Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303442	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Al Peds	829 Riverbend Drive, Gadsden, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the Bacteriology Quality Control (QC) records, and an interview with Testing Personnel (TP) #1, the laboratory failed obtain and retain the manufacturer's insert for BD BBL Taxo A discs (Bacitracin discs) as per Plan of Correction presented to CLIA after the 7/7/2017 survey. The findings include: 1. After a review of the Bacteriology records, the surveyor determined the testing personnel had failed to correctly document the Bacitracin (Taxo A) discs QC. [Refer to D5471.] 2. During an interview with TP #1 on 9/12/2019 at 1:25 PM, the surveyor asked for the manufacturer's insert for the BD BBL Taxo A disc. TP #1 stated the laboratory had never obtained the insert for this reagent. 3. As the interview continued at approximately 1:35 PM, the surveyor explained the importance of obtaining and retaining the manufacturer's insert for the BD BBL Taxo A discs, since it included the manufacturer's instructions for the required QC. The insert specified the laboratory should ensure each new lot number of discs performed as expected: Strep pyogenes (Group A) should produce a positive reaction, a "Zone of inhibition" around the "A" disc, and Strep agalactiae (Group B) should produce a negative reaction, "No zone of inhibition". 4. This is a repeat deficiency. .
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 the laboratory policy and procedure manual, a review of the Bacitracin ("A" disc) Quality Control (QC) logs, and an interview with Testing Personnel #1, the laboratory failed to ensure the manual included a procedure for correct performance and documentation of Bacitracin QC, since the previous survey. The findings include: 1. Refer to D5471. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, reviews of the quality control (QC) and the patient data logs, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to verify the calibration by running QC before patient testing resumed. This was noted on one of three 2018 calibrations performed on the Horiba Medonic M Series Hematology analyzer. The findings include: 1. A review of calibration records for the Medonic Hematology analyzer revealed the instrument was calibrated on 7/12/2018 at 14:48 (2:48 PM). A review of the daily Hematology QC printouts and Levi-Jennings charts revealed QC was only run in the early morning on this date. 2. A review of the Medonic M Series User's Manual on page 62 revealed, under Section 7.2 Calibration, "...17. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. ...". In addition in bold handwritten print at the top of this page was the note: " * Do QC after cal [calibration] every time". 3. During an interview on

	9/12/2019 at 11:08 AM, Testing Personnel #1 confirmed the laboratory had no documentation of QC after the 7/12/2018 calibration. The surveyor then asked if any patient testing had occurred after 2:48 PM (after the calibration); Testing Personnel #1 checked the records and stated eight patient CBCs (Complete Blood Counts) had been performed. Thus the above noted findings were confirmed. 4. This is a repeat deficiency. Failure to perform and/or document QC after the Hematology calibrations has been cited in the last two surveys. .
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 Bacteriology Quality Control (QC) logs, and an interview with Testing Personnel (TP) #1, the laboratory failed to specify expected (acceptable) quality control results for positive and negative Bacitracin ("A" disc) QC, and failed to document the results for the negative Taxo A disc QC for two years, since the previous survey. The findings include: 1. A review of the Bacteriology records revealed the testing personnel documented the lot number, expiration and test performance dates, and the QC "Results" for each new lot number of Bacitracin (Taxo A) discs. At the top of the page the testing personnel listed "S. pyogenes (A)" and "S. agalactiae (B)" with the lot numbers. However, the Testing Personnel only documented "No growth within zone" as their QC results for each lot number of discs. There was no indication of whether this was the positive or negative QC result. 2. During an interview on 9/12/2019 at 1:25 PM, the surveyor asked TP #1 for the Bacitracin Quality Control procedure and the manufacturer's insert for the BD BBL Taxo A disc. TP #1 stated the laboratory did not have a procedure, and their vendor only sent the package of Taxo A discs; the laboratory had never received the insert for this reagent. The surveyor asked how the laboratory performed the Bacitracin QC. TP #1 stated after the previous CLIA survey, she implemented the new procedure, and the Strep pyogenes (A) "should have no growth in the zone". The surveyor noted Strep agalactiae (B) was also listed at the top of the QC log, and asked about use and documentation for this QC organism. TP #1 stated she "smeared" the "B" organism on an agar plate and applied a Taxo disc, however she did not know she needed to document the observed QC results. 3. As the interview with TP #1 continued at approximately 1:35 PM, the surveyor explained the CLIA requirement of performing and documenting positive and negative QC to verify the expected reactivity of each lot number of bacitracin discs. The laboratory should document the actual reactions observed and specify the expected results. Both the positive (Group A) and negative (Group B) QC organisms should should be plated on agar with a Taxo A disc, however the S. pyogenes should produce hemolysis (a "halo") with a "Zone of inhibition" (a positive reaction) around the "A" disc; the S. agalactiae should have "No zone of inhibition" (a negative reaction) around the "A" disc. SURVEYOR ID#32558 Licensure and Certification Surveyor