Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0649758	04/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Md Dept Of Health	1770 Ashland Ave, Baltimore, MD	

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) conducted an announced CLIA recertification survey at the MD Department of Health from April 16, 2024 to April 18, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiencies were found during the announced routine CLIA recertification survey performed from April 16, 2024 to April 18, 2024.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #2 (TS #2), the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate the submitted results for one of 20 events. Findings include: 1. Record review on 04/17/2024 of 2022 and 2023 proficiency testing records revealed the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate the submitted results for one of 20 events. a. 2022 FrozenMicro 1 Event - five of five results (BOR-1, BOR-2, BOR-3, BOR-4, BOR-5) were not graded by the proficiency testing program. In the "Performance Summary" report under "Comments" stated, "Not scored". A review of the "2022 FrozenMicro 1 Event Notes" under the section, "Event Specific Information:" stated, "Not scored samples receive a 100% score but this may not be indicative of instrument/method performance and labs must perform an internal written self-evaluation to satisfy the regulatory/accreditation requirements." 2. Record review on 04/17/2023 of 2022

	Frozen Micro 1 Event proficiency testing records revealed no evidence the laboratory documented a self-evaluation of non-graded results. 3. Interview with TS #2 on 04/18 /2023 at 12:20 pm confirmed the findings above.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, written laboratory policy and procedures, patient test requisitions, patient test reports, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to follow written policies and procedures for handling and transporting specimens submitted for Carbapenemase testing for three of three patient reports. Findings include: 1. Review on 04/17/2024 of the "GeneXpert Carba-R" assay manufacturer's instructions revealed the following under "Sample Preparation and Storage" stated, "Rectal Swab Samples: Swabs in the transport tube can be stored at 15-28 C for up to five days." 2. Review of the laboratory's written policy and procedures revealed the following under "Cepheid Xpert CARBA-R SOP" section "Acceptable specimens:" stated, "1. The swabs are stable at 15-28 C for up to five days." 3. Record review of patient test requisitions and patient reports tested on 02 /23/2024 revealed the following for three of three patients: a. Patient specimen number A24517881 - Collected on 02/22/2024, received in the laboratory on 02/23 /2024 at 13.9C (colder than the minimum acceptable temperature), and reported on 02 /26/2024. b. Patient specimen number A24517880 - Collected on 02/22/2024, received in the laboratory on 02/23/2024 at 13.9C, and reported on 02/26/2024. c. Patient specimen number A24517881 - Collected on 02/22/2024, received in the laboratory on 02/23/2024 at 13.9C, and reported on 02/26/2024. 4. Interview with TS #4 on 04/18/2024 at 12:25 pm, confirmed the findings above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, review of the Remel Lowenstein-Jensen (L-J) Medium manufacturer's instructions, and confirmed in interview with the TS of mycobacteriology, the laboratory failed to ensure manufacturer's instructions were followed for storage/stability for 100 of 100 L-J media slants. Findings included: 1. Review of Remel Lowenstein-Jensen (L-G) Medium IFU 8500 package insert states, "Limitations: 1. Media containing malachite green, such as L-J Medium, is photosensitive an should not be exposed to light during storage." 2. During a tour of

	the Microbiology department media room on 4/18/2024 at 1:32pm, 100 tubes of Remel L-J media, slant tubes, Lot 798843, expiration date 2025-02-05, were observed in storage exposed to light. 3. During an interview on 4/18/24 at 1:33 pm, the TS of Mycobacteriology stated the L-J media slant tubes were not protected from light in the transparent refrigerators prior to inoculation, and confirmed the findings above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: Based on direct observation, review of manufacturer's instructions, and confirmed in an interview with the TS, the laboratory failed to monitor and document the room temperature requirements for 16 of 16 reagents stored in supply room 551. Findings included: 1. During a tour of the laboratory's microbiology section on 4/17/2024 at 1: 32pm, the following were observed in room 551 without temperature monitoring and documentation: a. One box BD BBL TB Auramine - Rhodamine T, Lot 3164265, expiration date 2024-05-31; manufacturer storage temperature requirements: 15-30C. b.Two boxes of BD TB Decolorizer, Lot 3306420, expiration date 2024-10-31; manufacturer storage temperature requirements: 15 - 30C. c. Two boxes of BD BBL TB Potassium Permanganate, expiration date 2024-11-30; manufacturer storage temperature requirements: 15-30C. d. Three boxes of BD TB Methylene Blue, expiration date 2024-11-30; manufacturer storage temperature requirements: 15-30C. e. Four boxes of BD BBL MycoPrep Kit, expiration date 2025-01-02; manufacturer storage temperature requirements: 15-25C. f. Four boxes of Sensititre Demineralized Water, expiration date 2026-03-26; manufacturer storage temperature requirements: 15 - 30C. 2. In direct observation, there was no thermometer placed in room 551. 3. During an interview on 4/17/24 at 1:56 pm, the TS stated that they did not monitor and document room temperature. *** Word Key: C = Celsius.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, direct observation,QC gram stain testing records, and interview with Technical Supervisor #1 (Microbiology) , the laboratory failed to ensure gram stains reagent (safranin) was not used passed its expiration date and used for 85 patients from testing date 3/5/2024 to the date of the survey as evidenced by: 1. In review of the manufacturer's instructions for the remel gram stain kit, under product deterioration states, "This product should not be used if... (2) the

	expiration date has passed...". 2. In direct observation at 1002 on April 17, 2024 in the microbiology lab 5th floor, the remel safranin lot #122743 expiration date March 1, 2024, had a sign on it "for research only" and was available for patient use. 3. In review of the gram stain QC records from testing date 3/5/2024 to date of the survey showed: - lot #122743 safranin was used for 85 patients. 4. In interview with Technical Supervisor #1 (CMS-209, microbiology) at 1100 in the laboratory stated that he was aware that the safranin had expired, they had ordered more kits from thermal fisher but the gram stain kits were back ordered.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #4 (TS #4), the laboratory failed to ensure 15 of 15 Molecular Biology centrifuges were functioning properly for one of one function checks from January 2023 through December 2023. Findings include: 1. A record review on 04/18/2024 of the 2023 "Division Of Molecular Biology Section: Molecular Diagnostics Laboratory Centrifuges - Quality Control Record Form" revealed no evidence the times were checked for 15 of 15 centrifuges: a. Fisher Scientific - Serial Number 41779777. b. Heraecus (Biofuge Pico) - Serial Number 40250907. c. Beckman Coulter - Serial Number ALK14M02. d. Beckman Coulter - Serial Number GD93D01. e. Beckman Coulter - Serial Number ALK02G02. f. ThermoFisher Sorvall Pico - Serial Number 40511342. g. ThermoScientific - Serial Number 41293508. h. Fisher Scientific - Serial Number 41765826. i. Thermo Fisher 17 - Serial Number 41765817. j. Thermo Fisher 17 - Serial Number 41773028. k. Thermo Fisher - Serial Number 41765830. l. Thermo Fisher - Serial Number 41765827. m. Thermo Fisher - Serial Number 41773026. n. Beckman Coulter - Serial Number ALK99L21. o. Thermo Fisher - Serial Number 41773027. 2. Interview with TS #4 on 04/18/2024 at 12:40 pm confirmed the laboratory performed a function check for the above centrifuges annually. 3. Interview with TS #4 on 4/18/2024 at 12:45 pm confirmed the laboratory failed to verify the time for 15 of 15 Molecular Biology centrifuges for one of one function checks.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the Legionella Culture procedure, the serology quality control (QC) records and an interview with the Technical supervisor (TS) #17, the laboratory failed to document each batch/shipment of Pathcon Buffered Charcoal Yeast Extract (BCYE) media and Fisher BCYE polymyxin B, vancomycin and anisomycin (PAV) media used for Legionella Culture for its selectivity, inhibition, and biochemical response and to perform at least one negative organism a for each lot used from April 27, 2022, to April 10, 2024. Finding Include: 1. A review of the BCYE and BCYE/ PAV media on April 18, 2024 at 12:55 am, revealed, the documented QC did not include a description of selectivity, inhibition, and biochemical response seen for 24 of 24 lots of the Pathcon BCYE media and 24 of 24 lots of the Fisher BCYE/ PAV used from April 27, 2022, to April 10, 2024. 2. A review of the Legionella Culture procedure revealed, the laboratory did not include the use of at least one negative organism to confirm the inhibitory/biochemical characteristic for the BCYE and BCYE/ PAV selective media. 3. From April 27, 2022, to April 10, 2024, 24 lots of Pathcon BCYE media and 24 lots of Fisher BCYE/ PAV media were used for patient testing. 4. An interview with TS#17 (Form CMS 209, Page 9) confirmed the finding above on April 18, 2024, at 1:05 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #2 (TS #2) and Technical Supervisor #4 (TS #4), the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for molecular diagnostic testing using four ABI 7500 Fast Dx RT PCR analyzers during the review period of January 2023 through December 2023. Findings include: 1. Record review on 04/18/2024 of the molecular diagnostics test menu revealed the laboratory performed Arbovirus/Encephalitis, Bordetella pertussis, Bordetella parapertussis, Bordetella holmesii, Chikungunya Virus, Dengue Virus, Herpes Simplex Virus, CDC Influenza AB Screening/A Subtyping/B Genotyping, Sars-CoV2-CDC Flu/SC2 Multiplex Assay, and Zika Virus testing using ABI 7500 Fast Dx RT PCR analyzers. 2. Interview with TS #4 on 04/18/2024 at 11:00 am confirmed the Arbovirus /Encephalitis, Bordetella pertussis, Bordetella parapertussis, Bordetella holmesii, Chikungunya Virus, Dengue Virus, Herpes Simplex Virus, CDC Influenza AB Screening/A Subtyping/B Genotyping, Sars-CoV2-CDC Flu/SC2 Multiplex Assay, and Zika Virus testing using four ABI 7500 Fast Dx RT PCR analyzers (ABI #1 Serial Number 27500820, ABI #2 Serial Number 275010609, ABI #3 Serial Number 275011712, ABI #5 Serial Number 275030148). 3. Record review on 04/14/2024 from January 2023 through December 2023 revealed no evidence the laboratory evaluated and defined the relationship between the four ABI 7500 Fast Dx RT PCR analyzers twice a year. 4. Interview with TS #2 and TS #4 on 04/18/2024 at 11:30 am confirmed the above 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 review of the laboratory policy, review of testing quality control (QC) documentation for newborn screening (NBS) mass spectrophotometer (MS), and interview with testing person #6 (Page 7 of CMS-209) the laboratory failed to document corrective action taken when QC failed with MS/MS runs on 2/9/2023 and 8/22/2023 as evidenced by: 1. In review of the laboratory policy, Laboratory Administration's Quality/Assurance manual pg 31 under heading of corrective action states, "corrective actions are documented, require corrective action measures and/or root cause analysis and may require follow up...". 2. In review of the QC testing documents on 2/9/2023 and 8/22/2023 the testing personnel did not document how they resolved quality control failures with the MS/MS runs. 3. In interview with testing person #6 on 4/16/2024 at 1205 stated that he didn't think that corrective actions they took after QC failure was documented to show that they had repeated the run.