Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1066904	01/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Blakeney Family Physicians	5815 Blakeney Park Drive, Suite 200-B, 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
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of the OSOM Mono (mononucleosis) dipstick package insert, review of 2022 and 2023 serum Mono quality control records, review of the laboratory's policies and interview with the TC (Technical Consultant) on 1/10/24, the Laboratory Director failed to ensure the laboratory performed two levels of external quality control material each day of testing and failed to implement an IQCP (Individualized Quality Control Plan) for its OSOM Mono dipstick tests to allow the laboratory to decrease the frequency of quality control performance. Findings: Review of the OSOM Mono dipstick package insert revealed in section "Quality Control: External Quality Control" that "Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot and with each new untrained operator." Review of the laboratory's 2022 and 2023 serum Mono quality control records revealed the performance of external quality controls with each new lot of OSOM Mono dipstick tests. Review of the laboratory's policies revealed an IQCP for the Abbott Acceava Mono cassette tests. In interview at approximately 11:00 a.m., the TC stated the following: 1. Abbott Acceava Mono cassette tests were in use in the laboratory prior to the implementation of the OSOM Mono dipstick tests. 2. A new IQCP was not

	created when the laboratory switched from the Abbott Aceava Mono cassette tests to the OSOM Mono dipsticks in March 2022.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based upon review of records to verify the performance characteristics of the Medonic Hematology analyzer, review of the laboratory's policies and procedures, and interview with the TC (Technical Consultant) on 1/10/24, the TC failed to verify the upper half of the reportable range of 1 of 5 analytes. Findings: Review of records to verify the performance characteristics of platelets on the Medonic Hematology analyzer revealed the following: 1. Five concentrations of linearity materials were used to assess the reportable range of platelets - Levels 1, 2, 3, 4 and 5. 2. The manufacturer's means for the linearity materials used are as follows respectively: 10 x10^9/L, 95 x10^9/L, 231 x10^9/L, 459 x10^9/L and 915 x10^9/L Review of the laboratory's Medonic M-Series Hematology Analyzer procedure revealed in a chart titled "Linearity-Regression and Linear Range" that the laboratory's reportable range for platelets is 30 x10^9/L -1800 x10^9/L. In interview at approximately 12:05 p.m., the TC confirmed that the reportable range for platelets in the LIS (Laboratory Information System) is 30 x10^9/L-1800 x10^9/L.