

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0650270	(X3) Date Survey Completed 07/17/2025
Name of Provider or Supplier Massachusetts Department Of Public Health	Street Address, City, State 305 South St, Jamaica Plain, MA	
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
D0000	A recertification survey was performed July 15 through July 17, 2025. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1240 Pre-Analytic Systems 493.1441 Laboratory Director, (high complexity)
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on observation, lack of room temperature records, and interview with the Quality Assurance Director, the laboratory failed to retain room temperature records for 12 of 12 months. Findings include: 1. Observation on 07/17/25 at 12:00 pm revealed the following collection kits stored in the laboratory's basement: a. Hologic Aptima Unisex Swab Specimen Collection Kit - Lot# 917111 (176 collection kits) with a manufacturer's storage requirement of 15 to 30C. b. Hologic Aptima Multitest Swab Specimen Collection Kit - Lot# 913085 (21 collection kits) with a manufacturer's storage requirement of 15 to 30C. 2. Review of room temperature records for the laboratory's basement storage area revealed no evidence of 2024 (January 2024 through December 2024) room temperature records. 3. Interview on 07/17/25 at 01:30 pm, the Quality Assurance Director confirmed the laboratory failed to maintain room temperature records for 2024.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on the laboratory's written policy and procedure, record review, and interview with the Quality Assurance Director, the laboratory failed to verify the accuracy of the Plaque Reduction Neutralization Test (PRNT) at least twice annually for 2024.

Findings include: 1. Review of the laboratory's written policy and procedure titled, "VI.044 PRNT: WNV, EEE, Zika and Denque viruses" section "Scope" stated, " EEE EIA positive samples will be tested by PRNT for EEE virus. Any WNV EIA positive samples will be tested by PRNT for WNV and SLE virus. Any Zika EIA positive samples will be tested by PRNT for Zika, Dengue 1, and Dengue 2." 2.

Record review from 01/01/24 through 12/31/24 revealed no evidence of twice annual accuracy for PRNT before 12/18/24. 3. Interview on 07/15/25 at 02:07 pm, the Quality Assurance Director confirmed the laboratory failed to perform twice annual accuracy assessment for PRNT in 2024. Word Key: WNV= West Nile Virus EEE= Eastern Equine Encephalitis EIA= Enzyme Immunoassay PRNT= Plaque Reduction Neutralization Test SLE= St. Louis Encephalitis

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, laboratory policies /procedures, the laboratory's online specimen submission instructions, patient records, and staff interview, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport temperature conditions). Refer to D5311.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of laboratory policy, manufacturer's instructions, the laboratory's online specimen submission instructions, patient records, and staff interview, the laboratory failed to have a system to ensure specimen integrity was maintained (transport temperature conditions) for 15 of 15 patient specimens for

mycobacteriology testing. Findings included: 1. During a tour of the laboratory's specimen receiving area (Room 1060) on 07/16/2025 at 10:25 am, incoming specimens for mycobacteriology testing shipped by FedEx, United Parcel Service (UPS), or by the client's courier service were observed. None of the specimens observed were monitored for transport temperatures. 2. The laboratory policy titled, "CS.001 Specimen Receiving Standard Operating Procedure" stated " ...PRINCIPLE / PURPOSE The Massachusetts State Public Health Laboratory (MA SPHL) is committed to providing the highest quality testing and services to the Commonwealth. Pre-analytical specimen receipt process must be standardized to ensure all specimens are handled in a safe uniform manner consistent with all testing requirements to avoid delays in patient testing, prevent misdirected specimens and ensure that all specimens are processed and stored in proper temperatures to minimize specimen rejection ..." This policy failed to define specific transport temperature for mycobacteriology specimens. Further review of the laboratory titled, "TB.020 GeneXpert RT PCR MTB /RIF" stated " ...Requirements (Acceptability and Rejection Criteria) A. The GeneXpert MTB/RIF assay will only be performed at the MA SPHL Mycobacteriology Laboratory for samples that meet the following criteria: a. Unprocessed Sputum is stable for up to 7 days at 2-8 C. b. Sediments may be stored at 2-8C for up to seven days before testing ..." 3. The manufacturer's instructions for the Cepheid GeneXpert MTB/RIF test assay stated, " ...8.2 Storage and Transport Sputum sediment: Store suspended sediments at 2-8C for up to seven days. Raw sputum: Transport and store specimens at 2-8C before testing whenever possible. If necessary, sputum specimens can be stored at a maximum of 35C for up to 3 days and then at 2-8C for an additional seven days ..." 4. Review of the laboratory's online "Manual of Laboratory Tests and Services" (<https://www.mass.gov/doc/manual-of-laboratory-tests-and-services/download>) revealed the site was no longer accessible for the laboratory's specimen submitters. 5. Review of patient records revealed the following sputum specimens were received on 07/16/2025. Transport temperature of the specimens was not monitored or documented by the laboratory. Specimen number 25TB08283; Expecterated Sputum Specimen number 25TB08284; Expecterated Sputum Specimen number 25TB08285; Expecterated Sputum Specimen number 25TB08286; Expecterated Sputum Specimen number 25TB08287; Expecterated Sputum Specimen number 25TB08288; Expecterated Sputum Specimen number 25TB08289; Expecterated Sputum Specimen number 25TB08293; Induced Sputum Specimen number 25TB08294; Induced Sputum Specimen number 25TB08295; Expecterated Sputum Specimen number 25TB08296; Expecterated Sputum Specimen number 25TB08297; Expecterated Sputum Specimen number 25TB08298; Expecterated Sputum Specimen number 25TB08299; Expecterated Sputum Specimen number 25TB08300; Expecterated Sputum 6. In an interview on 07/16/2025 at 10:35am, the Central Laboratory Services Supervisor was asked for documentation of transport temperature for received specimens. She stated that the laboratory does not monitor specimen receipt temperatures. This confirmed the findings. 7. The laboratory has an annual volume of 1250 specimens for tested for MTB/RIF on the Cepheid GeneXpert instrument. Work Key: RT PCR= Real Time Polymerase chain reaction MTB/RIF= Mycobacterium tuberculosis/Rifampin MA SPHL=Massachusetts State Public Health Laboratory 47272 II. Based on the laboratory's written policy and procedure, patient submission forms, final patient test reports, and interview with Technical Supervisor #4 (TS #4) and the Quality Assurance Director, the laboratory failed to have a system to ensure specimen integrity was maintained (transport temperature conditions) for six of six patient specimens. Findings include: 1. On 07/16/25 at 10:15 am, TS #4 confirmed the laboratory performed HIV (Human Immunodeficiency Virus), HCV (Hepatitis C), and Syphilis testing by Chemiluminescent Microparticle Immunoassay (CMIA) on the Abbott Alinity i

analyzer. 2. Review of the laboratory's written policy procedure, "ST.033 Abbott Alinity i testing for HIV, HCV and Syphilis by CMIA" under section, "COLLECTION /SUBMISSION OF SAMPLES" stated, "4. Serum is stable for up to 3 days at room temperature (15C to 30C) or 7 days at 2- 8C from date of collection for CMIA testing." 3. Review of "Specimen Submission Form (HIV/HCV/SYPHILIS TESTING)" and final patient reports revealed no evidence of transport temperature conditions for six of six patient specimens: a. Patient# 24VL100554- Specimen submitted for HIV, HCV, and Syphilis testing. Patient specimen collected on 10/30/24, received into the laboratory on 10/30/24, and reported on 11/01/24. b. Patient# 24VL100897- Specimen submitted for HIV, HCV, and Syphilis testing. Patient specimen collected on 10/30/24, received into the laboratory on 10/31/24, and reported on 11/04/24. c. Patient# 25VL24014- Specimen submitted for HIV, HCV, and Syphilis testing. Patient specimen collected on 03/14/25, received into the laboratory on 03/14/25, and reported on 03/18/25. d. Patient# 25VL44136- Specimen submitted for HIV, HCV, and Syphilis testing. Patient specimen collected on 05/20/25, received into the laboratory on 05/20/25, and reported on 05/21/25. e. Patient# 25VL44480- Specimen submitted for HIV, HCV, and Syphilis testing. Patient specimen collected on 05/20/25, received into the laboratory on 05/21/25, and reported on 05/21/25. f. Patient# 25VL62125- Specimen submitted for HIV, HCV, and Syphilis testing. Patient specimen collected on 07/10/25, received into the laboratory on 07/12/25, and reported on 07/15/25. 4. Interview on 07/16/25 at 01:35 pm with the Quality Assurance Director confirmed the laboratory failed to have a system in place to ensure specimen integrity from collection to submission of patient specimens as indicated above. 5. The laboratory's annual volume for CMIA performed on the Abbott Alinity i analyzer: a. HIV - 38,399 tests b. HCV - 38,343 tests c. Syphilis - 38,338 tests III. Based on direct observation, laboratory's written policy and procedures, patient requisitions, and interview with the laboratory technician, the laboratory failed to have a system to ensure specimen integrity was maintained (transport temperature conditions) for eight of eight patient specimens for lead testing. Findings include: 1. During a tour of the laboratory's specimen receiving area (Room 1060) on 07/16/2025 at 10:30 am, incoming specimens for lead testing shipped by FedEx, United Parcel Service (UPS), or by the client's courier service were observed. None of the specimens observed were monitored for transport temperatures. 2. The laboratory policy titled, "PB.001 Determination of Lead In Whole Blood by Graphite Furnace Atomic Absorption (GFAA) Spectrometry using the Perkin Elmer PinAAcle 900Z" stated, "Specimens should be shipped to the laboratory as soon as possible, no more than 14 days of collection. However, lead stability in blood tested by GFAAS has been shown to be comparable to the variation in the average precision of two quality control specimens contained in polypropylene and vacutainer tubes when held at 4C, or -20C for up to a 10-week period (Wang et al., 1985). Specimens should be refrigerated at 4C if not shipped for receipt by the laboratory within 5 days." 3. Review of patient requisitions for lead specimens received on 07/16/2025 revealed no evidence that the laboratory monitored or documented the transport temperature of the specimens: Specimen number 25BL02022 Specimen number 25BL02023 Specimen number 25BL02024 Specimen number 25BL02025 Specimen number 25BL02026 Specimen number 25BL02027 Specimen number 25BL02028 Specimen number 25BL02029 4. In an interview on 07/16/2025 at 10:40 am, the specimen receiving laboratory technician confirmed the laboratory did not monitor or document the transport temperatures of lead specimens. 5. The laboratory's annual volume for lead testing is 39,384 on the Perkins Elmer PinAAcle 900Z analyzer. IV. Based on direct observation, laboratory's written policy and procedure, review of the manufacturer's instructions, patient specimen submission forms, and interview with the Quality Assurance Director, the laboratory failed to have a system to ensure specimen

integrity was maintained (transport temperature conditions) for seven of seven patient specimens for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) testing. Findings include: 1. During a tour of the laboratory's specimen receiving area (Room 1060) on 07/16/2025 at 10:00 am, incoming specimens for CT/GC testing shipped by FedEx, United Parcel Service (UPS), or by the client's courier service were observed. None of the specimens observed were monitored for transport temperatures. 2. On 07/16/25 at 10:15 am, TS #4 confirmed the laboratory performed CT/GC testing using the Hologic Panther System and the Aptima Combo 2 Assay. 3. Review of the laboratory's written policy and procedure titled, "STD.007 APTIMA Combo 2 Assay for CT and GC on the Hologic Panther Instrument" stated, "This assay is used to detect CT and/or GC RNA in vaginal endo-cervical and male urethral swabs, and in urines from male patients. The Massachusetts Bureau of Infectious Disease and Laboratory Sciences has further validated this assay for use with rectal swabs, female urines and oropharyngeal swabs." This policy failed to specify transport conditions for CT/GC specimens. 4. Review of the manufacturer's instructions for the Aptima Multitest Swab Specimen Collection Kit and the Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens stated, section "Specimen Transport and Storage" stated, "After collection, transport and store the swab in the swab specimen transport tube at 2C to 30C until tested" 5. Review of patient "Specimen Submission Form (CHLAMYDIA/GONORRHEA TESTING)" for CT/GC specimens received on 07/16/2025 revealed no evidence the laboratory monitored or documented the transport temperature of the specimens: Specimen number 25VL62851 Specimen number 25VL62852 Specimen number 25VL62853 Specimen number 25VL62854 Specimen number 25VL62855 Specimen number 25VL62856 6. In an interview on 07/17/2025 at 01:30 pm, the Quality Assurance Director confirmed the laboratory did not monitor or document the transport temperatures of CT/GC specimens. 7. The laboratory's annual volume for CT/GC testing is 152,034 on the Hologic Panther System.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
 CFR(s): 493.1242(d)

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's client services manual and in interview with staff, the laboratory failed to ensure written instructions for specimen storage and stability of all tests were available to laboratory's clients for 18 of 18 months. Findings included: 1. Review of the laboratory's online "Manual of Laboratory Tests and Services" (<https://www.mass.gov/doc/manual-of-laboratory-tests-and-services/download>) revealed the site was no longer accessible for the laboratory's specimen submitters. 2. In an interview on 07/17/2025 at 9:30 am, the Quality Assurance Director stated that the website had been discontinued in January 2024 and confirmed that specimen submission instructions have not been available to the laboratory's clients since January 2024.

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:

Based on laboratory's written policy and procedure and interview with the Quality Assurance Director, the Laboratory Director failed to approve, sign, and date one of one procedure. Findings include: 1. On 07/16/25 at 08:30 am, the Quality Assurance Director confirmed the laboratory performed testing to rule out or confirm the following biological agents: a. Bacillus anthracis b. Brucella species c. Burkholderia mallei/pseudomallei d. Francisella tularensis e. Yersinia pestis. 2. Review of the laboratory's written policy and procedure titled, "BT.022 Laboratory Response Network real-time PCR for Biothreat Response Laboratory" implementation date 09/29/2023, revealed no evidence the Laboratory Director approved, signed, and date the policy and procedure. 3. In an interview on 07/16/25 at 03:37 pm, the Quality Assurance Director confirmed the Laboratory Director failed to approve, sign, and date the policy and procedure.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of manufacturers' instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for three of three months. Findings included: 1. During a tour of the mycobacteriology testing area (Room 757) on 07/16/2025 at 9:25 am, the following Kinyoun staining reagents were observed in use by the laboratory: One bottle TB Kinyoun Carbolfushsin; Lot number 147783; Expiration date 04/18/2025 One bottle TB Decolorizer; Lot number 143703; Expiration date 12/18/2025 One bottle TB Methylene Blue; Lot number 149511; Expiration date 06/19/2026 2. The manufacturers' instructions for each of the stains stated " ...Store product in its original container at room temperature (20-25 C) ..." 3. Review of the laboratory's environmental records for Room 757 (Feb - April 2025) revealed an acceptable room temperature range of 18 - 27 C. Further review of the records revealed the following dates when the recorded room temperatures were not within manufacturer's specifications (20-25 C): 02/04/2025; 19.4 C 02/05/2025; 19.7 C 02/06/2025; 19.4 C 02/07/2025; 19.7 C 02/12/2025; 19.7 C 02/13/2025; 19.7 C 02/14/2025; 19.4 C 02/18/2025; 19.2 C 03/04/2025; 18.6 C 03/05/2025; 19.2 C 03/10/2025; 18.4 C 03/11/2025; 19.4 C 03/12/2025; 19.9 C 03/13/2025; 19.8 C 03/24/2025; 18.6 C 03/27/2025; 19.4 C 04/02/2025; 19.8 C 04/03/2025; 19.5 C 04/08/2025; 19.4 C 04/11/2025; 19.7 C 04/14/2025; 19.7 C 04/17/2025; 19.8 C 04/22/2025; 19.4 C 04/23/2025; 19.8 C 4. In an interview on 07/16/2025 at 10:15 am, Technical Supervisor #4 confirmed that the room temperature acceptable range in room 757 was not within manufacturer's specifications for the Kinyoun staining reagents. II. Based on direct

observation, review of Bruker MALDI-ToF Biotyper operator's manual, laboratory procedure, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure environmental conditions were within manufacturer's specifications for nine of nine days. Findings included: 1. During a tour of the clinical microbiology testing area (Room 1060) on 07/16/2025 at 2:30 pm, a Bruker MALDI-ToF Biotyper 3.1 (Serial Number 8604562.03659) was observed. 2. The Bruker MALDI-ToF Biotyper 3.1 operator's manual stated system operation environmental requirements of 16-33 C and a relative humidity of 20 - 75%. 3. The laboratory's procedure titled "CM.001 Identification of Bacterial Isolates Using the Bruker MALDI Biotyper System" stated " ...Environmental Condition Requirements: The Operating range of the MALDI-TOF is 10 - 30 C ..." The operating range stated in the laboratory's procedure did not correspond to the manufacturer's specified temperature range. 4. In an interview on 07/16/2025 at 3:00 pm, the Quality Management Systems Manager was asked to provide documentation of room temperature and relative humidity monitoring for July 7 -15, 2025. Room temperature was monitored and documented. Relative humidity was recorded but the laboratory failed to define acceptable relative humidity criteria to include the manufacturer's specifications for the Bruker MALDI-ToF. This confirmed the findings. III. Based on direct observation, review of manufacturer's storage requirements, lack of laboratory environmental records, and confirmed in staff interview, the laboratory failed to ensure room temperature ranges were within manufacturer's specifications for 44 of 44 media preparation reagents. Findings included: 1. During a tour of the laboratory's "Media Prep" area (Room 0090) on 07/17/2025 at 9:30 am, a random sample of 44 different reagent powders to prepare microbiology nutrient media and broths was observed. 2. The following is a sampling of powdered media and broths and the manufacturer's temperature storage specifications (indicated on the container label): a. One container Millipore Glucose Monohydrate; Lot number K56139942513; Expiration 04/30/2029; Storage requirement 15-25 C b. One container Difco Tetrathionate Broth Base; Lot number 3353607; Expiration date 10/31/2025; Storage requirement 2 -25 C c. Four containers Difco Tetrathionate Broth Base; Lot number 4240828; Expiration date 03 /31/2026; Storage requirement 2 -25 C d. Three containers Difco Middlebrook 7H9 Broth; Lot number 271310; Expiration date 08/31/2026; Storage requirement 15-25 C e. One container Oxoid Listeria Enrichment Broth Base; Lot number 3294115; Expiration date 05/2026; Storage requirement 10-30 C f. One container Oxoid Blood Agar Base No. 2; Lot number 3393452; Expiration date 12/2026; Storage requirement 10-30 C 3. In an interview on 07/17/2025 at 10:05 am, the Central Laboratory Services Supervisor was asked to provide documentation of room temperature monitoring. No documentation was provided. This confirmed the findings. Word Key: TB-Mycobacterium tuberculosis C-degrees Celsius 47272 V. Based on manufacturer's instructions, room temperature records, and interview with Technical Supervisor #4 (TS #4) and the Quality Assurance Director, the laboratory failed to ensure the manufacturer's requirements for room temperature for five of 15 days. Findings include: 1. On 07/16/25 at 10:15 am, TS #4 confirmed the laboratory performed Anti-HCV assay (the detection of antibodies to the Hepatitis C virus) using the Abbott Alinity i analyzer. 2. Review of room temperature log, "ST.033 F#4 Alinity I Instrument Daily Run Log" revealed a room temperature range of 15C - 30 C. The operating range stated on the laboratory's room temperature log did not correspond to the manufacturer's specified temperature range. 3. Review of manufacturer's instructions section, "Specimen Storage" stated "Room temperature" requirement of 20 to 23C. 4. Review of room temperature records from 06/02/25 through 06/30/25 revealed the laboratory failed to ensure the manufacturer's requirements for room temperatures for five of 15 days: a. 06/02/25 - documented room temperature 23.8C b. 06/03/25 - documented room temperature 23.6C c. 06/04/25 - documented room

temperature 23.1C d. 06/05/24 - documented room temperature 25.0 C e. 06/06/25 - documented room temperature 25.0 C 5. Interview on 07/16/25 at 11:15 am with the Quality Assurance Director confirmed the findings above. VI. Based on manufacturer's instructions, humidity records, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to ensure the manufacturer's humidity requirements for four of four days. Findings include: 1. On 07/17/25 at 01:30 pm, TS #2 confirmed the laboratory performed molecular virology testing using Applied Biosystems 7500 Fast Dx Real-Time PCR (Polymerase Chain Reaction) instruments. 2. Review of the manufacturer's "Environmental Specifications" stated, "Humidity: 20 to 80% relative humidity, noncondensing". 3. Review of humidity records revealed the laboratory failed to ensure the manufacturer's humidity requirements for four of four days: a. 03/01/24 - documented humidity 18.5% b. 03/21/24 - documented humidity 18.0% c. 03/22/24 - documented humidity 15.4% d. 03/24/24 - documented humidity 19.6% 4. Interview on 07/17/25 at 02:00 pm with TS #2 confirmed the findings. VII. Based on manufacturer's instructions, freezer temperature records, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to ensure the manufacturer's freezer storage requirements for 11 of 11 days. Findings include: 1. On 07/17/25 at 01:40 pm, TS #2 confirmed the laboratory performed molecular virology testing using the Invitrogen SuperScript III Platinum One-Step qRT-PCR (Real-Time Polymerase Chain Reaction) Kit for the detection and quantification of RNA using the Applied Biosystems 7500 Fast Dx Real-Time PCR instruments. 2. Review of the manufacturer's "Storage" requirements stated, "Store components at -20C." 3. Review of freezer (8084 -20 Freezer (A) serial number 1116405401210614) records from 03/03/24 through 03/13/24 revealed the laboratory failed to ensure the manufacturer's freezer storage requirements for 11 of 11 days: a. 03/03/24 - documented freezer temperature -19C b. 03/04/24 - documented freezer temperature -19C c. 03/05/24 - documented freezer temperature -18C d. 03/06/24 - documented freezer temperature -19C e. 03/07/24 - documented freezer temperature -18C f. 03/08/24 - documented freezer temperature -18C g. 03/09/24 - documented freezer temperature -18C h. 03/10/24 - documented freezer temperature -19C i. 03/11/24 - documented freezer temperature -19C j. 03/12/24 - documented freezer temperature -19C k. 03/13/24 - documented freezer temperature -18C 4. Interview on 07/17/25 at 02:10 pm with TS #2 confirmed the findings.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on performance specification and establishment record review and interview with Technical Supervisor #6 (TS #6) and the Quality Assurance Director, the laboratory failed to establish performance specifications of analytical sensitivity and

	<p>analytical specificity for two of two instruments. Findings include: 1. On 07/16/25 at 10:30 am, TS #6 confirmed the laboratory performed Blood Lead testing using two Perkin Elmer PinAAcle 900Z Atomic Absorption Spectrometers: a. P900Z-1 - Serial number PBZS23091801 (available for patient use 09/06/24) b. P900Z -1 - Serial number PBZS23100201 (available for patient use 09/06/24) 2. Record review of implementation records for P900Z-1 and P900Z -2 revealed no evidence of establishment and verification of performance specifications for analytical sensitivity and analytical specificity. 3. In an interview on 07/17/25 at 09:35 am, the Quality Assurance Director confirmed the findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory policies/procedures, laboratory records, patient reports, and in interview with staff, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The laboratory director failed to ensure quality laboratory services for high complexity preanalytic systems. Refer to D6082</p>
<p>D6082</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies/procedures, laboratory records, patient reports, and in interview with staff, the laboratory director failed to ensure quality laboratory services for high complexity preanalytic systems, as evidenced by: 1. The laboratory failed to have a system to ensure specimen integrity was maintained (transport temperature conditions) for 15 of 15 patient specimens for mycobacteriology testing. Refer to D5311, I. 2. The laboratory failed to ensure written instructions for specimen storage and stability of all tests were available to laboratory's clients. Refer to D5317.</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory policy, laboratory personnel records, and confirmed in interview, Technical Supervisors failed to assess semiannual competencies for three of nine testing persons. Findings included: 1. The laboratory policy titled " QA.001 Training and Competency" stated " ...Responsibilities ...Technical Supervisor ... develop competency assessment schedules to ensure all staff have annual DOCs conducted in a timely manner ...conduct 6-month and annual competency assessments or delegate some of the tasks to a general supervisor or other qualified individual ... ultimately responsible for ensuring the competency of all technical staff that report to them ...Competency Assessment: Competency assessment will occur at 6 months post-employment, at one-year post-employment and annually thereafter ..." 2. A random review of the laboratory's personnel records revealed the following documentation: a. Testing Person #1 (as listed on the CMS 209 form) First competency assessment performed: Specimen Processing/Handling 07/2024 Second competency assessment performed: Arbovirus 12/2024 No documentation for the second assessment for specimen processing/handling and no documentation of the first competency assessment for Arbovirus testing was provided for the semiannual competency assessment. b. Testing Person #3 First competency assessment performed: Mumps IgM 01/2025 Viral Cell Cultures 01/2024 Arbovirus 08/2024 Specimen Processing 10/2024 No documentation for the second assessment was provided for the semiannual competency assessments c. Testing Person #51 First competency assessment performed: Maldi-Tof 03/2023 No documentation for the second assessment was provided for the semiannual competency assessments 3. In an interview on 07/15/2025 at 1:20 pm, the Quality Assurance Director confirmed the findings. Word Key: CMS=Centers for Medicare and Medicaid DOC=Documentation of Competency