

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2038737	(X3) Date Survey Completed 11/08/2019
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2018 and 2019 event logs and temperature logs 11/8/19, the laboratory failed to ensure corrective action was taken and documented when temperatures were outside the acceptable limits for performance of the Hemoglobin A1C Now glycated hemoglobin test. Findings: The laboratory's "Hemoglobin A1C NOW" procedure states on page 5 "... 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. ..." The "Lab General Maintenance" policy states "... Temperatures / Humidity ... Any temperatures out of range should have corrective action performed and should be documented on the temperature/general maintenance log or corrective action form. ..." 1. Random review of 2018 and 2019 event logs for screenings performed at various locations revealed the laboratory failed to document corrective action for room temperatures outside the acceptable limits of 20-28 degrees C (Celsius) when patient testing was conducted. Examples: a. 7/28/18 - room temperature documented as 14 degrees C; b. 8/24/18 -</p>

room temperature documented as 32 degrees C; c. 9/20/18 - room temperature documented as 19 degrees C; d. 10/17/18 - room temperature documented as 47 degrees C; e. 2/28/19 - room temperature documented as 32 degrees C; f. 3/26/19 - room temperature documented as 18 degrees C; g. 6/1/19 - room temperature documented as 19 degrees C. 2. Random review of 2018 and 2019 storage facility temperature logs revealed room temperatures out of range at one of the three storage facilities 7 days in January 2018 (1, 2, 4, 8, 15, 18, 19) with no corrective action documented.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on review of personnel records 11/8/19 and the deficiency cited at D6171, the laboratory failed to verify that 1 of 26 testing personnel (TP #10) met the minimum education requirements for performing high complexity testing.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high

school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the GS (general supervisor) and TP (testing personnel) 11/8/19, the laboratory failed to verify that 1 of 26 testing personnel (TP #10) met the minimum education requirements for performing high complexity testing. Review of personnel records revealed TP #10 had a Bachelor of Science degree in Exercise Science. Review of degree transcripts revealed TP #10 did not have enough credit hours in chemistry, biology, or medical laboratory technology to meet the minimum education requirements for performing high complexity testing. During interview at approximately 11:40 a.m., the GS stated they were unaware TP #10 did not meet the education requirements for high complexity testing. TP #1 stated they would contact TP #10 to see if she had any other education documentation.