Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0669008	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Novant Health Adult Primary Care	**Street Address, City, State** 50 Miller St Ste G, Winston-Salem, 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 review of laboratory procedure, review of operator's manual and review of 2017 and 2018 chemistry records 01/16/19, the laboratory failed to document the replacement of expired ISE (ion-selective electrode) reagents and Wash Solution on the Beckman AU480 chemistry analyzer. Review of laboratory procedure "Beckman Coulter AU480 Chemistry Analyzer" revealed the following, "ISE Reagents (Buffer, Mid-Standard, Reference, Low and High Serum Standards, Internal Reference Solution and Na+/K+ Selectivity Solution) Replacement of Buffer, Mid-Standard, and Reference solutions must be documented on the ISE Reagent Replacement log because the instrument does not keep an internal log of these reagents...4. Buffer, Mid-Standard, and Reference: stable for up to 90 days when opened and stored on the analyzer at 2-25 degrees Celsius...Wash Solution....Replacement of Wash Solution must be documented on the ISE Reagent Replacement log because the instrument does not keep an internal log of these reagents. Wash Solution is stable until the date printed on the label when stored at 2-25 degrees Celsius." Review of the Beckman Coulter AU480 operator's manual revealed "Starting the ISE Unit....2. Verify that the ISE reagents have not expired." Review of 2017 and 2018 "ISE Replacement logs" revealed the following: a. ISE Mid-Standard Solution, Lot #M610451, replaced 03/18/17, expiration 06/18/17; no documentation of ISE Mid-Standard replacement until 12/02/17. Expired ISE Mid-Standard reagent was in use for a period of approximately 6 months. b. Wash Solution, Lot #M607616, replaced 03/24/17, expiration 06/24/17; no documentation of Wash Solution replacement until 09/11/17. Expired Wash Solution was in use for a period of approximately 3 months. c. ISE Mid-Standard Solution, Lot

	#M707199, replaced 12/02/17, expiration 03/02/18; no documentation of ISE Mid-Standard replacement until 05/30/18. Expired ISE Mid-Standard reagent was in use for a period of approximately 2 months. d. Wash Solution, Lot #M704219, replaced 02 /14/18, expiration 05/14/18; no documentation of Wash Solution replacement until 06 /23/18. Expired Wash Solution was in use for a period of approximately 5 weeks.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2017 and 2018 hematology records 1/16/19, the laboratory failed to follow manufacturer's instructions for performing monthly maintenance on the Sysmex XS-1000i hematology analyzer. The Sysmex XS-1000i Instructions for Use state in chapter 9 "... 9.3 Monthly maintenance Carry out Monthly maintenance every month, or after every 1,200 analyses. ..." The manufacturer provides instructions for performing a monthly rinse to wash contaminants from the optical detector block flowcell. Review of the laboratory's 2017 and 2018 maintenance logs revealed the laboratory failed to perform and document the monthly rinse: 1. 8 of 12 months in 2017 (February, April, May, July, August, October, November, and December); 2. 7 of 12 months in 2018 (February, May, June, August, September, November, and December).