Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2038737	(X3) Date Survey Completed 06/28/2023
Name of Provider or Supplier Novant Health Corporate Health	**Street Address, City, State** 1399 Ashleybrook Lane, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of 2020, 2022, and 2023 API (American Proficiency Institute) proficiency testing records, the absence of records, and interview with the GS (general supervisor) 6/28/23, the laboratory failed to retain all proficiency testing records for at least two years. Findings: 1. Review of 2020, 2022, and 2023 API proficiency testing records revealed the laboratory failed to retain required records for all events. a. The laboratory failed to retain report forms for the 2020 API Chemistry Core 2nd and 3rd events, and the 2022 API Chemistry Core 2nd event. b. The laboratory failed to retain attestation statements signed by the laboratory director for the 2023 API Chemistry Core 2nd event and the 2023 API Chemistry Miscellaneous 1st event. c. The laboratory failed to retain attestation statements signed by the testing personnel for the 2020 API Chemistry Core 2nd and 3rd events and the 2022 API Chemistry Core 2nd event. d. The laboratory failed to retain graded results for the 2022 API Chemistry Core 3rd event, the 2023 API Chemistry Core 1st and 2nd events, and the 2023 API Chemistry Miscellaneous 1st event. 2. There were no records for 3 of 3 2021 API Chemistry Core test events and no records for the 2022 API Chemistry Miscellaneous

	2nd event available for review. During interview at approximately 11:20 a.m., the GS stated the laboratory performed the 2021 events, but they were unable to locate the records.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, the absence of records, and interview with the GS 6/28/23, the laboratory failed to retain records of quality assessment activity for at least two years. Review of the laboratory's quality assessment plan revealed activities to be performed on a quarterly basis. There were no records of quality assessment activity for 2020, 2021, and 2022 available for review. During interview at approximately 12:05 p.m., the GS confirmed there were no quality assessment records for 2020, 2021, and 2022 available.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based upon review of personnel records, the absence of competency records and interview with the GS 6/28/23, the laboratory failed to follow their policies to assess the competency of the GS and TS (technical supervisor) in 2022 and 2023. The findings include: Review of personnel records revealed there was no documentation of competency assessement for the TS or GS in 2022 or 2023. During an interview at approximately 11:30 a.m., the GS confirmed that no assessment of the competency of the laboratory's TS or GS was performed in 2022 or 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the absence of temperature logs, review of 2021, 2022, and 2023 temperature and humidity logs, and interview with the TS on 6/28/2023, the laboratory failed to monitor and document

	room temperature, refrigerator temperature, cooler temperature, and humidity as required for storage of supplies and instrument operation. Findings: Review of the laboratory's "Hemoglobin A1C NOW - High Complexity" procedure revealed "... Storage and Stability Kit ... If stored at room temperature (18-28 degrees Celsius), the test kits must be discarded after 4 months. ... The Monitors, Test Cartridges and Dilution Kits may be used until their printed expiration date when stored refrigerated (2-8 degrees Celsius). ... Quality Controls ... Unopened Nova-One Diagnostics (NOD) A1C control is stable until printed expiration date if stored frozen (-15 degrees Celsius to -25 degrees Celsius). ... Maintenance 1. Room Temperature and Humidity will be recorded at each test site to ensure environment meets manufacturer recommendations for testing. 2. Room Temperature and Humidity will be recorded when office personnel are present at the storage facility to ensure proper storage of A1CNow kits. 3. Cooler Temperature for quality control material will be recorded at each test site and monitored throughout each onsite screening to ensure controls are maintained at 2-8 degrees Celsius. 4. Refrigerator and freezer temperatures will be monitored and recorded at the storage facility when office personnel are present to ensure proper storage of quality control and linearity materials. ..." 1. A review of the laboratory's "Lab General Maintenance Logs" revealed the absence of 2021 and 2022 documentation of the room temperature, refrigerator temperature and humidity in a storage area at the satellite location where reagents and instrumentation are stored. During an interview at approximately 1:45 p.m., the TS confirmed the laboratory did not have documentation of the room temperature, refrigerator temperature and humidity of the storage area prior to 2023. 2. Review of 2022 and 2023 temperature and humidity logs for the "Community Cruiser" revealed the cooler temperature was not documented from 6/1/22 through 5/31/23. 3. Review of 2021, 2022, and 2023 temperature and humidity logs revealed the laboratory failed to monitor and document room temperature, cooler temperature, and humidity on the following dates: a. July 5, 6, 7, 8, 11, 12, 13, 14, 15, 2022 (9/21 days). b. May 1, 2, 20, 21, 22, 23, 27, 28, 30, 2023 (9/23 days).
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 upon review of the laboratory's policies and procedures, the absence of maintenance records and interview with the TS 6/28/23, the laboratory failed to perform and document monthly maintenance for the Afinion Dx instruments. The findings include: The laboratory's procedure "Abbott Afinion Hemoglobin A1c Dx Test, Section: F. Maintenance 3. Monthly" states "For regular maintenance (removal of dust particles, etc.), the cartridge chamber should be cleaned every 30 days." There was no documentation of the performance of monthly maintenance on the Afinion Dx instruments. During an interview at approximately 3:00 p.m., the TS stated the laboratory had not performed and documented monthly maintenance on its Afinion Dx instruments.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based upon the absence of records and interview with the TS 6/28/23, the laboratory failed to compare hemoglobin A1C results obtained from its different instruments to evaluate the relationship between test results and determine if a bias is present. The findings include: There was no documentation of the performance of an assessment of hemoglobin A1C results obtained from the laboratory's different instruments (Afinion A1c Dx and A1C Now) in 2021, 2022 or 2023. During an interview at approximately 3:00 p.m., the TS stated the laboratory has not performed and documented comparisons of hemoglobin A1C results obtained from its different instruments. She stated the Afinion Dx analyzers were only used at two testing events in 2022.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of 2022 and 2023 quality control records and interview with the TS 6 /28/23, the TS failed to review quality control records for hemoglobin A1C testing in 2022 and 2023 to ensure the maintenance of acceptable levels of analytic performance. Findings: A review of hemoglobin A1C quality control records for 2022 and 2023 revealed there was no documentation of review by the TS. During an interview at approximately 3:00 p.m., the TS confirmed that hemoglobin A1C quality control data was not reviewed in 2022 and 2023.