Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2130306	01/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Diamond Medical Laboratories Llc	66 Painters Mill Road #200, Owings Mills, 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
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on review of proficiency testing records, interview with the laboratory manager, and the technical consultant (TC), the laboratory failed to ensure that proficiency testing was performed for peripheral blood smear identification and urine sediment morphology. Findings: 1. The laboratory failed to enroll in the peripheral blood smear identification and urine sediment morphology. 2. The laboratory manager stated that they never received the pictures. 3. On the day of the survey the manager enrolled in PT to receive pictures for identification of blood cell and urine sediment morphology.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory manager, the laboratory did not document the corrective action procedures for PT failures. Findings: 1. The laboratory recevied "0", failure to participate for the 3rd event chemistry testing. 2. The laboratory did not document the investigation

	performed to determine the failure. 3. The laboratory manager stated they forgot to test the PT samples and submitted late once tested. 4. The laboratory manager tested the samples but did not evaluate the results to determine a pass or fail grade and score.
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 review of the written procedure manual and interview with the laboratory manager, the laboratory did not perform preventative maintenance procedures on the microscope. Findings: 1. The laboratory did not perform preventative maintenance procedures on the laboratory microscope. 2. The laboratory did not have procedures for cleaning and having the oculars checked on the microscope. 3. The laboratory manager stated that he was unaware that maintenance procedures needed to be performed on the microscope.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of validation records and interview with the laboratory manager, the laboratory did not run two levels of quality control each day of patient testing when performing bacteriology testing. Findings: 1. The laboratory was performing influenza and Clostridium Difficile testing with the Solana analyzer since October 2018. 2. The laboratory did not perform two levels of quality control each day of patient testing. 3. The manager stated that he thought the test and the analyzer was waived and QC was performed per change in lot number. 4. The manager confirmed that two levels of QC was not performed each day of patient testing.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of proficiency testing records, interview with the laboratory manager, and the technical consultant (TC), the TC failed to ensure that proficiency testing was performed for peripheral blood smear identification and urine sediment

	morphology. Findings: Refer to D2001 1. The laboratory failed to enroll in the peripheral blood smear identification and urine sediment morphology. 2. The laboratory manager stated that they never received the pictures. 3. On the day of the survey the manager enrolled in PT to receive pictures for identification of blood cell and urine sediment morphology.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of validation records and interview with the laboratory manager, the technical consultant did not ensure that two levels of quality control were ran each day of patient testing when performing bacteriology testing. Findings: Refer to D5449 1. The laboratory was performing influenza and Clostridium Difficile testing with the Solana analyzer since October 2018. 2. The laboratory did not perform two levels of quality control each day of patient testing. 3. The manager stated that he thought the test and the analyzer was waived and QC was performed per change in lot number. 4. The manager confirmed that two levels of QC was not performed each day of patient testing.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory manager, the technical consultant did not ensure that the laboratory documented the corrective action procedures for PT failures. Findings:D5221 1. The laboratory recevied "0", failure to participate for the 3rd event chemistry testing. 2. The laboratory did not document the investigation performed to determine the failure. 3. The laboratory manager stated they forgot to test the PT samples and submitted late once tested. 4. The laboratory manager tested the samples but did not evaluate the results to determine a pass or fail grade and score.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of training and competency records, interview with the laboratory manager, and the technical consultant (TC), the TC did not perform semiannual competency checks for the testing person that started testing in March 2018. Findings. The TC did not perform semiannual competency checks. The TC stated that she was unaware that semiannual competency procedures needed to be performed.