Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2005937	01/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Wadsworth Center - David Axelrod Institute	New York State Department Of Health, Albany, NY	

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 January 13-15, 2026. The facility was found to be NOT in compliance with the following CLIA conditions for specialties /subspecialties surveyed for 42 CFR: 493.1487 Laboratories performing high complexity testing; testing personnel;
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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: I. Based on newborn screening (NBS) laboratory technical supervisor interview and NBS laboratory test verification records review on January 13, 2026 at 10:00 am, the NBS laboratory failed to verify the accuracy for 10 of 66 tests it performed that were not included in subpart I at least twice annually in 2025. Findings included: 1. It was the practice of the NBS laboratory to perform and report patient test results for the following tests: hydroxyoctadecenoylcarnitine (C18:1OH), hydroxyhexanoylcarnitine (C6OH), methylglutarylcarnitine (C6DC), methylmalonylcarnitine (C4DC), ornithine, argininosuccinic acid, dedecenoylcarnitine (C12:1), dodecanolycarnitinbe (C12), hydroxyhexadecenoylcarnitine (C16:1(OH)), and metachromatic leukodystrophy (C16:0- and C16:1-OH sulfatides). 2. On January 13, 2026 at 10:00 am, the NBS laboratory technical supervisor confirmed that the laboratory maintained no mechanism to verify the accuracy of these tests not listed in subpart I at least twice annually. 3. According to the NBS laboratory technical supervisor, the NBS laboratory received approximately 20,000 patient specimens monthly. 41090 II. Based on a review of the laboratory's policy titled Proficiency Testing-Analysis Evaluation and Review, the laboratory's records, and an interview with General Supervisor #37, the laboratory failed to verify the accuracy of seven analytes one of two times in 2025. Findings Include: 1. A review of the laboratory policy QS-03SOP Proficiency Testing-

	Analysis Evaluation and Review, signed by the laboratory director on 12/01/2025, revealed, "4. Requirements for PT Sample Analysis, 4.1 Participation-At least semiannually each laboratory section is required to verify the reliability and accuracy of test methods for each analyte tested. This testing may be accomplished: by participating in a CMS-approved PT program, or by evaluating the accuracy of testing through an internal proficiency testing program ...Internal PT is required for any clinical test that are not included in an external PT." 2. A review of the laboratory's documents revealed that the laboratory performed one accuracy verification in 2025 for the seven Laboratory Response Network (LRN) analytes. 3. An interview on 1/15 /2026 at 11:55 AM, with General Supervisor #37, as listed on the CMS-209, confirmed these findings. Word Key: PT=proficiency testing
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 newborn screening (NBS) laboratory specimen processing personnel interviews and NBS laboratory specimen processing and quality assessment polices and procedures records review on January 13, 2026 at 11:00 am, the laboratory failed to establish a written procedure for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493. 1241 through 493.1242, specifically related to patient specimen processing of patient demographic information in 2025 and 2026. Findings included: 1. In the NBS laboratory, upon receipt of patient specimens, patient test requisition demographics information was entered into the laboratory's information system by NBS laboratory personnel. The entered patient demographics information was then verified for data entry accuracy. If patient demographics information was entered incorrectly, the patient's record is corrected and updated accordingly. 2. According to the NBS laboratory patient demographics information data entry supervisor on January 13, 2026 at 11:00 am, patient records which had been corrected and updated during the data entry verification review were reviewed daily for trend analysis. The NBS laboratory patient demographics information data entry supervisor confirmed that the laboratory maintained no written procedures for this quality assessment review. 3. On January 14, 2026 at 08:50 am, the NBS laboratory technical supervisor confirmed these findings. 4. According to the NBS laboratory technical supervisor, the NBS laboratory received approximately 20,000 patient specimens monthly.
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 director and virology culture cell lines preparation personnel interviews and virology culture cell lines preparation policies and procedures record review on January 15, 2026 at 11:45 am, since November 2025, the laboratory failed

	to have 8 of 8 written virology culture cell lines preparation procedures approved, signed, and dated by the current laboratory director before use. Findings included: 1. In the virology laboratory, it was the practice of the laboratory to maintain its own virology culture cell lines used to culture patient virology specimens for the following: HDck, HEL, Vero, Vero SLAM, CaCo, A549, and RD. 2. Since November 2025, the laboratory maintained no documentation to indicate that the written procedures used to maintain these virology culture cell lines had been approved, signed, and dated by the current laboratory director. 3. These findings were confirmed by virology culture cell lines preparation personnel on January 15, 2026 at 11:30 am. 4. According to virology testing personnel, the laboratory received approximately 2 patient virology culture specimens weekly.
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 observation, review of instrument operator's instructions, laboratory environmental records, and confirmed in interview with the Technical Supervisor, the laboratory failed to ensure room temperature and relative humidity (RH) were within manufacturer's specifications for 31 of 31 days. Findings: 1. During a tour of the mycobacteriology testing area (Room 6009) on 01/13/2026 at 1:00 pm, a MGIT 320 (Serial Number MT2027) and a MGIT 960 (Serial Number 6068) were observed in use by the laboratory. 2. The instrument operator's manual (MA-0117-C) stated " ... Operating Conditions Temperature 19C - 30C Humidity 30% - 80% Rh, non-condensing". 3. Review of the laboratory's temperature record log tags for room 6009 from 12/01/2025 through 12/31/2025 revealed an acceptable room temperature range of 17.8C - 25C. The laboratory's lower limit exceeded the manufacturer's specified limit of 19C. 4. Review of the laboratory's relative humidity record log tags for room 6009 from 12/01/2025 through 12/31/2025 revealed an acceptable relative humidity range of 35% - 85%. The laboratory's upper limit exceeded the manufacturer's specified limit of 80%. Further review of the relative humidity measurements taken 6 times a day every four hours revealed all of the laboratory relative humidity readings for 12/01/2026 through 12/31/2026 were below the manufacturer's specified lower limit of 30%. 5. In an interview on 01/13/2026 at 1:07 pm, the mycobacteriology technical supervisor confirmed the findings. Word Key: C=degrees Celsius 47107 II. Based on direct observation, review of the laboratory's policies, temperature records, and interview with the Technical Supervisor (TS) of the Bloodborne Viruses Laboratory (BVL), the laboratory failed to define freezer temperatures according to their own policy in storing extracted HIV-2 RNA, Murine Hepatitis Virus (MHV) Strain A59, and negative lysis/extraction controls for 12 of 12 months (January 2025 to December 2025). Findings Included: 1. During a tour of the laboratory on January 14, 2025 at 9:36 AM, the following in-house reagents and controls were observed stored within the -85 to -65 degrees Celsius ultralow freezer (UL #19) in Room 3027:

A. 250 aliquots of extracted HIV-2 RNA. B. 160 tubes of MHV Strain A59 diluted in TE buffer. C. 50 aliquots of negative lysis/extraction control. 2. Review of the laboratory's policy titled 'BVL-212 - Real-time PCR Assay for Qualitative Detection of Human Immunodeficiency Virus, Type 2 (HIV-2) RNA' stated the following storage instructions on page 6 of 20: "6.1.3. Nucleic acid extraction and PCR inhibition control: Mouse hepatitis virus (MHV) strain A59 is diluted with TE buffer. Aliquots are made and stored at -80 degrees Celsius. 6.1.4. Negative lysis/extraction control: Negative human plasma is aliquoted and stored at -80 degree Celsius ..." 3. Review of the laboratory's policy titled 'BVL-216&217 - EasyMag Lysis and Extraction Bench Notes' stated the following on page 2 of 2: "Immediately place aliquots on ice and store at -80 degrees Celsius." 4. Review of the laboratory's freezer temperature records revealed the temperature range for the ultralow freezer UL#19 in Room 3027 set to -85 to -65 degrees Celsius from January 2025 to December 2025, with the following dates where temperatures exceeded or fell under the -80 degrees Celsius storage temperature requirement in the laboratory's policy: A. January 2025: i. -81 degrees Celsius - 1/1/25 - 1/7/25, 1/9/25 - 1/31/25 B. February 2025: i. -81 degrees Celsius - 2/1/25 - 2/2/25, 2/4/25 - 2/6/25, 2/9/25, 2/12/25 - 2/26/25, 2/28/25 C. March 2025: i. -78 degrees Celsius - 3/27/25 - 3/28/25 ii. -81 degrees Celsius - 3/1 /25 - 3/19/25, 3/22/25 - 3/26/25 D. April 2025: i. -71 degrees Celsius - 4/2/25 ii. -77 degrees Celsius - 4/6/25, 4/30/25 iii. -78 degrees Celsius - 4/4/25, 4/7/25, 4/12/25, 4/21 /25, 4/24/25, 4/27/25 iv. -79 degrees Celsius - 4/1/25, 4/8/25, 4/20/25, 4/23/25 v. -81 degrees Celsius - 4/5/25, 4/11/25, 4/14/25 - 4/18/25, 4/25/25 - 4/26/25 E. May 2025: i. -77 degrees Celsius - 5/22/25 ii. -78 degrees Celsius - 5/8/25 - 5/10/25, 5/12/25 - 5/14 /25 iii. -79 degrees Celsius - 5/2/25, 5/11/25, 5/21/25, 5/24/25, 5/26/25 - 5/27/25, 5/30 /25 iv. -81 degrees Celsius - 5/15/25 - 5/19/25, 5/23/25, 5/25/25, 5/29/25, 5/31/25 F. June 2025: i. -78 degrees Celsius - 6/8/25 - 6/9/25, 6/11/25 - 6/12/25, 6/21/25 - 6/22 /25 ii. -79 degrees Celsius - 6/16/25 iii. -81 degrees Celsius - 6/3/25 - 6/5/25, 6/7/25 - 6 /8/25, 6/10/25, 6/15/25, 6/17/25 - 6/20/25, 6/24/25 - 6/25/25, 6/28/25 - 6/30/25 G. July 2025: i. -79 degrees Celsius - 7/1/25 - 7/3/25, 7/7/25, 7/10/25, 7/15/25, 7/17/25 - 7/18 /25, 7/22/25, 7/24/25 H. August 2025: i. -79 degrees Celsius - 8/12/25, 8/14/25 - 8/15 /25, 8/19/25 - 8/22/25, 8/25/25 - 8/26/25 - 8/30/25 ii. -81 degrees Celsius - 8/7/25 I. September 2025: i. -78 degrees Celsius - 9/18/25 ii. -79 degrees Celsius - 9/1/25 - 9/17 /25, 9/19/25 - 9/30/25 J. October 2025: i. -78 degrees Celsius - 10/24/25, 10/31/25 ii. -79 degrees Celsius - 10/1/25 - 10/23/25, 10/25/25 K. November 2025: i. -77 degrees Celsius - 11/17/25 ii. -78 degrees Celsius - 11/3/25, 11/5/25 - 11/7/25, 11/10/25 - 11 /16/25, 11/18/25 - 11/30/25 L. December 2025: i. -78 degrees Celsius - 12/1/25 - 12/11 /25, 12/13/25 - 12/17/25 ii. -79 degrees Celsius - 12/18/25, 12/23/25, 12/30/25 5. In an interview on January 15, 2025 at 8:35 AM, the TS of BVL confirmed that the temperature range for the ultralow freezer was not defined in accordance with the laboratory's policy for the storage of extracted HIV-2 RNA, MHV Strain A59 diluted in TE buffer and negative lysis/extraction control. III. Based on direct observation, review of the manufacturer's instructions, laboratory temperature records and interview with the Technical Supervisor (TS) of the Bloodborne Viruses Laboratory (BVL), the laboratory failed to define freezer temperatures in accordance with manufacturer's instructions for one of one Thermo Fisher Scientific Invitrogen SuperScript IV VILO Master Mix Reagent box. Findings Included: 1. During a tour of the laboratory on January 14, 2025 at 10:00 AM, one box of Thermo Fisher Scientific Invitrogen Superscript IV VILO Master Mix Reagent box (Lot Number 3027494) was observed stored within Freezer #53 in Room 3027. 2. Review of the manufacturer's instructions upon the reagent label stated a storage temperature requirement of -25 to -15 degrees Celsius. 3. Review of the laboratory's 'Logtag' temperature records (Serial Number A06300883380) for Freezer #53 revealed a temperature range set for -30 to 0 degrees Celsius. 4. In an interview on January 15, 2025 at 10:42 AM, the TS of BVL

	confirmed that the temperature range for Freezer #53 was not defined in accordance with manufacturer's instructions of the Invitrogen VILO Master Mix Reagent. IV. Based on direct observation, review of the manufacturer's instructions, temperature records and interview with the General Supervisor (GS) of the Diagnostic Immunology (DI) Section, the laboratory failed to define room temperatures in accordance with manufacturer instructions for two of two InBios Chagas Detect Plus Rapid Test boxes. Findings Included: 1. During a tour of the laboratory on January 15, 2025 at 11:18 AM in Room 3,001 of the DI section of the laboratory, two boxes of InBios Chagas Detect Plus Rapid Test Boxes (Lot Number EE6325) were observed, with a manufacturer storage temperature requirement of 20 to 30 degrees Celsius. 2. Review of the laboratory's 'Logtag' room temperature records for Room 3,001 revealed an acceptable temperature range of 15 to 30 degrees Celsius. 3. In an interview on January 15, 2025 at 11:20 AM in Room 3,001, the GS of the DI section confirmed the room temperature range was too wide and not defined in accordance with manufacturer's instructions of the InBios Chagas Detect Plus Rapid Test.
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 and confirmed in interview with Testing Person-105, the laboratory failed to label three of three secondary containers of Lactophenol Cotton Blue staining reagent with identity of the reagent, storage requirements, and/or preparation date. Findings: 1. Observed in the mycology testing area (Room 4065) on 01/14/2026 at 11:12am, three secondary drop bottles were observed stored in a drawer. A. Two bottles labeled "Lot# 1/13/2027 BCBR82776V" The original of "BCBR82776V" was unknown at the time of the observation. The reagent was not labeled with storage information or preparation date. B. One bottle labeled "Lot # 2022 Lactophenol Cotton Blue" The reagent was not labeled with storage information and preparation dates. 2. During an interview on 01/14/2026 at 11:15 am, testing person-105 confirmed the secondary bottles were not labeled with reagent identification, storage requirements, and preparation dates. II. Based on observation, review of laboratory policy, and confirmed in interview with Testing Person-105, the laboratory failed to label 15 of 15 Mycosel media slants, 7 of 7 Potato Dextrose Agar (PDA) media slants, and 60 of 60 Sabouraud Dextrose Agar (SDA) media plates with identity of the reagent, storage requirements, preparation date and expiration date. Findings: 1. Observed in the mycology testing area refrigerator (Room 4065) on 01/14 /2026 at 11:25 am were: 15 Mycosel media slants 7 Potato Dextrose Agar (PDA) media slants 60 Sabouraud Dextrose Agar (SDA) media plates None of the individual slants (tubes) and plates were labeled with the identity of the media, storage requirements, the preparation date, or the expiration date. 2. The laboratory's policy titled "QS-14 Reagent: Inventory, Quality Control and Labeling" stated the following: " ...7.2. Reagents made in-house - must be labeled, as applicable, with the: 7.2.1. name of the material 7.2.2. titer, strength, or concentration (if applicable) 7.2.3. storage conditions 7.2.4. in-house preparation date Alternately, the date made can be described in a method SOP or can be labeled with a unique identifier which can be

traced back to its origination 7.2.5. expiration date 7.2.6. other relative information (storage conditions, hazards)." 3. During an interview on 01/14/2026 at 11:30 am, testing person-105 confirmed each individual slant and plate was not labeled with the required information. III. Based on observation, review of laboratory procedure, laboratory records, and confirmed in interview with the Technical Supervisor, the laboratory failed to have a system in place for documenting and tracking manufacturer's lot numbers and expiration dates for one of one quality control (QC) organisms. Findings: 1. During a tour of the mycobacteriology testing area on 01/13 /2026 at 1:00 pm, a box of aliquoted ATCC 25177 QC organisms was observed. The preparation date of 12/14/2023 was indicated on the box label. The laboratory used the date of preparation as the lot number for the aliquots. The lot number for the aliquots stored in the box was "121423". The box and vials were not labeled with manufacturer's lot number, storage requirements, or expiration date. 2. The laboratory's policy titled "AFB-0016 Processing Isolates" stated the following: " ... Preparation of ATCC strain aliquots: 1. Control strain ATCC 25177 is purchased frozen from ATCC. Thaw vial at room temperature ... 4. Divide the mixture into 0.6 ml aliquots. Label aliquots with the date prepared and an expiration date 15 years from the date they were prepared. Store at -80+-5C. This will be the ATCC stock solution. 5. To make working solution for MGIT QC: transfer 0.6ml of the ATCC 25177 stock solution into a new 7H9 broth with OADC. Mix well. 6. Use this 7H9 broth to inoculate a 7H10 plate, a chocolate agar plate, and several MGIT broths. 7. Incubate MGIT tubes in BACTEC MGIT 960 instrument. Incubate 7H10 and chocolate agar at 37+/-2C in CO2 incubator ... 9. When the MGIT broth grows, make at least 52 freezer aliquots ...This will be the working solution. 10. Label these freezer aliquots with the date they were prepared (this will serve as the lot number) and the expiration date (10 years from date they were prepared.) Store them at -80+/-5C. 11. Once a week, and with each new lot number of MGIT tubes, remove one aliquot of working ATCC solution and start a MGIT tube to be used for quality control as described below ..." 3. Review of the laboratory record titled "QC Organism Subculture Preparation Record" revealed the laboratory form documented first generation storage stock preparation date, initials of preparer, lot number of the organism and expiration date. The form was also used to document data for second, third, fourth and fifth generation stock data entries. The following was the only data documented on the form: "1st Generation Storage Stock Preparation: Date Prepared: 12/14/2023; Organism Lot# 70017057; Expiration None" No other information was documented on the form provided. Further review of the laboratory record titled "MGIT Broth and Instrument QC" revealed the laboratory used ATCC 25177 Control Stain Lot# 112823 for MGIT quality control the weeks of 11/17/2025, 11/24/2025, 12 /01/2025, 12/08/2025, 12/15/2025, 12/20/2025, 12/29/2025, and 01/05/2025. The laboratory was asked to provide the "QC Organism and Subculture Preparation Record" for Lot# 112823. No documentation was provided. 4. In an interview on 01 /13/2026 at 1:07 pm, the mycobacteriology technical supervisor confirmed the laboratory did not have a system to document and track the preparation, storage, and use of QC organisms. Word Key: ATCC=American Type Culture Collection AFB=Acid Fast Bacilli 41090 IV. Based on a review of the laboratory's policy titled Reagent: Inventory, Quality Control, Labeling, direct observation, and an interview with Technical Supervisor #2, the laboratory failed to label one of two solutions with storage requirements and the expiration date. Findings Include: 1. A review of the laboratory policy QS-14SOP Reagent: Inventory, Quality Control, Labeling, version 3.1, signed by the laboratory director on 12/24/2025 revealed, "7.2. reagents made in-house - must be labeled, as applicable, with the:7.2.1. name of the material 7.2.2. titer, strength, or concentration (if applicable) 7.2.3. storage conditions 7.2.4. in-house preparation date Alternately, the date made can be described in a method SOP or can

	be labeled with a unique identifier which can be traced back to its origination 7.2.5. expiration date 7.2.6. other relative information (storage conditions, hazards)." 2. On 01/13/2026 at 13:52 in room 3071, the surveyor observed one container of 70% ethanol with no storage requirements or expiration date on the container. 3. An interview on 01/14/2026 at 10:25 AM, with Technical Supervisor #2, as listed on the CMS-209, confirmed the reagent container was not labeled with the storage conditions or expiration date.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory quality control (QC) records, patient records, and confirmed in interview with the Technical Supervisor, the laboratory failed to ensure QC results met criteria for acceptability before resulting four of five patient results. Findings: 1. The manufacturer's instructions for the Biomerieux ETEST Antimicrobial Susceptibility Testing stated " ...Quality Control ... Do not report patient results when quality control results are outside the stated QC ranges ..." 2. Review of the ETEST quality control records for 08/29/2025, 11/20 /2025, and 11/21/2025 revealed the laboratory had an acceptable QC criteria of 0.03 - 0.12 ug/mL (microgram per milliliter) MIC (Minimum Inhibitory Concentration) for the Clindamycin and Erythromycin antibiotics tested using the Biomerieux ETEST system. Further review of the quality control records revealed the following documented QC results that were documented as "Pass" but were outside of the acceptable range: a. 08/29/2025 Clindamycin; MIC result 0.125 ug/mL Erythromycin; MIC result 0.125 ug/mL b. 11/20/2025 Clindamycin; MIC result 0.125 ug/mL 3. Review of patient records for 08/29/2025, 11/20/2025, and 11/21/2025 revealed the laboratory reported Clindamycin and/or Erythromycin results for the following patients: IDR2500063431 IDR2500063433 IDR2500062821 IDR2500082647 4. In an interview on 01/15/2026 at 9:53am, the Bacteriology Technical Supervisor confirmed the findings.
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 direct observation, review of the manufacturer's instructions, laboratory

	policy, humidity records, patient testing records, non-conforming (NC) event /corrective action records, and interview with the General Supervisor (GS) of the Diagnostic Immunology (DI) section, the laboratory failed to document corrective actions taken when humidity dropped below established operating parameters of the DiaSorin Luminex Flexmap 3D Instruments for three of three days (random review from October 2024 to January 2025) during which patient testing was performed. Findings Included: 1. During a tour of the laboratory on January 15, 2025 at 11:16 AM in Room 3,001 of the DI section of the laboratory, two DiaSorin Luminex Flexmap 3D Instruments (Serial Numbers FM3DD20062021, FM3DD18341021) were observed. 2. Review of the manufacturer's instructions titled 'Luminex FLEXMAP 3D User Manual' stated the following on page 9: "Environmental Conditions - Shipping and Operating relative humidity: 20% to 80%, non-condensing". 3. Review of the laboratory's 'Logtag' humidity records revealed an acceptable range of 20-80% and the following dates when patient testing was performed upon the Luminex FLEXMAP 3D instruments, when humidity dropped below the lower threshold requirement, with no corrective action documented: A. November 2024 - 11/14, 11/29 B. October 2025 - 10/9 4. Review of patient test records, revealed the following patient IDs upon which testing was performed when humidity fell below acceptable range on the Luminex FLEXMAP 3D instruments: A. November 2024 - i. 11/14 - Patient IDs: IDR240068184-01, IDR240068185-01, IDR2400068190-01, IDR2400068192-01, IDR2400068193-01, IDR2400068194-01, IDR2400068195-01, IDR2400068295-01, IDR2400068319-01, IDR2400068360-01, IDR2400068375-01, IDR2400066490-01, IDR2400067148-01, IDR2400067282-01, IDR2400067345-01, IDR2400068196-01, IDR2400068197-01 ii. 11/29 - Patient IDs: IDR2400071734-01, IDR2400072001-01, IDR2400072006-01, IDR2400072007-01, IDR2400072008-01, IDR2400072010-01, IDR2400072011-01, IDR2400072016-01, IDR240002017-01 B. October 2025 - i. 10/9 - Patient IDs: IDR2500072704-01, IDR2500072707-01, IDR2500072836-01, IDR2500072866-01, IDR2500073047-01, IDR2500073342-01, IDR2500073361-02, IDR2500073415-01, IDR2500073445-01, IDR2500073801-01. 5. Review of the laboratory's policy titled 'SOP DI-01 Diagnostic Immunology Laboratory Corrective Action, Non-conformance Procedure Version 2.0' on page 1 of 3: "2. Definitions and Identification of Nonconforming Events: 2.1 Conformity is all about meeting requirements, so when a process or product does not meet specifications, a nonconforming event has occurred. Nonconformities include but are not limited to, equipment or reagent failure, improper specimens, transcription errors, unacceptable PT, correct reports and customer complaints..." 6. Review of the laboratory's NC event logs for humidity titled 'DIL Non-conforming Event Log' revealed documentation of humidity falling below range in Room 3001, 3005 and 3009 on October 2024 alongside review of Quality Control (QC), Calibrator results and supervisor review, but no further documented corrective actions for humidity. 7. In an interview on January 15, 2025 at 2:48 PM in the conference room, the GS of the DI section confirmed the issues with humidity falling below acceptable range in the DI section, and lack of corrective action documentation on each day of occurrence since October 2024.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.

	This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid 209 personnel form, laboratory personnel records, and interview with the Laboratory Director, the laboratory failed to ensure two of ten testing persons met the requirements to perform high complexity testing. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, laboratory policy, laboratory personnel records, and confirmed in interview with the Laboratory Director, the laboratory failed to ensure two of ten testing persons (TP) met the requirements to perform high complexity testing. Findings: 1. A review of testing persons listed on the laboratory's CMS-209 personnel form revealed TP-21 and TP-24 were performing high complexity testing. 2. A random review of the laboratory's personnel records for ten testing persons listed on the CMS-209 that included educational qualifying documentation (educational transcripts and diplomas) revealed TP-21 and TP-24 did

	not meet the educational requirements for high complexity testing personnel. 3. In an interview on 01/13/2026 at 1:00 pm, the Laboratory Director was asked to provide any additional educational qualifying documentation for TP-21 and TP-24. The provided documents failed to qualify the testing persons. This confirmed the findings.