

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1037371	(X3) Date Survey Completed 01/03/2020
Name of Provider or Supplier Amity Medical Group	Street Address, City, State 824 Lower Dallas Highway, Dallas, NC	
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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 Beckman Coulter AcT diff2 hematology analyzer calibration and quality control (QC) records, review of laboratory procedures, review of Quality Assessment (QA), and review of laboratory logs 1/3/2020, the laboratory failed to retain all Calibration and QC performed on the Beckman Coulter AcT Diff 2 hematology analyzer. Findings: The laboratory's Quality Assurance plan states, "QC records are stored in the extended lab and are retained for a minimum of two years." a. Review of the 2018 laboratory logs revealed the laboratory performed patient testing 11/13/18-11/17/18 and 11/19/18-11/20/18. Review of the Beckman Coulter AcT Diff 2 QC records revealed documentation of at least 2 levels of acceptable QC was not available for this time period. b. Review of the 2019 calibration records and review of the November 2019 monthly QA checklist revealed the 5/28/19 Act Diff Calibration documentation was not available.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation and review of the 2018 Hematology Calibration records 1/3 /2020, the laboratory failed to discard supplies and calibration material that had exceeded the expiration date. Findings: During tour of the laboratory at approximately 9:20am, the surveyor observed the following expired supplies, that were available for use: 1.) a. OraQuick HCV (Hepatitis C virus antibody) controls, lot #0006667397, expired 6/30/19-located in the refrigerator; b. Quantimetrix Dropper Plus Urinalysis Dipstick control , lot #44620A, expired 11/2019-located in the refrigerator; c. Binax Now RSV (Respiratory Syncytial Virus) kit, lot #096623, expired 12/28/19- located in laboratory cabinet. 2.) Review of the 2018 calibration records for the Act Diff 2 Hematology analyzer revealed the 6 month calibration was performed on 8/3/2018. The manufacturer's assay sheet for the S-Cal Calibrator- lot number 4743, used for the calibration revealed the calibrator expired on 6/16/2018. Review of records also revealed changes were made to the calibration factors for Hemoglobin(Hgb) and White Blood Cell(WBC) based on the results of the calibration.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of procedures, review of 2018 and 2019 Beckman Coulter Act Diff 2 Hematology calibration records, and interview with the office manager 1/3/2020, the laboratory failed to perform calibration at least once every 6 months and failed to document the quality control required after calibration was performed. Findings: The Procedure for the Coulter Act Diff 2 Series Analyzer states under CALIBRATION FREQUENCY, " Calibrate at least once every six months..." The procedure also states under VERIFYING THAT CALIBRATION IS ACCEPTABLE, " Analyze QC material. The control results should fall within expected ranges." a. Calibration records revealed the Hematology analyzer was calibrated 11/8/17, 9 months later on 8 /3/18, and 15 months later on 11/1/19. During interview at approximately 12:30pm, the office manager confirmed the calibrations were performed past the 6-month time frame. She stated calibration was performed on 5/28/19, but the records were not available at time of survey to confirm the required calibration was performed. b. The

laboratory failed to document testing three levels of quality control material after calibration to verify the acceptability of the AcT Diff 2 analyzer on 11/1/19.