

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0668319	(X3) Date Survey Completed 08/20/2026
Name of Provider or Supplier Centers For Disease Control And Prevention I	Street Address, City, State 1600 Clifton Road Ne, Buildings 17,18 And 23, Atlanta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on laboratory director interviews and proficiency testing record review on July 28, 2026 at 02:50 pm, the laboratory failed to maintain copies of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the proficiency testing program, signed by the laboratory director. Findings included: a. For the following proficiency testing events, the laboratory's copy of the proficiency testing program's report forms used by the laboratory to record proficiency testing results showed that the attestation statements provided by the proficiency testing program were not signed by the laboratory director: 2025 WSLH first proficiency testing event viral, limited, 2025 CAP second proficiency testing event bacteriology, 2025 API third proficiency testing event microbiology, 2025 CAP third proficiency testing event viral markers series 6, 2026 CAP first proficiency testing event bacteriology, and 2026 CAP second proficiency testing event viral markers. b. The laboratory director confirmed these findings on July 28, 2026 at 02:50 pm. c. According to laboratory records, the laboratory performed and reported 8,788 patient test results annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on laboratory personnel interviews and STAT (Specimen Triage and Tracking) laboratory and LIMS (Laboratory Information Management System) protocol record review on August 6, 2026 at 12:30 pm, the laboratory failed to establish comprehensive written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified for all aspects of the laboratory's preanalytic systems specified in 493.1241 through 493.1242, specifically related to patient specimen processing. Findings included: a. A majority of the patient specimens received by the laboratory are initially accessioned by the laboratory's STAT laboratory before being distributed to the testing laboratories. b. According to STAT laboratory personnel, occasionally, patient specimens that do not meet the laboratory's criteria for acceptability are received. That is, a patient specimen is received in which there is a discrepancy in the documents, specimen labeling, storage, and/or transport of the specimen. c. According to STAT laboratory and LIMS personnel, documentation of these discrepancies are recorded in the LIMS. d. On August 6, 2026 at 12:30 pm, laboratory personnel confirmed that the laboratory maintained no written policies and procedures for an ongoing mechanism to monitor and assess information collected in the LIMS when patient specimens are received in which there are discrepancies in the documents, specimen labeling, storage, and/or transport of these specimens. e. According to laboratory records, the laboratory performed and reported 8,788 patient test results annually.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

I. Based on review of the Clinical and Environmental Microbiology Branch (CEMB) procedures, lack of media preparation procedures, and interview with the CEMB technical supervisors (TSs), the laboratory failed to have a signed procedure in place for the preparation of CHROMagar plates for 2 of 2 years. Findings: a. Review of the CEMB procedure revealed that the laboratory did not have signed procedures available for the preparation of CHROMagar plates for 2 years (August 2024 to August 2026). b. By interview on August 18, 2026, at 10:30 am, the CEMB TSs confirmed there were no procedures available for the preparation of CHROMagar plates. II. Based on review of the Rickettsial Zoonoses Branch (RZB) procedures and interview with the RZB technical supervisors (TSs), the laboratory failed to include counterstain quality control (QC) procedures in the Serology for Rickettsial Disease and Q Fever Using Indirect Immunofluorescence Antibody procedure for 2 of 2 years (August 2024 to August 2026). Finding: a. A review of the Serology for Rickettsial Disease and Q Fever Using Indirect Immunofluorescence Antibody procedure revealed that QC procedures were not address for performing QC for Eriochrome Black T, 1.65% counter stain prepared in-house for 2 of 2 years. b. By interview on August 19, 2026 at 3:00 pm, the RZB TSs confirmed counterstain QC procedures were not included in the Serology for Rickettsial Disease and Q Fever Using Indirect Immunofluorescence Antibody procedure. c. Per the laboratory's CLIA Laboratory Information Summary Report, the laboratory had a 2025 annual patient test volume of 174 and a 2026 annual patient test volume of 91 as of July 6, 2026 for the Serology for Rickettsial Disease and Q Fever Using Indirect Immunofluorescence Antibody procedure. III. Based on review of the Poxvirus and Rabies Branch (PRB) procedures and interview with the PRB technical supervisors (TSs), the laboratory failed to include counterstain quality control procedure (QC) in 3 of 3 Fluorescent microscopic examinations procedures. Finding: a. Per the laboratory's CLIA laboratory Information Summary Report, the laboratory performs the following three fluorescent microscopic examinations that included the use of Evan Blue counterstain which was prepared in-house: - Detection of Rabies Virus Antibodies by IFA; - Detection of Rabies Virus Neutralizing Antibodies by RFFIT; and, - Rabies Virus Antigen Detection by DFA. b. Review of fluorescent microscopic examination procedures revealed that these three procedures did not address performing QC for the Evans Blue counterstain. c. Interview with the PRB TSs on August 20, 2026 at 11:30 am confirmed Evan Blue counterstain QC was not included in these three Fluorescent microscopic examination procedures. d. Per the laboratory's CLIA Laboratory Information Summary Report, the laboratory had the following annual patient test volumes: - Detection of Rabies Virus Antibodies by IFA - 36 in 2025 and 18 in 2026; - Detection of Rabies Virus Neutralizing Antibodies by RFFIT - 148 in 2025 and 24 in 2026; and, - Rabies Virus Antigen Detection by DFA - 7 in 2025 and 4 in 2026.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

I. Based on LSDB (Laboratory Science and Diagnostics Branch) personnel interviews and Trichomonas susceptibility testing written protocol record review on August 20, 2026 at 01:15 pm, the laboratory failed to have the procedure detailing the formulation of Diamond's TYM media approved, signed and dated by the current laboratory director before use. Findings included: a. In the LSDB, it was the practice

	of the laboratory to use Diamond's TYM media when performing patient Trichomonas susceptibility testing. The Diamond's TYM media used by the laboratory was made by the laboratory. b. On August 20, 2026 at 01:15 pm, LSDB personnel confirmed that it had no documentation to indicate that the formula used by the laboratory to make the Diamond's TYM media had been approved, signed, and dated by the current laboratory director before the media was used to culture patient specimens. c. According to LSDB personnel, the laboratory performed and reported Trichomonas susceptibility testing results for approximately 12 patient specimens each month. 38555 II. Based on review of the infectious disease pathology branch (IDPB) procedures and interview with the IDPB technical supervisors (TSs), the laboratory failed to ensure that the Expected Result for Special Stains Procedure was signed by the current laboratory director (LD) from 2 of 2 years. Findings: a. Review of the IDPB Expected Result for Special Stain Procedure revealed the procedure was not approved, signed, and dated by the current laboratory director and had not been approved since February 22, 2018. b. By interview on August 19, 2026, the IDPB TSs confirmed that the Expected Result for Special Stains Procedure in use was not approved, signed, and dated by the current laboratory director.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on observation of the Clinical and Environmental Microbiology Branch (CEMB) laboratory areas and interview with the CEMB technical supervisor (TS), the laboratory failed to label 2 of 2 bottles of Biospec Products Zirconia/Silica beads with expiration dates. Findings: a. Observation of the CEMB laboratory on August 19, 2026 at 11:30 am revealed that the following two bottle were not labeled with expiration dates: - One bottle of Biospec Products 0.5mm Zirconia/Silica beads, cat number 110791052, date received: 07/06/2012 and date opened: 07/06/2012; and, - One bottle of Biospec Products 0.5mm Zirconia/Silica beads, cat number 110791052, date received: 06/12/2013 and date opened: 06/12/2013. b. By interview on August 19, 2026 at 11:45 am, the CEMB TS confirmed that the 2 above items were not labeled with expiration dates. c. Per the CEMB's CLIA Laboratory Information Summary Report, the laboratory had an annual patient test volume of 1,141 in 2025 and 1,073 in 2026 in which Biospec Products Zirconia/Silica beads were used. II. Based on observation of the Poxvirus and Rabies Branch (PRB) laboratory areas and interview with the PRB technical supervisor (TS), the laboratory failed to label 1 of 1 RT-PCR calibration kit and 1 of 1 spray bottle of 70% Ethanol with expiration dates. Findings: a. Observation of the PRB laboratory on August 20, 2026 at 1:30 pm revealed that the following products were labeled without expiration dates: - One spray bottle of 70% Ethanol labeled with prepped date: 6/09/2026; and, - One Applied Bio systems, RT-PCR calibration kit, lot# 2604596. b. By interview on August 20, 2026 at 1:45 pm, the PRB TS confirmed the above findings. c. Per the PRB's CLIA Laboratory Information Summary Report, the laboratory had a total annual patient test volume of 97 in 2025 and 2026 in which these products were used.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on Review of Poxvirus and Rabies Branch (PRB) procedures, review of microscope maintenance documentation, and interview with the PRB technical supervisor, the laboratory failed to follow their protocol and document daily maintenance for 3 of 3 microscopes. Findings: a. The PRB Microscope Use and Maintenance procedure under "10. Preventive Maintenance Procedure and Schedule, 10.1 Routine Maintenance, 10.1.2 Daily" stated: - "a. Clean lenses as needed using lens tissues and Zeiss Lens Cleaner only." - "b. Clean microscope stage using 70% isopropanol and Lint-free lab tissue." - "c. Check to make sure that the maximum operational hours of the mercury vapor HBO 100 (OSRAM 103/w2 rated for 300 hours) are not exceeded, and that the number of times the microscope is turned on does not exceed 200." - "d. Check that test controls exhibit the expected results. If controls fail, notify the Technical Supervisor immediately. An NCE and troubleshooting processes will be initiated." - "e. Record routine any daily maintenance needed in the comments section of the Fluorescence Microscope Use Log (CDC-007-00344)." b. Review of the PRB Microscope Use Log revealed that the above daily maintenance was not listed on the log nor documented for 2 of 2 years. c. The PRB laboratory used three Zeiss Axio Imager A2 microscopes for fluoresce antigen and antibody microscopic examinations. d. Interview with the PRB TS on August 20, 2026 at 12:00 pm confirmed that the laboratory failed to document daily microscope maintenance as stated in the above policy for all microscopes in use. e. Per the PRB's CLIA Laboratory Summary Report, the laboratory's total annual patient test volume for 2025 and 2026 was 97 in which the microscopes were used.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on LSDB (Laboratory Science and Diagnostics Branch) personnel interviews and free-living ameba antigen detection quality control record review on August 20, 2026 at 10:15 am, the laboratory failed to establish statistical parameters for free-living ameba antigen detection unassayed quality control materials over time through concurrent testing of quality control materials having previously determined statistical

	parameters. Findings included: a. In the LSDB, it was the practice of the laboratory to use unassayed positive quality control materials to monitor its patient free-living ameba antigen detection testing. b. On August 20, 2026 at 10:15 am, LSDB free-living ameba antigen detection testing records indicated that the positive Acanthamoeba species quality control material, lot number AC06292026-C, expiration date 06/29/2027, was in use to monitor patient free-living ameba antigen detection testing. c. According to LSDB records, the laboratory maintained no records to indicate that the statistical parameters for the positive Acanthamoeba species quality control material, lot number AC06292026-C, expiration date 06/29/2027, had been established over time through concurrent testing of quality control materials having previously determined statistical parameters. d. These findings were confirmed by LSDB personnel on August 20, 2026 at 10:15 am. e. According to LSDB personnel, the laboratory performed and reported approximately 18 patient free-living ameba antigen detection testing annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Poxvirus & Rabies Branch (PRB) laboratory procedures, lack of documentation, and interview with the PRB technical Supervisor (TS), the laboratory failed to document actions taken for 1 of 1 inconclusive patient test result found for Lyssavirus PCR testing. Findings: a. The Lyssavirus Real-Time RT-PCR Protocol stated on Page 15, Table 2, results matrix for LN34 assay table: "Result - Inconclusive, Beta-actin ct - Any, Action - Repeat or additional testing required." b. The laboratory was unable to provide documentation of any actions taken for the 1 (Specimen ID 25CREFC0277) of 1 Lyssavirus Real-Time RT-PCR patient test result which had an inconclusive test result of a ct value of 35.7 which was indicated on the Lyssavirus Real Time PT PCR Results worksheet, test date 08/1/2025. c. By interview on August 20, 2026 at 12: 50 pm, the PRB TS confirmed that actions taken were not documented for the above inconclusive patient test result.