Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0688523	02/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Montgomery Pediatric Associates	420 Cotton Gin Road, Montgomery, AL	

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 a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the laboratory failed to retain all documentation relevant to the processing and handling of PT samples for throat cultures. This was noted for seven out of seven Bacteriology events reviewed. The findings include: 1. A review of American Association of Bioanalysts (AAB) and American Proficiency Institute (API) PT records revealed no evidence of how throat culture samples were processed for interpretation. This affected all Bacteriology events reviewed in 2022 and 2023. 2. During an interview on 2/1/2024 at 10:13 AM, the Technical Consultant confirmed the above findings.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and

	493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of the Hardy Diagnostics Blood Agar Instructions for Use (IFU), a review of temperature records, a review of blood agar media Quality Control (QC), a review of BD BBL Taxo A discs package insert, a review of Taxo A disc QC, a review of patient reports, and interviews with the Technical Consultant and Testing Personnel #1, the laboratory failed to identify failures in quality as related to the throat culture testing process. The findings include: 1. Refer to D5413. 2. Refer to D5471. 3. Refer to D5479. 4. Refer to D5787. 5. Refer to D6022.
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: Based on a review of Policies and Procedures and an interview with Testing Personnel #1, the laboratory failed to establish a procedure for the Beckman Coulter AcT Diff 2 Hematology Analyzer specifying reference ranges and critical values for a Complete Blood Count (CBC). The findings include: 1. A review of the Beckman Coulter AcT Diff 2 procedure revealed no evidence of normal ranges or panic values for a CBC. 2. During an interview on 2/1/2024 at 4:00 PM, Testing Personnel #1 confirmed the above findings.
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 a review of the Hardy Diagnostics Blood Agar Instructions for Use (IFU), a review of temperature records, and an interview with the Technical Consultant, the laboratory failed to ensure the incubator maintained an acceptable temperature, as specified by the manufacturer's instructions. This was noted to affect patient testing two out of three months reviewed. The findings include 1. A review of the Hardy Diagnostics Blood Agar IFU revealed the media should be incubated at 35 degrees Celsius. 2. A review of temperature records revealed two months of patient testing when incubator temperatures were less than 35 degrees Celsius, as follows: A) In January 2023, the incubator temperature was documented at less than 35 degrees Celsius five out of 20 days in use. Six patients had throat cultures performed during this time. B) In February 2023, the incubator temperature was documented at less than 35 degrees Celsius three out of 20 days in use. 11 patients had throat cultures performed during this time. 3. During an interview on 2/1/2024 at 4:00 PM, Testing Personnel #1 confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the BD BBL Taxo A discs package insert, a review of the Taxo A disc quality control (QC), and an interview with Testing Personnel #1, the laboratory failed to check each lot and shipment of Taxo A discs for positive and negative reactivity with an appropriate control organism as per the manufacturer's instructions. This was noted from the date of the last survey, 2/9/2022, to the date of the current survey, 2/1/2024. The findings include: 1. A review of the BD BBL Taxo A package insert revealed the following under a section titled "User Quality Control": "...At the time of use, check performance with pure cultures of stable control organisms producing known, desired reactions..." 2. A review of the Taxo A disc QC log revealed a document that included the lot number and expiration date of the discs being used. No evidence of a lot number for "S. pyogenes" and "S. agalictica" was available for review. 3. During an interview on 2/1/2024 at 4:01 PM, Testing Personnel #1 explained how the laboratory used "control" organisms obtained from Proficiency Testing events. Furthermore, Testing Personnel #1 was unable to define or provide a procedure on how a pure culture was obtained from said Proficiency Testing samples.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies

	and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Hardy Diagnostics Blood Agar Instructions for Use (IFU), a review of blood agar media Quality Control (QC), a review of BD BBL Taxo A discs package insert, a review of Taxo A disc QC, and interviews with the Technical Consultant and Testing Personnel #1, the laboratory failed to adhere to manufacturer's instructions for Trypticase Soy Agar (TSA) and Taxo A discs. This was noted from the date of the last survey, 2/9/2022, to the date of the current survey, 2/1/2024. The findings include: 1. A review of the Blood Agar IFU revealed the following: "...Hardy Diagnostics recommends end users...perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction...". 2. A review of blood agar media QC from 3/10/2022 to 12/23/2023 revealed only visual defects of the media plates being documented. No evidence of a positive and negative organism used as control material for each lot and shipment was available for review. 3. During an interview on 2/1/2024 at 11:13 AM, the Technical Consultant confirmed the above findings. 4. A review of the BD BBL Taxo A package insert revealed the following under a section titled "PROCEDURE": "...Inoculate a Trypticase Soy Agar with 5% Sheep Blood plate with the test organism exhibiting beta-hemolysis on the primary isolation plate..." 5. During an interview on 2/1/2024 at 11:50 AM, Testing Personnel #1 explained how they use Taxo A discs with patient samples. This procedure included using the Taxo A disc on the patient's primary plate. Testing Personnel #1 did not mention inoculating a secondary plate using a pure culture from a primary plate.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a review of patient reports and an interview with Testing Personnel #1, the laboratory failed to maintain records that detailed each step of the throat culture process. This was noted for five out of five patient reports reviewed. The findings include: 1. A review of patient reports revealed no evidence of the following: A) Time and date of specimen collection B) Time and date of plating specimen on throat culture media C) Time and date of reading agar plate 2. During an interview on 2/1 /2024 at 4:00 PM, Testing Personnel #1 confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of the Hardy Diagnostics Blood Agar Instructions for Use (IFU), a review of temperature records, a review of blood agar media Quality Control (QC), a review of BD BBL Taxo A discs package insert, a review of Taxo A disc QC, a review of patient reports, and an interviews with the Technical Consultant and Testing Personnel #1, the Laboratory Director failed to identify failures in quality as related to the throat culture process. The findings include: 1. Refer to D5413. 2. Refer to D5471. 3. Refer to D5479. 4. Refer to D5787. 5. Refer to D6022.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of throat culture media quality control (QC), Taxo A disc QC, patient reports, and interviews with the Technical Consultant and Testing Personnel #1, the Laboratory Director failed to identify quality failures in the throat culture process. This was noted from the date of the last survey, 2/9/2022, to the date of the current survey, 2/1/2024. The findings include: 1. Refer to D5413. 2. Refer to D5471. 3. Refer to D5479. 4. Refer to D5787.
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 a review of Personnel records, a review of Policies and Procedures, and an interview with the Technical Consultant, the Technical Consultant failed to perform a six month competency for the Beckman Coulter AcT Diff 2 Complete Blood Count (CBC). This was noted for one out of one new Testing Personnel since the date of the last survey, 2/9/2022. The findings include: 1. A review of competency assessment records for Testing Personnel #4 revealed an initial training dated 6/20/2022 and a six month competency assessment dated 12/21/2022. No evidence of competency assessment for CBC testing was available for review. 2. A review of the Quality Assurance Plan revealed the following under the section titled "Personnel": "...All lab personnel will be trained in the lab area with personnel training evaluations at the end of the orientation training period, again in 6 months, and then annually by the Lab Director..." 3. During an interview on 2/1/2024 at 4:00 PM, the Technical Consultant confirmed the above findings.

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 a review of Personnel records, a review of Policies and Procedures, and an interview with the Technical Consultant, the Technical Consultant failed to assess competency for the Beckman Coulter AcT Diff 2 Complete Blood Count (CBC) annually. This was noted for four out of four Testing Personnel (TP) previously qualified since the date of the last survey, 2//9/2022. The findings include: 1. A review of Personnel records revealed timely annual competency assessments for TP #1, TP #2, TP #3, TP #5, and TP #6. However, no evidence of competency assessment for CBC testing was available for review. 2. A review of the Quality Assurance Plan revealed the following under the section titled "Personnel": "...All lab personnel will be trained in the lab area with personnel training evaluations at the end of the orientation training period, again in 6 months, and then annually by the Lab Director..." 3. During an interview on 2/1/2024 at 4:00 PM, the Technical Consultant confirmed the above findings.