

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0652812	(X3) Date Survey Completed 05/01/2025
Name of Provider or Supplier New Hampshire Public Health Lab	Street Address, City, State 29 Hazen Dr, Concord, NH	
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	Federal surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey at the NH Public Health Laboratories from April 29, 2025, to May 1, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA recertification survey that concluded on May 1, 2025, at 1:30 pm.
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of twice-annual verification of accuracy for MIA testing, and an interview with arbovirus supervisor, the laboratory failed to verify the accuracy of arbovirus MIA (Microsphere Immunoassay) testing at least twice a year in 2023 and 2024 (two of two years). Findings Included: 1. On the day of the survey, April 30, at 1:00 pm, a review of arbovirus PT testing records revealed, the laboratory verified the accuracy of arbovirus MIA testing once annually in 2023 and 2024. 2. The laboratory could not provide records of performing twice-annual verification for MIA testing for two out of two years (2023 and 2024). 3. By interview on April 30, 2025 at 1:35 pm, the arbovirus supervisor, confirmed PT for MIA testing was only performed once a year for the active testing season from May to December of each year.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p>

(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 review of laboratory procedures, manufacturer's instructions, the laboratory's online test menu, test requisitions and test reports, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport conditions) per their own specifications for 3 of 3 specimens for serology testing. 1. Review of the laboratory's procedure manual found the following: a. Procedure for Syphilis Rapid Plasma (RPR) Qualitative and Quantitative Card Test, Document ID: VI-NM-SOP-024, Revision: 5, Effective 1/30/2024 "6. SAMPLE HANDLING ... "The serum should be stored at 2-8C if testing is to be delayed more than 4 hours. Serum, removed from the clot, may be refrigerated at 2-8C for up to 5 days, or frozen at -20C or below." 2. Review of the manufacturer's instructions for use for the BD Macro-Vue RPR Card Tests found the following: a. "Specimen Collection and Preparation ...Serum, removed from the clot, may be refrigerated at 2-8C, for up to 5 days, or frozen at -20C or below ..." 3. Review of the laboratory's online test menu for clients found the following: a. "Rapid Plasma Reagin (RPR, for Syphilis) Qualitative ...Specimen: 1mL serum ...Instructions: Refrigerate specimens at 2-8C and transport within 5 days." 4. Review of patient test requisitions and test reports found the following: a. Specimen for RPR Qualitative testing- Accession number 2502140005, collected on 02/13/2025, received by the laboratory 02/14/2025. The temperature of the specimen when delivered to the laboratory was 19.7C with a note indicating "No Cold Pks". The laboratory reported a test result on 02/18/2025. b. Specimen for RPR Qualitative testing- Accession number 2503200005, collected on 03/19/2025, received by the laboratory 03/20/2025. The temperature of the specimen when delivered to the laboratory was 21.1C with a note indicating "No Cold Pack". The laboratory reported a test result on 03/24/2025. c. Specimen for RPR Qualitative testing- Accession number 2504100010, collected on 04/09/2025, received by the laboratory 04/10/2025. The temperature of the specimen when delivered to the laboratory was 24.4C with a note indicating "No CP". The laboratory reported a test result on 04/15/2025. II. Based on review of laboratory procedures, manufacturer instructions, the laboratory's online test menu, test requisitions and test reports, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport conditions) per their own specifications for 2 of 2 specimens for immunology testing. 1. Review of the laboratory's procedure manual found the following: a. Procedure for Focus Diagnostics HerpeSelect 1 and 2 Immunoblot, Document ID: VI-NM-SOP-018, Revision: 5, Effective 10/29/2024 "Preservation and storage of samples: "Separated serum/plasma should remain at 22C for no longer than 8 hours. If the assay will not be completed within 8 hours, refrigerate the sample at 2-8C. If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20C or colder." 2. Review of the manufacturer's instructions for use for the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG test found the following: "Specimen Collection and Handling ... Separated serum/plasma should remain at 22C for no longer than 8 hours. If the assay will not be completed within 8 hours, refrigerate the sample at 2-8C. If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20C or colder." 3. Review of the laboratory's online test menu for clients found the following: "Herpes Simplex Virus (HSV) Antibody IgG (Type 1 and 2) ...

Specimen: 1-2 mL serum ...Instructions: Refrigerate at 2-8C and transport within 2 days of collection." 4. Review of patient test requisitions and test reports found the following: a. Specimen for Herpes IgG Immunoblot test, Accession number 2405160036 collected on 05/15/2024, received by the laboratory on 05/16/2024. The temperature of the specimen when delivered to the laboratory was 23.4C. The laboratory reported a test result on 05/24/2024. b. Specimen for Herpes IgG Immunoblot, Accession number 2408290391 collected on 08/28/2024, received by the laboratory on 08/29/2024. The temperature of the specimen when delivered to the laboratory was 23.2C. The laboratory reported a test result on 09/05/2024. The laboratory failed to ensure specimens submitted for testing maintained transport temperatures specified in their own procedures, required by the manufacturer and listed in their online test menu. Word Key: BD - Becton Dickinson C - degrees Celsius IgG - immunoglobulin G

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:
Based on review of the MIA (Microsphere Immunoassay) standard operating procedures (SOP), review of the Bio-plex system validation reports, and interview with the arbovirus supervisor, the laboratory failed to include in their arbovirus MIA SOP a procedure for performance and documentation of corrective actions after system validation failures from 2023 to date of survey 2025. Findings included: 1. On April 30, 2025 at 1:15 pm, review of Arbovirus MIA calibration/ validations records for the the Bio-Plex 200 system revealed a validation failure on September 10, 2024 at 3:13 pm, the low validation kit control (#64559629) failed fluidics, reporter and classifyfy validations. 2. Further review revealed, the low validation kit control was re-run again on September 10, 2024 at 04:10 pm - Classifyfy validation failed, and at 05: 24 pm - Optics validation failed. 3. The laboratory could not provided documentation of corrective actions performed. 4. Review of the arbovirus MIA SOP revealed, the SOP did not include corrective actions to take when the system validations fail. 5. By interview on April 30, 2025 at 1:30 pm, the arbovirus supervisor confirmed the manufacturer was contacted September 11, 2024 to trouble shoot the issues, and the

validations passed September 11, 2024 at 9:42 am, but the corrective actions performed were not documented.

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 of the laboratory, review of room temperature and humidity records, review of manufacturers manuals and interview with the virology supervisor, the laboratory failed to define room temperature and humidity conditions for the virology laboratories (rooms 226 and 328) where one of one Hologic Panther and two of two Thermo Scientific King Fisher Flex's were in operation to perform patient testing in 2024. Finding Included: 1. The Thermo Scientific King Fisher Flex User Manual, Chapter 6, Technical specifications, Operating conditions stated, "+5C to +40C; maximum relative humidity 80% for temperatures up to 31C, decreasing linearly to 50% relative humidity at 40C". 2. The Hologic Panther System Operator's Manual , table 4. environmental requirements stated, "ambient temperature - operating: 15C-30 C, relative humidity - operating: 20-85% non-condensing". 3. On April 29, 2025 at 11:30 am, observation of the laboratory revealed, one of one Hologic Panther and two of two Thermo Scientific King Fisher Flex's were in operation to perform patient testing. 4. Review of room temperature and humidity records revealed, the laboratory did not define room temperature and humidity conditions for rooms 226 and 328 in the virology laboratory areas for: a. Room 226 - 2024: humidity from July to December. b. Room 226 - 2024: humidity from April to June c. Room 328 - 2024: room temperature and humidity from July to December. 5. By interview, the virology supervisor confirmed the above findings on April 29, 2025 at 11:45 am. Key: C = Celsius

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 interview with laboratory staff, the laboratory failed to label laboratory prepared microbiology media with the identity (name of the media), storage requirements, preparation and expiration dates. Findings Included: 1. During tour of the laboratory on 04/30/2025 at approximately 1 pm, a refrigerator in the

microbiology section of the laboratory was found to store laboratory prepared culture media in tubes. The various tube culture media were stored in racks with hand written labels taped to the front of each rack that contained an abbreviated name, a date and initials. The individual culture media tubes were not labeled with the name of the culture media, the storage requirements or the preparation and expiration date of the media. A sampling of the racks were labeled as follows: "SMAC #1 2-4-25 NP" "Andrade Salicin #3 4-29-25 NP" "Mot #1 2-25-25 NP" "Mot #4 4-23-25 NP" "Mio #2 4-23-25 NP" 2. During the tour of the laboratory on 04/30/2025 at approximately 1 pm, the microbiology supervisor stated that the individual tubes of laboratory prepared media were not labeled with the name of the media, the storage requirements or the preparation and expiration dates. 38555 II. Based on observation of the virology laboratory and interview with the virology supervisor, the laboratory failed to label three of three buffer bottles in use with preparation and expiration dates. Findings Included: 1. Observation of the virology laboratory on April 29, 2025 at 2:30 pm revealed the following bottles without preparation and expiration dates: a. one of one bottle of Invitrogen Ambion Nuclease-free water (lot#2301548) - no expiration date. b. one of one bottle of a prepared daily wash - no preparation and expiration date. c. one of one bottle of Fisher Bioreagents Absolute Ethanol 200 proof (lot#210849) - no expiration date. 2. The virology supervisor confirmed the above bottles were not labeled with preparation and expiration dates on April 29, 2025 at 2:35 pm. RNA - Ribonucleic Acid.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of the Hologic Panther manufacturer's manual, review of the mag wash maintenance logs, and an interview with virology supervisor, the laboratory failed to perform the mag wash after each testing day, as described by the manufacturer from a sampling of four of four months in 2025. Findings Included: 1. The Hologic Panther System Diagnostic Manual, Mag Wash Clean, stated, "it is required that this task be performed daily after each testing day". 2. A review of the Panther Mag Wash Maintenance Log report revealed that the mag wash was set to run on Tuesday mornings. 3. Review of a sampling of test totals for Aptima Combo 2 and Aptima HCV revealed, from January 1, 2025 to April 29, 2025, the laboratory did not perform a mag wash after each testing day for: a. 5 of 5 Testing days in January 2025. b. 6 of 6 Testing days in February 2025. c. 5 of 5 Testing days in March 2025. d. 6 of 6 Testing days in April 2025. 4. By interview, the virology supervisor confirmed on April 30, 2025 at 8:55 am that the mag wash was not performed after each testing day. HCV = Hepatitis C Virus.