COLLEGE of AMERICAN PATHOLOGISTS

December 2024 Changes

Limited Service Laboratory Checklist

CAP Accreditation Program

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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text**. Changes appear in a track changes format that compares the previous checklist edition to the December 26, 2024 edition.** Requirements with significant revisions will display a “Revised” flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a “Revised” flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that are new or have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

2024 CHECKLIST EDITION CHANGES
NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement		Action Taken	2024 Requirement	
		New	LSV	38698
		New	LSV	39550
		New	LSV	40010
		New	LSV	41325
		New	LSV	44772
		New	LSV	44773
		New	LSV	44774

*Deleted – Removed the requirement from the checklist edition
*Merged – Combined the requirement with a similar requirement in the same or different checklist
*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists ~~from the CAP website (cap.org)~~ 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.

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).*

HEMATOLOGY SECTION

MANUAL HEMATOCRIT

*****REVISED** 12/26/2024***

LSV.38240 Microhematocrit Centrifuge **Phase I**

The speed of the microhematocrit centrifuge is checked at least annually.

NOTE: Relative centrifugal field (RCF) must be sufficient to achieve maximum packing of cells. ~~The~~It is recommended that the centrifuge ~~must~~ be capable of sustaining an RCF of 10,000 to 15,000 at the periphery for five minutes.

If the centrifuge speed cannot be checked by the user, the laboratory must annually compare centrifuge test results against another centrifuge with known speed and constant packing time. If the laboratory does not have such an instrument, another laboratory or an outside vendor may be used for this comparison.

Evidence of Compliance:

✓ Records of microhematocrit centrifuge speed checks

REFERENCES

1) Clinical and Laboratory Standards Institute. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard;* 3rd ed. CLSI document H07-A3. CLSI, Wayne, PA, 2000.

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 ~~to all~~(printed copies or electronic data) to users and sites where reports are received.

~~*This system*~~*The laboratory must ensure that such data* is ~~*usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable*~~*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

REFERENCES

1) Trost DC, *et al*. Probability-based construction of reference ranges for ratios of log-Gaussian analytes: an example from automated leukocyte counts. *Am J Clin Pathol*. 2002;117:851-856
2) Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition.* CLSI Document EP28-A3c. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.
3) Etzell, JE. For WBC differentials reporting absolute numbers. *CAP Today.* 2010; 3:12
4) Richardson-Jones A, Twedt D, Hellman R. Absolute versus proportional differential leukocyte counts. *Clin Lab. Haem.* 1995:17(2), 115-123

COAGULATION SECTION

SPECIMEN COLLECTION AND HANDLING - COAGULATION

***REVISED** 12/26/2024*

LSV.38683 Fill Volume and Specimen Mixing - Coagulation **Phase I**

Instructions for the acceptable fill volume and mixing of specimen collection tubes for coagulation testing are defined and followed.

NOTE: The recommended proportion of blood to the sodium citrate anticoagulant volume is 9:1. Inadequate filling of the collection device will decrease this ratio, and may lead to inaccurate results for calcium-dependent clotting tests, such as the PT and aPTT. The effect on clotting time from under-filled tubes is more pronounced when samples are collected in 3.8% rather than 3.2% sodium citrate. The effect of fill volume on coagulation results also depends on the reagent used for testing, size of the evacuated collection tube, and citrate concentration. A minimum of 90% fill is recommended; testing on samples with less than 90% fill should be validated by the laboratory. It is unacceptable to combine the contents from separate, underfilled sodium citrate collection tubes.

~~*Manufacturer's instructions for specimen mixing must be followed.*~~

Samples should be gently inverted to prevent clotting, in keeping with the manufacturer's instructions and laboratory's specimen collection instructions as described in GEN.40100.

Evidence of Compliance:

✓ Records of rejected specimens

REFERENCES

1) Peterson P, Gottfried EL. The effects of inaccurate blood sample volume on prothrombin time (PT) and activated partial thromboplastin time. *Thromb Haemost.* 1982;47:101-103
2) Adcock DM, Kressin D, Mariar PA. Minimum specimen volume requirements for routine coagulation testing. Dependence on citrate concentration. *Am J Clin Pathol.* 1998;109:595-599
3) Reneke J, *et al*. Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/L (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998;109:754-757
4) Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays ~~and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition~~.* 6th ed. CLSI ~~Document~~guideline H21~~-A5 (ISBN 1-56238-657-3).~~ Clinical and Laboratory Standards Institute, ~~940 West Valley Road, Suite 1400,~~ Wayne, PA ~~19087-1898 USA, 2008.~~, 2024.

LSV.38695 Specimen Handling for Plasma-based Testing - Coagulation Phase II

Coagulation tests are promptly performed on fresh plasma, or the platelet-poor plasma is frozen until testing can be performed.

NOTE: After blood collection, there is progressive degradation of the labile coagulation factors V and VIII, leading to increasing prolongation of the aPTT and PT. The allowable time interval between specimen collection and sample testing depends on the temperature encountered during transport and storage of the specimen. Allowable time intervals are as follows:

1. *PT specimens, uncentrifuged or centrifuged with plasma remaining in the capped tube above the packed cells, or as centrifuged plasma separated from the cells, should be kept at room temperature (18 to 24°C) and tested no longer than 24 hours from the time of specimen collection. PT specimens should not be refrigerated (during storage).*
2. *aPTT specimens ~~that are~~, uncentrifuged or centrifuged with plasma remaining in the capped tube above the packed cells should be kept at room temperature (18 to 24°C) and tested no longer than 4 hours after the time of specimen collection.*
3. *aPTT specimens that are centrifuged and plasma separated from cells can be kept for 4 hours refrigerated (2 to 8°C) or at room temperature (18 to 24°C). Samples for unfractionated heparin testing should be centrifuged within one hour from the time of specimen collection*
4. *Samples for other coagulation factors (eg, thrombin time, protein C, factor V, factor VIII) have variable stability and should be kept in the same manner as aPTT samples*

If PT or aPTT testing cannot be performed within these times, platelet-poor plasma should be removed from the cells and frozen at –20°C for up to 2 weeks or at –70°C for up to 12 months. If a laboratory has established an allowable time interval different than that detailed above, data must be available to verify that coagulation testing is valid in the time interval established.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays ~~and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition~~.* 6th ed. CLSI ~~Document~~guideline H21~~-A5 (ISBN 1-56238-657-3).~~ Clinical and Laboratory Standards Institute, ~~940 West Valley Road, Suite 1400,~~ Wayne, PA ~~19087-1898 USA, 2008~~, 2024.
2) Adcock DM, *et al*. The effect of time and temperature variables on routine coagulation tests. *Blood Coag Fibrinolysis.* 1998;9:463-470
3) Neofotistos D, *et al*. Stability of plasma for add-on PT and aPTT tests. *Am J Clin Pathol.* 1998;109:758-763
4) Davis KD, *et al*. Use of different thromboplastin reagents causes greater variability in international normalized ratio results than prolonged room temperature storage of specimens. *Arch Pathol Lab Med.* 1998;122:972-977

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

LSV.38698 Specimen Handling for Whole Blood-Based Testing - Coagulation Phase II

Specimens for whole blood-based coagulation testing are handled according to manufacturer's instructions or as validated by the laboratory.

NOTE: Specimens must not be:

- *Heated, refrigerated, or frozen*
- *Centrifuged - Centrifuged specimens must be rejected. Reconstitution of a centrifuged specimen by mixing is not adequate.*

For additional specimen handling for platelet function studies, refer to LSV.38707.

*****REVISED** 12/26/2024***

LSV.38705 Platelet Function Studies Phase II

Platelet functional studies (platelet aggregation or initial platelet function test) are performed within an appropriate period after venipuncture.

NOTE: Following venipuncture, platelets continue to activate in vitro, so that platelet functionality becomes abnormal after a period of several hours. ~~The laboratory must ensure that platelet~~

~~*functional studies (platelet aggregation or initial platelet function test) are completed between 30 minutes and four hours from the time of phlebotomy, or erroneous results could be obtained.*~~
Manufacturer's instructions for specimen stability must be followed for FDA-cleared/approved platelet function study assays~~.~~ (platelet function is generally not stable past 4 hours, although certain manufacturers may have more stringent requirements).

~~*PRP (platelet rich plasma) should be used within three to four hours of platelet donation. The effects of time are related to changes in pH, which are directly related to the escape of CO_2 from the PRP sample tube. Platelets may be refractory to epinephrine when using PRP samples tested within 30 minutes of venipuncture; this is cited as the rationale for not testing PRP until at least 30 minutes after phlebotomy. There is evidence to suggest that this initial platelet refractoriness and subsequent gain of function occurs because centrifugation releases ADP from red blood cells and platelets. Specimens collected for whole blood aggregometry should be stored capped at room temperature and tested within four hours.*~~

Evidence of Compliance:
✓ Records of testing completed within the defined time period

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Platelet Function Testing by Aggregometry; Approved Guideline*. CLSI document H58-A. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2008.
2) Winokur R, Hartwig JH. Mechanism of shape change in chilled human platelets. *Blood*. 1995; 85:1796-1804.
3) Mani H, Kitchmayr K, Klaffling C, et al. Influence of blood collection techniques on platelet function. *Platelets*. 2004;15(5):315-318.
4) Kattlove HE, Alexander B. The effect of cold on platelets. I. Cold-induced platelet aggregation. *Blood.* 1971;38(1):39-48.
5) Kattlove HE, Alexander B, White F. The effect of cold on Platelets. II. Platelet function after short-term storage at cold temperatures. *Blood*. 1972;40(5):688-695.

COAGULATION STUDIES

FIBRINOGEN (EXCLUDING IMMUNOLOGIC METHODS)

Fibrinogen can be measured using different methodologies. The following testing methods for fibrinogen are applicable to the requirements in this section:
~~1~~1. The Clauss method (a functional assay based on the time to fibrin clot formation when excess thrombin is added to patient plasma).
~~2~~2. The PT-derived fibrinogen assay (an assay which reports a fibrinogen level based on the prothrombin time).

The requirements in this section are not applicable to immunologic methods, which measure fibrinogen antigens. Relevant requirements for immunologic methods are covered in the "Coagulation Tests Based on Direct Measurement of Analytes" section.

RESULTS REPORTING - VISCOELASTIC TESTING

***NEW** 12/26/2024*
LSV.39550 Viscoelastic Testing - Error Communication **Phase II**

If viscoelastic testing for hemostasis analysis is performed in the laboratory and the results are viewable remotely by clinical personnel in real-time, the laboratory promptly communicates analytic errors to the responsible clinical personnel.

NOTE: Because real-time laboratory data is viewable by clinical personnel prior to reporting the final test results, the laboratory must ensure that there is training of staff for prompt notification to the responsible clinical personnel when analytic errors are detected. Communication must be recorded.

Evidence of Compliance:
✓ Records of communication to responsible clinical personnel when analytic errors are detected

CHEMISTRY SECTION

PROFICIENCY TESTING

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

LSV.40010 Hemoglobin A1C Testing **Phase I**

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

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

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

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

REFERENCES
1) Sacks DB, Arnold M, Bakris GL, et al. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. *Clin Chem*. 2023; 69(8):808-68.

RESULTS REPORTING

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

LSV.41325 eGFR and LDL Cholesterol Calculated Test Results **Phase I**

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

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

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

Evidence of Compliance:
✓ Patient reports with information on the calculation used **OR**
✓ Test reference guide or other mechanism for providing calculation information

REFERENCES
1) Inker LA, Eneanya ND, Coresh J, et al. New Creatinine- and Cystatin C-Based Equations to Estimate GFR without Race. *N Engl J Med.* 2021; 385(19):1737-49.
2) Sampson M, Ling C, Sun Qian, et al. A New Equation for Calculation of Low-Density Cholesterol in Patient With Normolipidemia and/or Hypertriglyceridemia. *JAMA Cardiol.* 2020; 5(5):540-48.

GENERAL CHEMISTRY

HIV PRIMARY DIAGNOSTIC TESTING - CHEMISTRY

***REVISED** 12/26/2024*

LSV.41346 HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing Phase I

The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

NOTE: If additional testing after a primary screening test is recommended by public health authorities, the laboratory:

- *Performs additional testing reflexively if the specimen is suitable and the test is performed in house, or*
- *Sends additional testing to a referral laboratory if the specimen is suitable, or*
- *Provides guidance to providers on submission of additional specimens, if needed for supplemental or confirmatory testing.*

The US Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) provide recommendations for HIV testing. Guidelines and recommended algorithms can be found on the CDC and APHL websites.

~~*This checklist item does not apply to the testing of individuals from whom human derived products for therapeutic use are being derived or other types of testing performed for the monitoring of HIV infection (eg, viral load, CD4 counts). Reporting HIV results to public health is not within the scope of this checklist item.*~~

Evidence of Compliance:

✓ Patient reports with initial screening results and reflexive testing results and/or guidance

REFERENCES
1) Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014. Accessed 11/19/2019.
2) Association of Public Health Laboratories. Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm. January 2019. Available at APHL Publications. Accessed 11/19/2019.
3) National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (US). Divisions of HIV/AIDS Prevention; Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. Available at: https://stacks.cdc.gov/view/cdc/50872. Published January 2018. Accessed 4/2/2023.

BLOOD GAS ANALYSIS

***REVISED** 12/26/2024*

LSV.41370 Collateral Circulation Phase II

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

NOTE: ~~The~~Any of the various technologies ~~available have been~~ evaluated in the published literature~~.~~ are acceptable. Consensus should be established between the ~~laboratory~~point-of-care program and involved clinicians to define situations that require testing for collateral circulation, ~~including preferred technique(s) and situations in which such a test is medically useful in averting~~

~~potential~~*if any, to potentially avert* *patient~~/client~~ injury.* ~~The site from where the sample was obtained must be recorded.~~

Evidence of Compliance:

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

REFERENCES

1) Vaghadia H, *et al*. Evaluation of a postocclusive circulatory hyperaemia (PORCH) test for the assessment of ulnar collateral circulation. *Can J Anaesth.* 1988;35:591-598
2) Cheng EY, *et al*. Evaluation of the palmar circulation by pulse oximetry. *J Clin Monit.* 1989;5:1-3
3) Levinsohn DG, *et al*. The Allen's test: analysis of four methods. *J Hand Surg.* 1991;16:279-282
4) Fuhrman TM, *et al*. Evaluation of collateral circulation of the hand. *J Clin Monit.* 1992;8:28-32
5) Furhman TM, *et al*. Evaluation of digital blood pressure, plethysmography, and the modified Allen's test as a means of evaluating the collateral circulation to the hand. *Anaesthesia.* 1992;47:959-961
6) Fuhrman TM, McSweeney E. Noninvasive evaluation of the collateral circulation to the hand. *Acad Emerg Med.* 1995;2:195-199
7) O'Mara K, Sullivan B. A simple bedside test to identify ulnar collateral flow. *Ann Intern Med.* 1995;123:637
8) Starnes SL, *et al*. Noninvasive evaluation of hand circulation before radial artery harvest for coronary artery bypass grafting. *J Thorac Cardiovasc Surg.* 1999;117:261-266
9) Cable DG, *et al*. The Allen test. *Ann Thorac Surg.* 1999;67:876-877

BODY FLUIDS SECTION

MANUAL CELL COUNT - BODY FLUID

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

The diluting fluid is checked for ~~non-specimen~~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

AUTOMATED CELL COUNT - BODY FLUID

***REVISED** 12/26/2024*

LSV.43698 Background Checks - Automated Counts **Phase II**

Instrument background counts are performed each day of testing on the diluent fluid and lysing agent to check for contamination that might affect cell counts.

NOTE: This can be done by processing these fluids on the instrument used for cell counting and checking for the presence of significant background in the diluting fluids and lysing agents.

For any external diluting fluid not part of the instrument's reagent system, the laboratory must check for interfering background particulates each day of use. Checking can be done by examining samples of these fluids under the microscope. 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 **OR** records of interfering background particulate checks on external dilution fluids/reagents

SEMEN ANALYSIS

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

REFERENCES
1) Schlegel PN, Sigman M, Collura B, et al. Diagnosis and treatment of infertility in men: AUA/ASRM Guideline Part I. *J Urol* 2021;205(1):36-43.
2) Vasectomy Update 2010. *Can Urol Assoc J*. 2010 October; 4(5):306-309

MICROBIOLOGY SECTION

SPECIMEN COLLECTION AND HANDLING - MICROBIOLOGY

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

LSV.44772 Blood Culture Collection **Phase II**

Sterile techniques for drawing and handling of blood cultures are defined, made available to individuals responsible for specimen collection and practiced.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Blood Cultures*. 2nd ed. CLSI guideline M47. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.
2) Baron EJ, *et al.* Blood Cultures IV. Cumitech 1C. 2005. ASM Press: Washington, DC
3) Carroll KC, Pfaller MA, Landry ML, et al, eds. *Manual of Clinical Microbiology.* 12th ed. Washington, DC: ASM Press; 2019.
4) Leber, AL (ed). Clinical Microbiology Procedures Handbook. 4th ed. Washington DC: ASM Press; 2016.

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

LSV.44773 Blood Culture Contamination **Phase II**

The laboratory monitors blood culture contamination rates and has established an acceptable threshold.

NOTE: The laboratory must determine and regularly review the number of contaminated cultures. Tracking the contamination rate and providing feedback to units and persons drawing cultures has been shown to reduce contamination rates. Other measures for consideration in monitoring blood culture contamination include the types of skin disinfection used, line draws, and the use of diversion devices.

The threshold may be established in collaboration with other relevant institutional groups (eg, infection prevention). The laboratory must perform and record corrective action if the threshold is exceeded.

Evidence of Compliance:

✓ Records of contamination rates and corrective action if threshold is exceeded **AND**

✓ Records of feedback to responsible parties

REFERENCES

1) Bekeris LG, Tworek JA, Walsh MD, Valenstein PN. Trends in blood culture contamination: a College of American Pathologists Q-TRACKS study of 365 institutions. *Arch Pathol Lab Med.* 2005;129:1222-5.
2) Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Blood Cultures*. 2nd ed. CLSI guideline M47. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.
3) CDC Division of Laboratory Systems, Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals. Accessed February 8, 2024. https://www.cdc.gov/labquality/blood-culture-contamination-prevention.html

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

LSV.44774 Blood Culture Volume **Phase I**

The laboratory monitors blood cultures from adults for adequate volume and provides feedback on unacceptable volumes to blood collectors.

NOTE: Larger volumes of blood increase the yield of true positive cultures. The volume collected must be in accordance with manufacturer instructions (in most systems it is 20 mL, but smaller volumes may be recommended in some systems).

Evidence of Compliance:

✓ Records of monitoring of volume at a defined frequency **AND**

✓ Records of feedback to responsible parties

REFERENCES

1) Novis DA, *et al*. Solitary blood cultures. A College of American Pathologists Q-Probes study of 132778 blood culture sets in 333 small hospitals. *Arch Pathol Lab Med.* 2001;125:1290-1294
2) Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Blood Cultures*. 2nd ed. CLSI guideline M47. Clinical and Laboratory Standards Institute, Wayne, PA; 2022.
3) Baron EJ, *et al.* Blood Cultures IV, Cumitech 1C, 2005, ASM Press; Washington, DC

LSV.44775 Group B Streptococcus Screen **Phase II**

Group B streptococcus screens from pregnant women are collected and ~~identified~~ tested in accordance with the current guidelines.

NOTE: Universal prenatal screening for vaginal and rectal Group B streptococcal (GBS) colonization of all pregnant women at 36 to 38 weeks gestation is recommended. The optimum specimen for this test is a vaginal/rectal swab and results may be compromised if only a vaginal swab is submitted. Detection of GBS in urine cultures in this population should also be addressed.

Procedures for collecting and processing clinical specimens for GBS culture or molecular testing and performing susceptibility testing to clindamycin and erythromycin for highly penicillin allergic women are also included in the guidelines. Only the results of clindamycin should be reported.

Erythromycin should not be reported and is tested only for the purpose of determination of possible inducible clindamycin resistance.

REFERENCES
1) Filkins L, Hauser J, Robinson-Dunn B, Tibbetts R, Boyanton B, Revell P. American Society for Microbiology Clinical and Public Health Microbiology Committee, Subcommittee on Laboratory Practices. Guidelines for the Detection and Identification of Group B *Streptococcus.* March 10, 2020.
2) Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing.* 34th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute, Wayne, PA; 2024.

MEDIA

***REVISED** 12/26/2024*

LSV.45390 Media QC - Purchased/Acquired Phase II

An appropriate sample from each lot and shipment of each purchased/acquired medium for bacterial, mycobacterial, or mycologic culture is checked before or concurrent with initial use for each of the following:

1. **Sterility**
2. **Ability to support the growth of organisms intended to be isolated on the media by means of stock cultures or by parallel testing with previous lots and shipments**
3. **Biochemical reactivity, where appropriate**

NOTE: The laboratory must have records showing that all media are sterile, able to support growth, and are appropriately reactive biochemically. This checklist requirement does not apply to commercially prepared additives that are reconstituted when added to mycobacterial media.

An individualized quality control plan (IQCP), including all required elements of IQCP, may be implemented by the laboratory to allow for the acceptance of the quality control performed by the media supplier ~~for media listed as "exempt" in the CLSI Standard M22-A3, Quality Control for Commercially Prepared Microbiological Culture Media.~~ . The media supplier's records must be retained and show that the QC performed meets the ~~CLSI standard and~~ checklist requirements. Please refer to the IQCP section of the All Common Checklist for the requirements for implementation and ongoing monitoring of an IQCP. ~~End user quality control must be performed on the following, regardless of the exempt status:~~

- ~~*Campylobacter agar;*~~
- ~~*Chocolate agar;*~~
- ~~*Media for the selective isolation of pathogenic Neisseria;*~~
- ~~*Other media not listed on Table 2 of M22-A3 (eg, dermatophyte test medium);*~~
- ~~*Media used for the isolation of parasites, viruses, Mycoplasmas, Chlamydia;*~~
- ~~*Mueller-Hinton media used for antimicrobial susceptibility tests; or*~~
- ~~*Media commercially prepared and packaged as a unit or system consisting of two or more different substrates, primarily used for microbial identification.*~~

~~*Laboratories receiving media from media suppliers must have records showing that the quality control activities performed by the media supplier meet the CLSI Standard M22-A3, or are otherwise equivalent.*~~ *Problems with media deterioration or loss of reactivity in properly-stored media prior to the expiration date must be reported to the manufacturer, with records retained by the laboratory as part of corrective action.*

Laboratories using ~~exempt~~ media that have not implemented ~~an IQCP or are using media that do not qualify for~~ an IQCP must continue to test each lot and shipment of media and retain records of such testing.

Laboratories that supply uninoculated media to ~~referring~~ laboratories referring specimens to them are responsible for the quality control of the media. ~~The laboratory~~ and must provide ~~records or certification of~~ media quality control records with each shipment. If the supplying laboratory uses an IQCP for media, it may instead provide a copy of the applicable ~~approved~~ IQCP or IQCP

summary statement ~~must be available to the referring~~to the laboratory receiving the media (it is not necessary for the supplying laboratory ~~upon request. Records~~to provide the data used to develop the IQCP). In this case, the director of the receiving laboratory must approve the IQCP and retain the record to shop acceptance of ~~media quality control or the manufacturer's certificates of quality for each shipment must be available to the recipient~~the media QC processes.

Evidence of Compliance:

- ✓ Individualized quality control plan for the media approved by the laboratory director, as applicable **AND**
- ✓ Records of media quality control **AND**
- ✓ Records of reports of media problems/defects to manufacturers or referral laboratories supplying media

REFERENCES

1) Clinical and Laboratory Standards Institute. *Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard;* 3rd ed. CLSI document M22-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2004.
2) Clinical and Laboratory Standards Institute~~.~~ (CLSI). *Performance Standards for Antimicrobial Disk Susceptibility Tests~~; Approved Standard. 13th~~*. 14th ed. CLSI ~~document~~standard M02. Clinical and Laboratory Standards Institute, Wayne, PA; ~~2018~~2024.
3) 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(e)]
4) Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Detection of Fungi in Clinical Specimens-Direct Examination and Culture.* 2nd ed. CLSI guideline M54. Clinical and Laboratory Standards Institute, Wayne, PA; 2021. ..

IMMUNOLOGY SECTION

CALIBRATION AND STANDARDS - NONWAIVED TESTS

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

~~*The following requirements for calibration, calibration verification and AMR verification apply only to analyses that provide truly quantitative measurements expressed in mass units per unit volume (eg, gm/L or mg/ml) OR in units traceable to a reference preparation or standard that is calibrated in mass units per unit volume. If these criteria are not met, the measurement is NOT quantitative and this section is not applicable.*~~

NOTE: Explanatory notes and definitions on calibration, calibration verification and analytic measurement range verification 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.

BLOOD TYPE, GROUP, AND/OR ANTIBODY SCREENS

***REVISED** 12/26/2024*

LSV.46565 Historical Record Check **Phase II**

ABO/Rh results are compared with historical result records for each patient for at least the preceding 12 months.

NOTE: The purpose of this comparison is to detect sample/patient identification errors or other errors that might lead to the attribution of an incorrect blood type or antibody screen result to a patient. The historical record search can be performed manually by qualified laboratory personnel or with a validated computer system capable of performing historical checks. Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant government agency in its

jurisdiction. If the laboratory performing the testing does not maintain records that would allow this check to be performed, the testing shall be reported with a disclaimer alerting the ordering physician that the check has not been performed and that verifications of the sample's identity and the test results are strongly recommended.

Evidence of Compliance:
✓ Records of historical checks **OR**
✓ Records of LIS historical check validations

SYPHILIS SEROLOGY

***REVISED** 12/26/2024*

LSV.46605 ~~**Anti-Treponemal**~~**Syphilis Antibody Screening** **Phase II**

If the laboratory ~~uses anti-treponemal antibody testing as a~~ offers screening ~~test~~ for syphilis ~~infection, all specimens with an initial positive result have a non-treponemal test (eg, RPR, VDRL) performed. If results of the two~~, a complete screening algorithm is followed including appropriate confirmatory/secondary tests ~~are discordant, a second treponemal test on a different platform (eg, TPPA) is required~~.

NOTE: Screening for ~~syphilis~~infection by ~~starting~~Treponemal pallidum can be performed by initial testing with ~~an anti-~~either a nontreponemal (lipoidal antigen) antibody test (ie, traditional syphilis screening) or a treponemal antibody test ~~first~~ (ie, ~~the~~ reverse sequence syphilis screening ~~algorithm) has been shown to be an effective way to screen for infection with Treponema pallidum. It is still acceptable to use RPR or VDRL assays to test for active syphilis (forward algorithm).~~). The reverse ~~algorithm~~screening algorithm (with anti-treponemal antibody testing performed initially) may be preferred in cases of recent infection ~~and~~ or in cases of late latent or tertiary syphilis when ~~non-treponemal~~nontreponemal antibodies may not be detectable ~~or have disappeared over time~~ (even in the absence of adequate treatment~~), respectively. Given~~).

Regardless of the method used, a positive (reactive) result in the primary screening assay must be reflexively tested by at least one secondary test method. In the traditional syphilis screening algorithm, a nontreponemal (lipoidal antigen) antibody screening assay must be reflexively tested by an anti-treponemal assay (such as EIA or TPPA).

In the reverse sequence screening algorithm, a treponemal antibody screening assay must be tested by a nontreponemal (lipoidal antigen) assay (such as RPR or VDRL). When discordant results are obtained (screening anti-treponemal antibody positive, nontreponemal (lipoidal antigen) negative), an additional anti-treponemal test (eg, TPPA or EIA) must be performed given the possibility of false positive results in anti-treponemal antibody screening assays ~~however, in cases where the second tier non-treponemal test is negative (non-reactivity), a second anti-treponemal test (eg, TPPA) must be performed. This reflex~~.

Reflex testing in either algorithm may be performed on site or by a referral laboratory.

If the nontreponemal (lipoidal antigen) antibody test is performed to monitor treatment of patients with known syphilis infection (not as a screening tool), anti-treponemal antibody testing is not required. Because anti-treponemal antibodies persist after successful treatment, ~~guidelines recommend performing a non-treponemal test (RPR or VDRL) to help determine if infection~~testing patients with previously diagnosed syphilis using a reverse algorithm approach is ~~current or past. RPR and VDRL are also the assays that~~discouraged; therefore, laboratories should ~~be used to monitor~~ provide a clear option for providers to order nontreponemal (lipoidal antigen) titers directly for following serologic response to treatment.

This checklist requirement only applies to testing serum/plasma specimens. For testing CSF specimens, stand-alone anti-treponemal (eg, FTA-ABS or TPPA) and ~~non-treponemal (~~/or

nontreponemal (lipoidal antigen) (eg, VDRL) tests may be used at the discretion of the laboratory director.

Evidence of Compliance:

✓ Records of ~~non-treponemal test confirmation~~confirmatory testing of positive ~~anti-treponemal~~screening antibody results with appropriate secondary assays

REFERENCES
1) ~~Workowski KA, Bolan GA. Sexually transmitted disease guidelines, 2015. *MMWR Recomm Rep.* 2015;64(RR-03):1-37.~~Papp JR, Park IU, Fakile Y, Pereira L, Pillay A, Bolan GA, CDC laboratory recommendations for syphilis testing, United States, 2024. *MMQR Recomm.*
2) Rhoads DD, et al. Prevalence of traditional and reverse-algorithm syphilis screening in laboratory practice. A survey of participants in the College of American Pathologists syphilis serology proficiency testing program. *Arch Pathol Lab Med.* 2017;141(1):93-97.

HIV PRIMARY DIAGNOSTIC TESTING - IMMUNOLOGY

***REVISED** 12/26/2024*

LSV.47050 HIV Primary Diagnostic Testing - Supplemental and Confirmatory Testing Phase I

The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

NOTE: If additional testing after a primary screening test is recommended by public health authorities, the laboratory:

- *Performs additional testing reflexively if the specimen is suitable and the test is performed in house, or*
- *Sends additional testing to a referral laboratory if the specimen is suitable, or*
- *Provides guidance to providers on submission of additional specimens, if needed for supplemental or confirmatory testing.*

The US Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) provide recommendations for HIV testing. Guidelines and recommended algorithms can be found on the CDC and APHL websites.

~~*This checklist item does not apply to the testing of individuals from whom human derived products for therapeutic use are being derived or other types of testing performed for the monitoring of HIV infection (eg, viral load, CD4 counts). Reporting HIV results to public health is not within the scope of this checklist item.*~~

Evidence of Compliance:

✓ Patient reports with initial screening results and reflexive testing results and/or guidance

REFERENCES
1) Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447. Published June 27, 2014. Accessed 11/19/2019.
2) National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (US). Divisions of HIV/AIDS Prevention; Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens, Available at: https://stacks.cdc.gov/view/cdc/50872. Published January 2018. Accessed 4/2/2023.
3) Association of Public Health Laboratories. Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm. January 2019. Available at APHL Publications. Accessed 11/19/2019.