Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0696801	02/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Primary Care Clemmons	6301 Stadium Drive, Clemmons, 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
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of 2020, 2021, and 2022 quality assessment monitors, and interview with the TC (technical consultant) 2/1/23, the laboratory director failed to ensure the quality assessment program was maintained to assure the quality of the laboratory services offered. Findings: The laboratory's quality assessment plan states "...V. PROCESSES / PROGRAM COMPONENTS Quality Assessment Activities 1. Quality Assessment Activities, also known as monitors, will be completed by the testing personnel throughout each year in moderately and highly complex laboratories. 2. Each activity (monitor) will include instructions for completion and reporting. 3. All laboratory personnel must be familiar with and follow the written quality assessment plan and safety policies. ..." The plan includes quarterly monitors and an annual assessment to be completed each year. Review of 2020, 2021, and 2022 quality assessment monitors revealed: 1. There were no quality assessment monitors documented for the 2020 3rd and 4th quarters. 2. There were no quality assessment monitors documented for the 2021 1st and 2nd quarters. 3. There were no annual assessments documented for 2020, 2021, or 2022. During interview at approximately 12:40 p.m., the TC confirmed the quality assessment monitors had not been completed as specified in the quality assessment plan.

D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 HemoCue WBC (white blood cell) quality control records 2/1/23, TP (testing personnel) failed to follow the laboratory's policy for validation of each new lot number of control material used on the HemoCue WBC analyzer. Findings: Review of the "HemoCue WBC Analyzer" procedure revealed on page 3 "... Validation of New Lot of Control material The following actions are taken prior to implementation of a new lot number of quality control material: 1. The new lot number of control material is to be tested in parallel with the existing control material. 2. The new lot number of control material will be tested a minimum of 1 time prior to use. ... 4. The results must be compared to the manufacturer's assay ranges and confirmed that the values are within acceptable limits. Document results on the HemoCue WBC QC Lot Validation Study log. ... 6. The manufacturer's package insert, all instrument correlation documentation from the validation study, and any other information regarding the study, will be secured together (stapled or paper clipped) and maintained for 2 years. ..." Review of 2020, 2021, and 2022 HemoCue WBC quality control records revealed there was no documentation the following lot numbers of control material were validated prior to use: 1. HC06201, HC06202, HC06203, expiration 9/5/20; 2. HC09201, HC09202, HC09203, expiration 12/5/20; 3. HC12201, HC12202, HC12203, expiration 3/5/21; 4. HC03211, HC03212, HC03213, expiration 6/5/21; 5. HC06211, HC06212, HC06213, expiration 9/5/21; 6. HC09211, HC09212, HC09213, expiration 12/5/21; 7. HC12211, HC12212, HC12213 expiration 3/5/22; 8. HC03221, HC03222, HC03223, expiration 6/5/22; 9. HC09221, HC09222, HC09223, expiration 12/5/22. B. Based on review of the laboratory's IQCP (Individualized Quality Control Plan) for ACR (albumin/creatinine ratio) testing and review of 2020, 2021, and 2022 ACR quality control records, TP failed to follow their IQCP to ensure quality control results were documented and were acceptable prior to reporting patient test results, failed to document refrigerator and room temperatures and humidity daily, and failed to ensure recorded values were within acceptable limits. Findings: Review of the laboratory's IQCP for Afinion ACR testing states "... External controls (Alere Afinion ACR Controls, Levels 1 and 2) will be tested with each new lot or shipment of test materials, when training new employees, anytime an unexpected result is obtained, and once weekly, on the first day of patient testing. Results will be within the manufacturer's defined range published in the package insert for the control lot number in use. If QC results are not within acceptable limits, corrective action will be taken and QC will be rerun and acceptable prior to running patient specimens. Levey-Jennings charts are reviewed weekly. If there is any failure, this plan will be reevaluated. ... Refrigerator temperatures and room temperature and humidity are monitored each day of operation. Corrective action will be taken if temperatures are not acceptable and testing will be suspended until the temperature is acceptable. 1. TP failed to ensure quality control was tested and the results were acceptable prior to testing patients. Examples: a. On 6/29/21, the Level 1 control was outside the acceptable limits and was not retested. 9 patients were tested between acceptable quality control runs. b. During February 2022, Level 1 and Level 2 controls were not tested weekly, but were tested on only 1 day, 2/28/22. 84 patients

	were tested 2/1/22 - 2/27/22. c. Level 1 and Level 2 controls were not tested between 1 /9/23 and 1/31/23. 33 patients were tested during this time. 2. TP failed to document all dates that quality control material was tested. Examples: a. Level 1 (lot #10208616) and Level 2 (lot #10208617) controls with expiration date of 7/13/21, open date of 2/18/21, and open expiration date of 4/15/21 were tested on 3/15/21 and 3 /22/21. Control results were also documented in another row, indicating testing was performed on 1 day after 3/22/21, but there was no date documented. b. Level 1 (lot #10208616) and Level 2 (lot #10208617) controls with expiration date of 7/13/21, open date of 2/18/21, and open expiration date of 4/15/21 were tested on 2 days with no testing dates documented. 3. TP failed to ensure refrigerator and room temperature were documented and were within acceptable limits. Examples: a. Room and refrigerator temperatures were not documented 6/18/20 - 6/21/20. b. Room temperature and humidity were not documented 7/2/21 and 7/6 - 7/9/21. c. Room temperature was outside acceptable limits 3/1/22 and 4/11/22.