Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0649758	04/21/2022
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory personnel competency assessment records and interviews with laboratory managers and technical supervisors (TS) on 4/20/2022 at 8: 30 and 10:30 am, the laboratory failed to follow written policies and procedures to assess the competency for all testing personnel (TP) and establish written policies and procedures to assess TS and general supervisors (GS) for competency in 2020 and 2021. Findings Included: 1. The Laboratories Administration Quality Assurance Manual V2.0.7, C. Divisions - Technical Training and Competency, 2. Employee Continuing Competency states, "Environmental and Clinical testing personnel must demonstrate competency at least annually for each procedure they are trained to perform and when a test methodology or instrumentation changes". 2. On the day of survey, 04/20/2022 at 8:30 and 10:30 am, review of a sampling of competency assessment records revealed, the laboratory failed to perform all TP competency assessments annually in 2020 and 2021. 3. Review of the Administration employee continuing competency policy and MDH Laboratories Administration Quality Assurance Manual revealed, the laboratory did not establish a TS or GS competency assessment policy. 4. During the summation on 4/21/2022 at 5:00 pm, the laboratory confirmed they did not follow their written policy to assess testing personnel TP for competency assessment and did not establish a written policy to assess TS and GS for competency.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to monitor and document the defined conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting (see D5413), establish test performance specifications for its HIV-1 NAAT Assay test system before reporting patient HIV-1 NAAT Assay test results (see D5423), perform maintenance as defined by the laboratory and/or manufacturer (see D5429), and ensure that for each test system the laboratory had control procedures that monitor the accuracy and precision of the complete analytic process (see D5441).
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 laboratory personnel interview and document review of logs for refrigerators, freezers, and ambient room temperatures, the laboratory failed to monitor temperatures to ensure the proper operation of test systems. Findings included: 1. Review of the Temperature Log for the refrigerator and freezer (ID#00062392) being used to store reagents and samples and confirmation by interview of TS and GS 4/20/2022 at 10:30 AM showed: i. Missing temperature recordings for 2/16/2022 and 3/7-3/9/2022. ii. No monthly sign off as indicated by required log data slot and no indication of who was designated to review on the log or other policy. 2. Review of the Temperature Log Room 421 and confirmation by interview of TS and GS 4/20/2022 at 10:30 AM showed: i. Missing temperature recordings for 2/16/2022 and 3/7-3/9/2022. ii. No monthly sign off as indicated by required log data slot and no indication of who was designated to review on the log or other policy. 3. According to laboratory personnel interviews with TS from 4/20/2022 and confirmation by review of submitted data on the CMS CLIA 116 form, the laboratory performed and reported approximately 435,393 Virology and 94,999 General Immunology assays annually.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and a record review of the laboratory's HIV-1 NAAT Assay test system policies, procedures, and test specifications data on April 21, 2022, the laboratory failed to establish test performance specifications before reporting patient HIV-1 test results. Findings included: 1. Review of the laboratory test result report (Specimen Number A22005227001) and interview with the TS on 4 /21/2022 at 10:00 AM confirmed that the HIV-1 NAAT Assay is a Laboratory Developed Test. 2. Review of available laboratory documents, interview with the TS on 4/21/2022 at 10:00 AM, and follow up interview with the LD on 4/21/2022 at 4:05 PM, showed that the laboratory was only able to provide the raw data for the validation of the HIV-1 NAAT Assay and was unable to provide a validation showing that the laboratory had established performance specifications for this assay. 3. According to laboratory personnel interviews with TS from 4/21/2022 and confirmation by review of submitted data, the laboratory performed and reported approximately 8 patient HIV-1 NAAT Assays between 3/2020 and 4/2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on review of the Becton Dickinson FACS Calibur Flow Cytometry analyzer maintenance records, review of Becton Dickinson FACS Calibur Flow Cytometry user manual and interview with the technical supervisors (TS) on 4/21/2022 at 3:00 PM, the laboratory failed to follow the manufacturer user manual and document monthly maintenance for the Becton Dickinson FACS Calibur Flow Cytometry analyzer in 2020, 2021 and 2022. Finding Included: 1. The Becton Dickinson FACS Calibur Flow Cytometry analyzer maintenance log lists nine maintenance tasks to be performed on a monthly basis. 2. The The Becton Dickinson FACS Calibur Flow Cytometry analyzer maintenance log states, "Maintenance schedule is in accordance with manufacturers user manual preventative maintenance schedule (FACSCaliber user manual)". 3. Review of the Becton Dickinson FACS Calibur Flow Cytometry analyzer maintenance records on 4/21/2022 at 2:50 PM revealed, the laboratory did not document monthly maintenance tasks performed in 2020, 2021 and 2022. 4. The TS confirmed the findings above on 4/21/2022 at 3:30 PM. B. Based on review of the M2000sp Maintenance Log SN10489 (3 of 3 months reviewed), review of M2000rt System Maintenance Log SN275021267 (9 of 10 months reviewed), and confirmed by

	interview with the technical supervisor (TS) on 4/21/2022 at 8:30 AM, the laboratory failed to follow the manufacturer and laboratory requirements for performing and documenting weekly maintenance. Findings Included: 1. The M2000sp System Maintenance Log SN10489 requires the performance and documentation of weekly maintenance. i. Review of the March 2021 maintenance log showed that while testing was performed, weekly maintenance was not performed or documented for weeks 1,3, and 4. ii. Review of the June 2021 maintenance log showed that while testing was performed, weekly maintenance was not performed or documented for weeks 1,2, and 3. iii. Review of the March 2022 maintenance log showed that while testing was performed, weekly maintenance was not performed or documented for weeks 1,2, and 3. 2. The M2000rt System Maintenance Log SN275021267 requires the performance and documentation of weekly maintenance. i. Review of the January to June 2021 maintenance logs showed that while testing was performed, weekly maintenance was not performed or documented during each month. ii. Review of the January to June 2022 maintenance logs showed that while testing was performed, weekly maintenance was not performed or documented during each month (Except for Week 4 in February and March). 3. Based on information provided by the laboratory on the CMS CLIA 116 form and confirmation by the TS on 4/21/2022 at 8:30 AM, the laboratory performs approximately 435,393 Virology tests annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals for virology tests run on the 7500 Fast Dx Real Time PCR Instruments, review of 7500 Fast Dx Real Time PCR Instrument quality control (QC) records, and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to establish QC performance specification procedures for lot to lot QC performed for SARS-CoV2, Influenza, HSV, and Arbovirus tests run on the 7500 Fast Dx Real Time PCR Instruments from March 5th, 2020 to April 21st, 2020. Findings Included: 1. Review of the 7500 Fast Dx Real Time PCR Instruments QC records revealed, the following test assays used floating means with no established ranges: a. SARS-CoV2 -CDC FluSC2 Multiplex Assay. b. SARS-CoV2 Thermo Taqpath Multiplex Assay. c. Influenza. d. HSV. e. Arbovirus PCR Testing. 2. On 04/21/2022 at 3:00 pm, the TS confirmed there were no established QC performance procedures in use describing the laboratories process for floating means without establishing ranges, which was reaffirmed by the LD. 3. The CMS CLIA 116 form signed by the laboratory director on April 8th, 2022, states the laboratory performed and reported approximately 435,393 Virology tests a year.