

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0993008	<b>(X3) Date Survey Completed</b>  01/21/2020
<b>Name of Provider or Supplier</b>  North Whiteville Urgent Care	<b>Street Address, City, State</b>  614 North J K Powell Blvd, Whiteville, 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>
<b>D6004</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the laboratory manager 1/21/2020, the laboratory director failed to ensure technical consultant (TC) duties were performed by personnel meeting the qualification requirements for a TC and failed to ensure that all duties were properly performed. Findings: The laboratory's "LABORATORY DIRECTOR /DELEGATION OF DUTIES" states "The laboratory director is responsible for the overall operation of the laboratory and the competency of all laboratory personnel. To assist in his duties, several of the responsibilities of the laboratory director may be delegated to the laboratory manager... The lab manager will assist in the training and assessments of laboratory personnel. The lab manager will do periodic quality assurance reviews of personnel records to ensure that all training and assessments of personnel and documentation is current." Review of personnel records revealed: 1. The laboratory manager did not have documentation available that she meets the requirements to serve as TC. 2. Competency evaluations for Testing personnel (TP) were performed by the Office manager and TP #1. The Office manager performed the competency evaluation for TP#1 in April 2019, and the 6-month competency</p>

evaluation for TP# 4 in December 2018. TP#1 performed the competency evaluations for TP#2, TP#3, and TP#4 in April 2019. 3. TP#1 has a high school diploma and does not meet the requirements to serve as a TC. The office manager did not have documentation available that she meets the requirements to serve as a TC. 4. 6-month competency evaluation was not performed or documented for TP#3. See D6053. 5. Annual competency evaluations in 2018 were not performed or documented for TP#1, TP#2, and TP#3. See D6054 At approximately 11:25am, the laboratory manager confirmed the office manager and TP#1 performed competency evaluations for the TP.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 personnel records and interview with the Laboratory manager 1/21/2020, the TC failed to perform and document competency evaluation for 1 of 4 TP (TP#3) at least semiannually during the first year. Findings: Review of personnel records revealed TP#3 was trained on the Cell Dyn 1700 hematology analyzer in April 2017. There was no semiannual( six month) competency completed for TP#3 during her first year of testing patient specimens. During interview at approximately 11:25am, the Laboratory manager stated the laboratory was not performing testing between July 2017 and February 2018. She confirmed a semiannual competency evaluation was not performed for TP#3 when testing resumed.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of the personnel records and interview with the Laboratory manager 1/21/2020, the TC failed to perform and document annual competency evaluations for 3 of 4 TP. Findings: Review of personnel records revealed there was no annual competency evaluations completed for TP#1, TP#2, and TP#3 in 2018. During interview at approximately 1 pm, the Laboratory manager confirmed the 2018 competency evaluations were not performed if not on file in the personnel records.