supervisor, or other technologist) is available for consultation, when needed.

LSV.43856 Sperm Morphology Reference **Phase I**

There is a file of unusual slides or current atlas of sperm morphology, available for training and reference.

LSV.43857 Stain Usage **Phase I**

Stains are used to facilitate morphologic classification of cell types in semen (as opposed to performing differentials of unstained preparations).

LSV.43859 Leukocyte Confirmation Techniques **Phase I**

There is an additional procedure beyond unstained brightfield microscopy to ensure the accurate distinction of leukocytes from other round cells (eg, Wright's, leukocyte alkaline phosphatase, or myeloperoxidase stains).

NOTE: This requirement only applies to laboratories that differentiate leukocytes from other round cells on the patient report.

Evidence of Compliance:

- ✓ Patient records or worksheets indicating use of additional procedure

LSV.43862 Stain QC **Phase II**

Quality control of all stains is performed and recorded to check for contamination and intended reactivity each day of use.

Evidence of Compliance:

- ✓ Records of stain QC

LSV.43866 Stain Quality **Phase II**

The stains used (Wright's, Papanicolaou, eosin-nigrosin, peroxidase etc.) and slide preparations are of sufficient quality to demonstrate the cellular characteristics for which they are designed.

Evidence of Compliance:

- ✓ Examples of each type of stained slide available for microscopic review by inspector, as applicable