

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0872587	(X3) Date Survey Completed 11/15/2019
Name of Provider or Supplier Novant Health Forsyth Pediatrics Kernersville	Street Address, City, State 240 Broad Street, Kernersville, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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: Based on review of the laboratory's policies and procedures, review of 2017, 2018, and 2019 API (American Proficiency Institute) proficiency testing records, and interview with TP (testing personnel) 11/15/19, the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested. The laboratory's "In-House Critical Values" policy states "All Critical values shall be repeated and then reported to the ordering physician or the person responsible for that patient. ..." Review of 2017, 2018, and 2019 API proficiency testing records revealed the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested. Examples: 1. 2017 3rd event hematology - sample HEM-13 had a critical value for WBC (white blood cell count), and sample HEM-15 had critical values for WBC and hemoglobin. There was no documentation that the samples were retested to confirm the critical values. 2. 2018 1st event hematology - sample HEM-01 had critical values for WBC and hemoglobin, and samples HEM-03 and HEM-04 had critical values for WBC. There was no documentation that the samples were retested to confirm the critical values. 3. 2018 2nd event hematology - sample HEM-06 had a critical value for WBC, and sample HEM-08 had critical values for WBC and hemoglobin. There was no documentation that the samples were</p>

retested to confirm the critical values. 4. 2018 3rd event hematology - samples HEM-11 and HEM-13 had critical values for WBC, and sample HEM-15 had critical values for WBC and hemoglobin. There was no documentation that the samples were retested to confirm the critical values. 5. 2019 1st event hematology - sample HEM-02 had critical values for WBC and hemoglobin. There was no documentation that the sample was retested to confirm the critical values. 6. 2019 2nd event hematology - sample HEM-10 had critical values for WBC and hemoglobin. There was no documentation that the sample was retested to confirm the critical values. During interview at approximately 10:30 a.m., TP #1 stated that patient specimens with panic values are retested to confirm, so proficiency samples should be treated the same way.

D2009

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on review of 2017, 2018, and 2019 API (American Proficiency Institute) proficiency testing records and interview with TP (testing personnel) 11/15/19, the laboratory failed to ensure TP signed the attestation statements to indicate who tested each sample. Review of 2017, 2018, and 2019 API proficiency testing records revealed attestation statements for the 2017 3rd, the 2018 1st, 2nd, and 3rd, and the 2019 1st hematology test events did not indicate which TP tested the vaginal wet prep, KOH (potassium hydroxide) prep, and urine sediment samples. During interview at approximately 10:40 a.m., TP #1 stated she is the only TP who performs those tests. She confirmed she performed the testing but did not sign the attestation statements.

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 11/15/19 and the deficiency cited at D6065, the laboratory failed to verify that 1 of 15 testing personnel (TP #6) 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 11/15/19 and interview with the TC (technical consultant) 11/15/19, the laboratory failed to verify that 1 of 15 testing personnel (TP #6) met the minimum education requirements for performing moderate complexity testing. Review of personnel records for TP #6 revealed there were no education credentials available for review. During interview at approximately 3:30 p.m., the TC stated TP #6 was asked to bring in her education credentials prior to the survey but had not brought them in yet.