Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0684578	03/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Elizabeth Pediatrics	2630 East 7th Street, Suite 101, Charlotte, 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
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 review of laboratory procedure "Abbott Afinion Hemoglobin A1c Dx Test" and interview with technical consultant (TC) 3/4/24, the procedure for the Afinion glycosylated hemoglobin (HbA1c) failed to include the type and levels of quality control (QC) reagents. Findings: Review of laboratory procedure "Abbott Afinion Hemoglobin A1c Dx Test" revealed "D. Quality Control (QC)...2. External: a. Both levels of external controls must be tested...". The procedure fails to include the type

	and levels of QC reagent. Interview with TC at approximately 3:50 p.m. confirmed the procedure for the Afinion glycosylated hemoglobin (HbA1c) failed to include the type and levels of quality control (QC) reagents.
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 surveyor observation and interview with technical consultant (TC) 3/4/24, the laboratory failed to discard quality control (QC) reagents, QC organisms and collection swabs that had exceeded their expiration dates and were available for use. 1. The laboratory failed to discard QC reagents and organisms that had exceeded their expiration dates. Findings: During laboratory tour at approximately 12:50 p.m., the surveyor observed the following QC reagents and QC organisms in the laboratory refrigerator available for use: a. One bottle of QC reagent, Abbott MultiAnalyte Control, Lot #902953067, with an expiration date of 2/23/24. b. One "Kwik Stik" QC container, S. Agalactiae (B), Lot #710-27-2, with an expiration date of 5/3//23. c. One "Kwik Stik" QC container, S. Pyogenes (A), Lot #314-26-3, with an expiration date of 7/31/23. Interview with TC at approximately 12:50 p.m. confirmed the QC reagent and QC organisms had exceeded their expiration dates. She stated the "Kwik Stik" QC organisms were used for throat culture controls and the facility ceased performing throat cultures in March of 2022. Surveyor was able to confirm the last throat culture performed was 8/25/21. The TC also stated the Abbott MultiAnalyte Control QC reagent was used in the testing of a waived lipid panel currently performed by the laboratory. 2. The laboratory failed to discard collection swabs that had exceeded their expiration dates. Findings: During laboratory tour at approximately 12:50 p.m., the surveyor observed 4 green top "Copan Sterile R" swabs, Lot #172C-P20-2007450 with an expiration date of 5/31/23. Interview with TC at approximately 12:50 p.m. confirmed the 4 swabs were expired and available for use.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of verification of performance records for the Afinion glycosylated hemoglobin (HbA1c) analyzer and interview with technical consultant (TC) 3/4/24,

	the laboratory failed to verify the precision of the Afinion HbA1c analyzer. Findings: Review of verification of performance records for the Afinion HbA1c analyzer revealed all verification testing was performed on one day, 3/24/23, and by one operator. The verification failed to include variances of day to day runs and operators. Interview with TC at approximately 3:15 p.m. confirmed the precision verification of the Afinion HbA1c analyzer failed to include variances of day to day runs and operators. They stated the performance verification must have been completed by the service representative.