Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	21D0649758	03/05/2020
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	An announced CLIA recertification survey was conducted at the Maryland Department of Health Laboratory on March 3-5, 2020 by the CMS Philadelphia location CLIA surveyors.The laboratory was surveyed under 42 CFR part 493 CLIA Regulations.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the CAP (College of American Pathologists), D (Bacteriology) 2018 and 2019 proficiency testing (PT) records, patient testing records and interview with the Bacteriology Technical Supervisor 2 (TS2), the laboratory did not test the proficiency testing samples it receives from the PT program in the same manner as it tests patient specimens. Findings: 1. The Bacteriology, Culture Record for patient revealed patient samples tested only by Identification (ID) by latex Antigen (Ag). 2. The Bacteriology, PT records for CAP (College of American Pathologists), D (Bacteriology) event C for 2018 revealed PT sample with Accession ID# DIAGA18100891 was tested by ID by latex Ag ,VITEK MS Matrix Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF) Anaerobic and Aerobic Plated, and Sensititre instrument. Accession ID# DIAGA18100891 appeared on the following testing records: a.The Bacteriology, VITEK MS (MALDI-TOF) Results sheet for

	Accession ID# DIAGA18100891-1 b.Anaerobic Plate results for Accession ID# DIAGA18100891B-1 c.Aerobic Plate results for Accession ID# DIAGA18100891C-1 d.The Bacteriology, Simple Combo Report from Sensititre instrument for Specimen# A18100891001CAP 3. During the survey on 03/03/2020 at 11:30 AM the Bacteriology Technical Supervisor 2 (TS2) confirmed that the laboratory tested PT sample by additional testing methods of MALDI-TOF and Sensititre instrument.
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 record review and interview the laboratory failed to establish and verify performance specifications for 2 of 2 new analytes tested using MAC-ELISA. Findings include: 1.The Powassen Virus MAC-ELISA Performance Evaluation failed to include sensitivity for the assay, and was signed by TS #4 on April 4,2019 and lab director on May 3, 2019. 2. The TS #4 has stated in interview performed on March 3, 2020 that she believed the requirement did not apply because the platform was existing prior to April 24, 2003. 3. The laboratory had performed this test and reported results on 106 patients prior to March 3, 2020. 4. The Jamestown Canyon Virus MAC-ELISA Performance Evaluation signed by the TS#4 on August 23, 2019 and laboratory director on August 28, 2019 lacked establishment of analytic sensitivity and specificity. The evaluation included testing of only serum samples. 5. TS#6 stated during interview at approximately 8:50 am on March 4, 2020 that patient testing included the testing of cerebrospinal fluid(CSF) samples. The TS further confirmed that no CSF samples were included in the assay evaluation study.
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: Based on maintenance record review, procedure manual and interview with Technical supervisor (TS#8), the laboratory in the NBS division failed to perform preventative maintenance as defined by the manufacturer for the Quattro Micro API (Ariel) instrument for February 2018. Findings include: 1. Review of Daily Maintenance log records performed on March 3,2020 at approximately 11:50 AM revealed documentation showing "in- line filter changed on 03/24/18". 2. CMS Surveyor

	requested the weekly and monthly maintenance records. At approximately 12:00 PM, TS#8 stated "The weekly maintenance is not needed, we only service the instrument daily and periodically as needed if the TIC(total ion chromatogram) is not accepted." 3. Procedure manual of the Quattro Micro API instrument was reviewed at approximately 12:25 PM, demonstrating daily, weekly, monthly and periodic maintenance is required for the instrument. 4. TS#8 confirmed on March 3, 2020 at 12:25PM that the laboratory failed to perform maintenance as defined by the manufacturer.
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 record review and interview, the laboratory did not have control procedures in place that monitor performance of the Autodelfia instrument to determine what factors influence observed changes. Findings include: 1. A review of the quality control (QC) records for January 23, 2018 for the Autodelfia Instrument (1275) of the Newborn and Childhood Services (NBS) division showed for the neo-T4 analytes low control, 7 out of 65 points were greater than 2 standard deviations (SD) outside of QC limits. There was no documentation in the QC records documenting acknowledgement of the erratic low control performance. 2. During an interview on March 5, 2020 at approximately 9:30AM, the technical supervisor (TS#3) explained that as long as 2 of 3 controls are within limits the runs are accepted. TS#3 confirmed that there was no investigation to determine what factors might have influenced the low control performance.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that the quality assessment programs were maintained consistently among the different laboratory divisions and that corrective actions were monitored to confirm that they were effective. Findings include: 1. The Laboratories Administration QA Manual did not include defined criteria for initiating a Problem Corrective Action. 2. During interview conducted on March 5, 2020 at approximately 2:15PM the laboratory's

	quality assurance officer stated that corrective actions that take place in each division stay within each division and are not monitored at the overall LA QA level. 3. The Laboratories Administration QA program did not identify failure to ensure all proficiency testing is performed in the same manner as patient testing (refer to D2006), did not identify a failure to establish perfromance specifications for new testing (refer to D5423), did not identify a failure to ensure all equipment maintenance was performed in accordance with manufacturer instructions (refer to D5429), and did not identify a failure to establish control procedures that monitor conditions that can influence test performance (refer to D6094)