Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0132652	05/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of College of American Proficiency (CAP) Proficiency Test (PT) reports and an interview with the laboratory testing person, the laboratory did not evaluate, perform and document remedial action for the PT score that was less than 100% for the 2nd event in 2017 for hematocrit testing. Findings Include: It was confirmed with the laboratory medical assistant processor on the date of survey at approximately 11:15 am, that the laboratory failed to evaluate the results received for: 2017 second event Hematocrit = 80%
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on a review of calibration records and an interview with the laboratory testing person, the laboratory failed to calibrate the Horiba ABX Micros hematology analyzer every six months. Findings Include: 1) It was confirmed with the testing person at approximately 11:00 am on May 15, 2018 that the laboratory failed to follow the manufacturers and/or CLIA regulations to calibrate the ABX Micros every six months. 2) Calibration was performed on May 24, 2017 and then on January 3, 2018. 3) The Horiba ABX Micros was out of calibration from November 24, 2017 through January 2, 2018. 4) Approximately 38 patient specimens were tested and results released during that time.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, QC records and confirmed in an interview with the laboratory director and testing person at the time of the survey, the laboratory director failed to ensure that the QC program was maintained for hematology testing. Refer to: D5437