

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0672443	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Henderson County Department Of Public Health	Street Address, City, State 1200 Spartanburg Highway, Suite 100, Hendersonville, 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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 personnel records and interview with TP (testing personnel) #1 on 8/13/24, the laboratory director failed to ensure that testing personnel competency evaluations for 3 of 5 testing personnel (TP #3, TP #4, TP #5) were performed by personnel who met the qualification requirements to serve as technical consultant in a moderate complexity laboratory. Findings: 1. Review of personnel records for TP #3 revealed: a. Competency evaluations performed in June 2022 and May 2023 were performed by TP #2. b. The competency evaluation performed in June 2024 was performed by TP #1. 2. Review of personnel records for TP #4 revealed: a. The competency evaluation performed in May 2023 was performed by TP #2 . b. The competency evaluation performed in June 2024 was performed by TP #1. 3. Review of personnel records for TP #5 revealed: a. The competency evaluation performed in December 2023 was performed by TP #2. b. The competency evaluation performed in June 2024 was performed by TP #1. 4. Review of personnel records for TP #1 revealed TP #1 has a high school diploma and does not meet the qualification requirements to serve as technical consultant in a moderate complexity laboratory. 5.</p>

Review of personnel records for TP #2 revealed TP #2 has an associate degree in medical laboratory technology and does not meet the qualification requirements to serve as technical consultant in a moderate complexity laboratory. During interview at approximately 12:20 p.m., TP #1 confirmed that she and TP #2 had performed competency evaluations for the providers (TP #3, TP #4, and TP #5).

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with TP #1 on 8/13/24, the laboratory director failed to ensure that prior to testing patient specimens, 1 of 2 testing personnel (TP #2) had received appropriate training and could perform all testing operations reliably to report accurate patient hematology test results. Findings: Review of personnel records for TP #2 revealed there were no training records for the new Sysmex XN-430 hematology analyzer installed in December 2023. During interview at approximately 12:35 p.m., TP #1 confirmed that there were no training records for TP #2 for the new hematology analyzer. TP #1 stated she was the only one available for training when the instrument was installed.