

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0238795	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Caswell Family Medical Center	Street Address, City, State 439 Us Highway 158 West, Yanceyville, 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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of personnel records, and interview with TP (testing personnel) 2/16/23, the laboratory director failed to ensure that specific policies and procedures were established for evaluating the competency of all testing personnel as required. Findings: Review of the "Laboratory Quality Assurance and Quality Control Process" policy revealed "... Competency is reviewed at the time an employee is hired, at six months and annually thereafter. ..." The policy did not describe how the competency evaluations are conducted, including who is responsible, the criteria for acceptability, and the steps to take if competency requirements are not met. Review of personnel records revealed TP #1 had performed the competency evaluations for TP #2 and TP #3 during 2021 and 2022. TP #1's 2020 competency was performed by TP #2, and her 2021 competency was performed by a former TP. During interview at approximately 10:30 a.m., TP #1 confirmed that she had performed the competency evaluations for TP #2 and TP #3. She verified that her 2020 was performed by TP #2 and her 2021 competency was performed by a former TP. She stated the laboratory director had</p>

reviewed and signed off on them, but they did not realize the competency evaluations had to be performed by the laboratory director or technical consultant.

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 personnel records and interview with TP (testing personnel) 2/16/23, the technical consultant (laboratory director) failed to perform and document a competency evaluation for 1 of 3 TP (TP #2) during 2020. Review of personnel records for TP #2 revealed competency evaluations performed in 2019, 2021, and 2022. There were no records available for a 2020 competency evaluation. During interview at approximately 10:20 a.m., TP #1 stated they were unable to locate TP #2's 2020 competency evaluation. TP #1 stated she was unsure whether TP #2 had a competency evaluation in 2020.