Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0668015	08/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Discovery Pediatrics	10313 Georgia Av Suite 303, Silver Spring, 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**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the lead testing person, the laboratory did not ensure that the testing person who performed the test initialed the instrument printouts with the PT samples test results in the same manner at the patients. Findings: 1. The PT records from the 3rd event of 2016 through the 1st event of 2018 (5 events) were reviewed. The instrument printouts attached to the attestation worksheet did not include the initials of the person who performed the test in the same manner as the patients. 2. The attestation worksheet from the 3rd event of 2016 listed 6 different testing personnel signatures; the 1st event of 2017 listed 4 different testing personnel signatures; the 2nd and 3rd events of 2017 listed 7 different testing personnel signatures; and the 1st event of 2018 listed 2 different testing personnel signatures. 3. The attestation worksheets had multiple signatures and the instrument printouts had no signatures. There was no way to determine who performed each of the PT specimens. 4. During the survey on 08/09

	/2018 at 1:30 pm the lead testing person confirmed that the instrument printout attached to the attestation worksheets did not include the initials of the testing person who performed the test as required.
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 the policies and procedures and interview with the lead testing person, the laboratory did not establish written policies and procedures for assessing the testing personnel as defined in subpart M- CFR 493.1413(b)(8) through (9): Findings: 1. The laboratory's written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 2. Evaluations must be performed at six months and annually thereafter unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. 3. During the survey on 08/09/18 at 1: 30 PM the lead testing person confirmed that the policies and procedure manual did not include a written training program along with worksheets for the documentation of the of the training of the testing personnel and medical assistants who perform pre-analytical and analytical preparation.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the procedure manual and interview with the lead testing person, the laboratory did not have written policies and procedures for throat cultures that included all steps required for testing and for testing and maintaining the quality control organisms used monitoring the Bacitracin discs (Taxo A). Findings: 1. The "Throat Culture" procedure that was reviewed states: "The sample is spread on the appropriately labeled Strep Select Agar with 5% sheep blood plate (Healthlink)." The procedure did not define what was required to label a plate appropriately. 2. The "Throat Culture" procedure that was reviewed states: "This stock culture is maintained by periodic subculture on trypticase soy agar with 5% sheep blood (TSA, HealthLink) (Note--not Group A select agar)." The procedure did not define how to subculture, how to label the plate, and where to store subcultured organism until they are needed each week. 3. The "Throat Culture" procedure that was reviewed states: "All patient and control results are reviewed periodically by the lab supervisor." The quality assurance (QA) worksheet requires a quarterly review of laboratory records. 4. The purpose of QA audits are to ensure that the QA activities are performed and appropriate action are taken when these QA activities deviate from what is required. Quarterly audits allow problems to go unresolved for up to 90 days without intervention. 5. During the survey on 08/09/18 at 1:30 PM the lead testing person confirmed that the throat culture procedure did not include all the required written instructions that the laboratory staff follow to ensure accurate and reliable patient test results. II. Based on review of the procedure manual and interview with the lead testing person, the laboratory did not have written policies and procedures for entering and reporting patient test results. Findings: 1. According to the testing person the bacteriology results are manually entered into the laboratory information system (LIS) and the instrument printouts with the hematology results are scanned into the LIS and attached to the patients electronic medical records (EMR). 2. Once the hematology results are scanned and attached to the patients EMR the instrument printouts are shredded. 3. During the survey on 08/09/18 at 1:30 PM the lead testing person confirmed that the procedure manuals did not have written policies and procedures for manually entering the bacteriology results and scanning, attaching and shredding the hematology instrument printouts to the EMR.
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 review of the hematology quality control (QC) records and interview with the lead testing person, the laboratory did not ensure that hematology QC materials were not used after their expiration date. Findings: 1. The QC records for the

	hematology analyzer for 2017-2018 were reviewed. The hematology records show that on 01/02/17 the QC materials expired. The next QC lot started on 01/04/17. 2. The records show that the expired lot of hematology QC materials were tested on 01 /03/17 along with 5-6 patients. 3. During the survey on 08/09/18 at 1:30 PM the the lead testing person confirmed that the laboratory had used expiration QC materials when testing and reporting patient test results.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality assessment (QA) records and interview with the lead testing person, the laboratory director did not provide written QA policies and procedures explaining QA activities and how to document the review of activities at the end of each month to ensure the quality of laboratory services. Findings: 1. According to the "Laboratory Personnel Report (CLIA) (CMS-209)", the laboratory director is acting as the technical consultant. 2. The policy labeled "Lab Director" states: "(3) Ensure that quality assurance and quality control programs are designed, formalized, implemented and monitored." 3. The QA worksheet labeled "Laboratory Director Quarterly Review" were reviewed. There were 9 separate reviews performed during a 22 month period (09/30/16 through 08/08/18). According to the testing person the QA worksheets were completed by someone other than the technical consultant. 4. The policy and procedure manual that was reviewed did not include written QA policies and procedures explaining the QA activities to be performed. The QA worksheet was not part of the procedure manual. The QA worksheet included documented review of temperature charts, maintenance, equipment, reagent, quality control and several other laboratory functions. 5. The purpose of QA audits via the worksheet are to ensure that the QA activities are performed and appropriate action are taken when these QA activities deviate from what is required. Quarterly audits allow problems to go unresolved for up to 90 days without intervention. 6. During the exit conference on 08/09/2018 at 1:30 PM the laboratory director acting as the technical consultant confirmed that the laboratory did not have written QA policies and procedures and that the QA worksheet was not being completed by the technical consultant listed on the "Laboratory Personnel Report (CLIA) (CMS-209)" form.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by:

	Based on review of the proficiency testing (PT) results and interview with the lead testing person, the laboratory director acting as the technical consultant did not ensure that written policies and procedures established to define how PT samples were to be used to evaluate the testing personnel. Findings: 1. The lead testing person explained that the PT samples were being used to evaluate all the testing personnel. The testing personnel would test 1-2 PT samples that would be evaluated after the results were returned from the PT agency. This data was kept with the PT records. 2. There was no written procedures for the evaluation of the competency using PT samples that included: defining how the PT samples would be distributed among the testing personnel; how they would be evaluated; corrective actions to be taken when there were failures; and where the records would be stored. For additional information refer to Tag D5209. 3. During the survey on 08/09/18 at 1:30 PM the lead testing person confirmed that the laboratory did not have a written competency procedure that included the evaluation of the testing personnel using PT samples.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the annual evaluations and interview with the laboratory director acting as the technical consultant, the technical consultant did not ensure that all testing personnel received an annual competency review by the qualified technical consultant. Findings: 1. The laboratory currently has five testing persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." The laboratory director is acting as the technical consultant. 2. The testing personnel evaluation records for 2017 and 2018 were reviewed. Four of the five testing persons had their annual review performed and documented by a testing person with an associates degree. The technical consultant is required to have a Bachelor of Science degree with two years experience. 3. During the survey on 08/09/2018 at 1:30 PM the laboratory director acting as the technical consultant confirmed that the annual evaluations for 2017 and 2018 were not performed by the qualified technical consultant.