Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0239062	02/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Guilford Medical Associates, Pa	2703 Henry Street, Greensboro, 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
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 observation and interview with the TC (technical consultant) and TP (testing personnel) 2/17/20, the laboratory failed to discard supplies that exceeded their expiration dates. During a tour of the laboratory at approximately 2:30 p.m., the surveyor observed the following supplies in a cabinet in the laboratory, available for use: 1. One partial container of Detergent B, lot #50628 with expiration date 10/26/18; 2. Two containers of Detergent B, lot #51748 with expiration date 4/26/19; 3. One full and one partial container of Water Bath Additive, lot #53384 with expiration date 10 /19/19. During interview at approximately 5:20 p.m., the TC and TP #1 confirmed that the supplies were expired.
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 the laboratory's policies and procedures, review of 2018 and 2019 Architect calibration verification records, and interview with TP (testing personnel) 2 /17/20, the laboratory failed to perform and document calibration verification at least once every six months. The laboratory's "Architect Chemistry Analyzer" procedure states "... Calibration verifications are performed every 6 months on all analytes." Review of calibration verification records for the Architect chemistry analyzer revealed that calibration verification was performed only once in 2018 (June) and once in 2019 (July-August). In addition, review of calibration verification records for the Architect chemistry analyzer revealed that calibration verification for HDL (high density lipoprotein) and triglycerides was performed in 2019, but the results were not available for review at the time of the survey. During the exit interview at approximately 5:05 p.m., TP #1 confirmed that calibration verification was performed only once in 2018 and 2019 and was not performed at least once every six months.