

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1071328	(X3) Date Survey Completed 07/18/2018
Name of Provider or Supplier Start Community Clinic	Street Address, City, State 5975 Federal Highway 80, Rayville, LA	
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	A CERTIFICATION SURVEY was performed at Start Community Clinic - CLIA # 19D1071328 on July 18, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Horiba Medical ABX Micros 60 Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 18, 2018 revealed the laboratory utilizes the Horiba Medical ABX Micros 60 Hematology analyzer for Complete Blood Count (CBC) testing. 2. In interview on July 18, 2018 at 9:40 am, Personnel 2 stated the Horiba Medical ABX Micros 60 Hematology analyzer was installed by the service representative in December 2017 and the laboratory started patient testing in January 2018. 3. Review of the laboratory's performance verification studies revealed the laboratory did perform accuracy, precision, reportable range and reference range studies; However, the studies were not reviewed and signed off by the Laboratory Director. 4. In interview on July 18, 2018 at 10:24 am, Personnel 3 (Technical Consultant) stated she reviewed the performance studies but she did not have the Laboratory Director sign off on the studies.</p>

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.