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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D2003619         | <b>(X3) Date Survey Completed</b><br><br>12/19/2018 |
| <b>Name of Provider or Supplier</b><br><br>Novant Health Northwest Family Medicine   | <b>Street Address, City, State</b><br><br>7607 - B Highway 68 North, Oak Ridge, NC |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D2006</b>              | <p>TESTING OF PROFICIENCY TESTING SAMPLES<br/>CFR(s): 493.801(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's policies and procedures, review of 2017 and 2018 API (American Proficiency Institute) proficiency testing records, and interview with the TC (technical consultant) 12/19/18, the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested. Findings: The laboratory's "Quality Assessment Plan" states "... III. Proficiency Testing 1. Proficiency testing (PT) samples are tested, to the extent possible, exactly like patient specimens; the same number of times and using the same personnel and methods as for patient testing. ..." Review of 2017 and 2018 API proficiency testing records revealed: 1. On the 2017 1st, 2nd, and 3rd hematology test events and the 2018 1st, 2nd, and 3rd hematology test events, the laboratory provided responses for provider-performed microscopy tests they do not perform on patients. For example, on the 2018 3rd hematology test event, the laboratory provided responses for fecal leukocytes, fern test, nasal smear, pinworm preparation, sperm presence/absence, and urine sediment identification. The TC confirmed during interview at approximately 9:50 a.m. that the laboratory does not routinely perform these tests on patients. 2. Proficiency sample test results were not documented in the same manner as patient test results. Examples: a. On the 2017 1st hematology test event, proficiency sample</p> |

results for vaginal wet prep and vaginal wet prep/ KOH (potassium hydroxide) were documented on API report forms by three different providers, but were not documented on the paper test result forms routinely used to document patient results. All three providers signed the attestation statement, so it was unclear whose results were designated to be submitted. The TC stated during interview at approximately 10:10 a.m. that one of the providers does not perform wet prep tests on patients, but the provider thought she still had to participate in proficiency testing. b. Hemocue WBC (white blood cell count) test results for proficiency testing samples were documented on sticky notes for the 2017 2nd and 3rd hematology test events and the 2018 1st hematology test event, but not on the paper test result forms routinely used to document patient results.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on review of personnel records 12/19/18 and the deficiency cited at D6065, the laboratory failed to ensure that 1 of 4 testing personnel (TP #2) met the minimum education requirements for performing moderate complexity testing.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on review of personnel records and interview with the TC (technical consultant) 12/19/18, the laboratory failed to ensure that 1 of 4 testing personnel (TP #2) met the minimum education requirements for performing moderate complexity testing. Review of personnel records for TP #2 revealed an associate degree in medical assisting. There was no documentation of a high school diploma or GED (high school graduation equivalency diploma). During interview at approximately 11:00 a.m., the TC stated that TP #2 had been asked to provide a copy of her high school diploma or GED. The TC confirmed the requested credentials were not available for review during the survey.