

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0670854	(X3) Date Survey Completed 12/10/2021
Name of Provider or Supplier Stephen F Austin State University	Street Address, City, State 2106 Raguet Street, Nacogdoches, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the laboratory's verification studies performed on the Abbott CD Ruby hematology analyzer, review of the CMS Form 116 and staff interview it was determined the laboratory director failed to ensure 2 (accuracy and precision) of 4 verification studies' components were evaluated. Findings included: 1. Surveyor observations on 12/10/2021 at 0910 hours in the laboratory revealed the laboratory used the Abbott CD Ruby instrument(serial number 71313BG) for hematology analysis. 2. Review of the laboratory's verification studies for the Abbott CD Ruby hematology analyzer (performed in February of 2020) revealed there was no documentation of evaluation of the data for accuracy and precision. 3. Review of the CMS Form 116 submitted at the time of the survey and signed by the laboratory director on 12/06/2021 revealed the laboratory performed</p>

approximately 1600 hematology tests annually. 4. In an interview on 12/10/2021 at 1210 hours in the laboratory the Laboratory Director, after review of the data, stated that she was not aware that the studies were missing the above components. This confirmed the findings.