Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2072482	12/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Corporate Wellness	8700 Sudley Road, Manassas, VA	

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
D0000	An announced on-site CLIA recertification survey was conducted at Novant Health Corporate Wellness on November 30, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on November 4, 2020 and virtual record review conducted on November 16, 2020. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems, D6093 - 42 C.F.R. 493.1445 Condition: Laboratory Director, D6108 - 42 C.F.R. 493.1447 Condition: Laboratory Technical Supervisor.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, proficiency testing (PT) records, Quality Control (QC) records, lack of documentation and interviews, the laboratory failed to follow their established PT policy to test PT specimens in the same manner as patients for two (2) of three (3) American Proficiency Institute (API) Glycohemoglobin (Hgb A1C) events in 2020. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Proficiency and Split Sample Testing", which stated, "V. Procedure- 8. After preparation, the samples will

	be tested in the same manner as any patient...Quality Control must be performed according to the same frequency as required for patient samples or according to your IQCP." 2. Review of the laboratory's policies and procedures revealed a policy, "Hemoglobin A1C NOW", which states, "External-Quality Control should be performed with each new shipment and/or lot number, everyday of patient testing and each site/event of patient testing when multiple sites/events are done on the same day, each new untrained operator, whenever problems are identified, and every 30 days to ensure storage conditions have not been affected if test kit has been stored for more than a month since the last control testing." 3. Review of the laboratory's 2020 API PT documentation revealed the laboratory performed analysis of the Hgb A1C PT samples as follows: 2020 1st Event performed on 1/27/2020; 2020 2nd Event performed on 5/26/2020; and 2020 3rd Event performed on 9/9/2020. 4. Review of the laboratory's QC documentation for Hgb A1C revealed QC was performed on 5/26 /2020. The surveyor requested QC documentation for 1/27/2020 and 9/9/2020. The laboratory provided no documentation for review. 5. In an interview with the Technical Supervisor 1 and testing personnel A on November 30, 2020 at approximately 9:45 AM, the findings were confirmed.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, and interviews, the laboratory failed to rotate PT among the nine (9) personnel who performed GlycoHemoglobin (Hgb A1C) patient testing from August 1, 2018 and up to the date of the inspection on 11/30/2020. Findings include: 1. Review of the CMS 209 form revealed 9 testing personnel (TP) listed as having performed/reported patient Hgb A1C testing during the twenty seven (27) months reviewed. 2. Review of the laboratory's American Proficiency Institute (API) PT documentation (2019 Events 1-3, 2020 Events 1-3) revealed that TP A signed as testing personnel on the following attestation statements: 2019 1st Event; 2019 2nd Event; 2019 3rd Event; 2020 1st Event; 2020 2nd Event; 2020 3rd Event. TP A performed six (6) of the six (6) events reviewed. (See Personnel Code Sheet.) 3. In an interview with Technical Supervisor 1 on November 16, 2020 at approximately 9:45 AM, the findings were confirmed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on a review of the laboratory's policy and procedure manual, calibration verification records, quality control (QC) records, quality assessment (QA) documents and interviews, the laboratory failed to: 1. document calibration verification procedures every six months for Glycohemoglobin (Hgb A1C) patient testing according to their written procedure in calendar year 2020 (Cross Reference D5439); 2. perform QC procedures each day of patent testing for the A1C NOW analyzer for three (3) of seven (7) days from September 15, 2018 until May 8, 2019 (Cross Reference D5447); 3. to follow their written QA policy for the review of their analytic system from August 2018 to November 2020 (Cross Reference D5791).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, calibration verification records, and an interview, the laboratory failed to document calibration verification procedures every six months for Glycohemoglobin (Hgb A1C) patient testing according to their written procedure in calendar year 2020. Findings include: 1. Review of the laboratory's Quality Assurance (QA) procedures revealed a "Quality Control" policy that stated "Calibration and Calibration Verification-Calibration Verification will be performed at least every six months for those tests which are not routinely calibrated with a minimum of 3 levels of calibration material if applicable. Calibration Verification will be performed following manufacturer's testing protocol and procedures." 2. Review of the A1C Now instrument calibration verification documentation from August 2018 until the date of the virtual record review on November 16, 2020, a total of twenty-seven (27), revealed the following records: 8/20 /2018. 2/7/2019, and 8/12/2019. The surveyor requested to review additional calibration verification records for the A1C Now analyzer in calendar year 2020. The laboratory provided no additional calibration verification documentation for review. 3. In an interview with the Technical Supervisor 1 (TS 1) on November 16, 2020 at approximately 10:15 AM, the findings were confirmed.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, quality control (QC) records, testing event listing, patient records, and interviews, the laboratory failed to perform QC procedures each day of patient testing for the A1C NOW analyzer for three (3) of seven (7) days from September 15, 2018 until May 8, 2019 when performing one hundred thirty-nine patients. Findings include: 1. Review of the A1C Now procedure revealed the following: "Quality Control-External,-Quality Control testing should be preformed with each new shipment and/or lot number; Every day of patient testing and at each site/event of patient testing when multiple sites/events are done on the same day..." 2. A review of the laboratory's event listing revealed testing events on the following dates: 9/15/2018, 9/29/2018, 10/25/18, 1/24/19, 2/23/19, 3/30 /19 and 5/8/19. A total of 7 events/dates. 3. A review of the laboratory's QC documentation for the A1C NOW revealed the following events/dates when QC was performed: 9/29/2018, 10/25/2018, 1/24/2019, 2/23/2019. The survey requested additional documentation of QC for the A1C NOW for 9/15/2018, 3/30/2019 and 5/8 /2019. The laboratory provided no documentation of the QC for the above listed events /dates. A total of 3 events/dates. 4. A review of the laboratory's patient logs revealed the following number of patients tested: 09/15/2018-49 patients; 03/30/2019-45 patients; and 05/08/2019-45 patients. A total of 139 patients tested. 5. In an interview with the Technical Supervisor1 (TS 1) on December 4, 2020 at approximately 4:00 PM, the findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of quality assurance (QA) policy, QA documents, lack of documentation and interview, the laboratory failed to follow their written QA policy for the review of their analytic test system from August 2018 to November 2020, a total of twenty-seven (27) months. Findings include: 1. Review of the QA policy, "Quality Control", revealed the following statements: "Quality Assessment Review- 1. Must include a review of QC results and graphs if applicable, proficiency testing results, incidence of specimen rejection, concerns or complaints from providers and any incidents related to each testing platform." 2. Review of QC records for the A1C NOW analyzer and QA documentation revealed a lack of documentation of the QA review according the to written policy from August 2018 to November 2020. The surveyor requested documentation of the QA review from August 2018 to November

	2020. The laboratory provided no additional documentation to review. 3. In an interview with the Technical Supervisor 1 (TS1) on November 16, 2020 at 10:20 AM, the findings were confirmed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Quality Assessment (QA) records, Quality Control (QC) records, lack of documentation and interviews, the laboratory director (LD) failed to: 1. ensure QC policies and procedures were followed for Glycohemoglobin (Hemoglobin A1C) testing using the A1C NOW analyzer for one hundred thirty-nine patients form September 2018 until May 2019 (see D6093); 2. ensure QA policies were maintained for Glycohemoglobin (Hemoglobin A1C) testing using the A1C NOW analyzer from August 2018 until November 2020 (see D6094).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Quality Control (QC) records, lack of documentation and interview, the laboratory director (LD) failed to ensure quality control policies and procedures were followed for Glycohemoglobin (Hemoglobin A1C) testing using the A1C NOW analyzer for one hundred thirty-nine patients form September 2018 until May 2019; (Cross Reference D5447).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Quality Assessment (QA) records, lack of documentation and interview, the laboratory director (LD) failed to ensure QA policies were maintained for Glycohemoglobin (Hemoglobin A1C) testing using the A1C NOW analyzer from August 2018 until November 2020 (Cross Reference D5791).
D6108	LABORATORY TECHNICAL SUPERVISOR

	CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's policies and procedures, laboratory personnel records, and interview, the Technical Supervisors failed to perform: 1. Semi-annual competency assessment for one new testing personnel (Cross Reference D6127); and 2. Annual competency assessment for three (3) of nine (9) testing personnel in 2019 (Cross Reference D6128).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's policy and procedures, testing personnel competency assessment records, lack of documentation, and interview, the Technical Supervisors (TS) failed to perform semi-annual competency assessment for one (1) new testing personnel (TP) from August 2018 until November 2020, a total of twenty-seven (27) months reviewed. Findings include: 1. Review of the CMS 209 form revealed two (2) personnel performed the duties of TS and nine (9) TP. One (1) of the 9 TP were identified as new testing personnel by the TS 1. 2. Review of the laboratory's policy manual revealed a policy, "Personnel Competency Assessment", that stated, "V. Procedure 1. Employee Competency Assessment Plan- a. Non-Waived Testing: The competency of each person to perform each testing platform must be assessed initially, at 6 months, at 12 months, and annually thereafter for non-waived testing..." 3. Review of the new personnel records revealed no semi-annual competency assessment for TP C whose initial training was in February 2019 (See Personnel Code Sheet). The surveyor requested to view the semi-annual competency assessment documentation for TP C. The laboratory provided no additional documentation for review. 4. In an interview with the Technical Supervisor (TS 1) on November 16, 2020 at approximately 9:45 AM, the findings were confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's policies and procedures, testing personnel records, lack of documentation, and interview, the Technical Supervisors (TS) failed to perform annual competency assessment evaluations in calendar year 2019 for three (3) of the nine (9) testing personnel (TP) reviewed. Findings include: 1. Review of the CMS 209 form revealed two (2) personnel performed the duties of TS and nine (9) TP. 2. Review of the laboratory's policy manual revealed a policy, "Personnel Competency Assessment", that stated, "V. Procedure 1. Employee Competency Assessment Plan- a. Non-Waived Testing: The competency of each person to perform each testing platform must be assessed initially, at 6 months, at 12 months, and annually thereafter for non-waived testing..." 3. Review of the 9 TP competency records revealed the following TP lacked a 2019 annual competency assessment: TP C, D, and H (See Personnel Code Sheet). The surveyor requested to review the documentation of the 2019 annual competencies for TP C, D, and H. The laboratory provided no additional documentation for review 4. In an interview with the Technical Supervisor (TS) 1 on November 16, 2020 at approximately 9:40 AM, the findings were confirmed.