Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1027412	12/13/2018
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
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 surveyor's review of hematology calibration records and an interview with the laboratory supervisor/testing person, the laboratory failed to calibrate the ABX Horiba Micros 60 hematology analyzer at the six month intervals as required by the manufacturer. FINDINGS: The laboratory supervisor/testing person confirmed on December 12, 2018 at approximately 1:30 PM, the surveyor's findings that the analyzer was calibrated on September 19, 2017 and again on July 12, 2018 therefore, the analyzer was out of calibration for 4 month period. Approximately 240 patient specimens were tested and reported for hematology during the above time frames when the analyzer was out of calibration.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's calibration verification records and an interview with the laboratory supervisor/testing person, the laboratory failed to perform calibration verification at least once every six months for all analytes on the Roche Cobas e 411 endocrinology analyzer and the Roche Cobas 400 plus chemistry analyzer. FINDINGS: The laboratory supervisor/testing person confirmed on December 12, 2018 at approximately 10:30 AM, the surveyor's findings that the laboratory did perform a calibration verification for both instruments on November 18, 2017 and again on October 18, 2018. Therefore, the analyzers were out of calibration for 5 months. Approximately 300 patient samples were tested and reported during this time-period for both analyzers. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEYS CONDUCTED ON JANUARY 12, 2017 and JANUARY 7, 2015.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on surveyor's review of the Cytology procedure manual,workload form and an interview the pathologist/laboratory director, the pathologist failed to record the number of hours spent examining the cytology slides for the 2017 and 2018 calendar years. FINDINGS: 1. The pathologist/laboratory director confirmed on December 11, 2018 at approximately 11:30 AM, the surveyor's findings that the workload forms used to evaluate the workload limits in a 24 hour period did not contain the number of hours spent examining the cytology slides for the 2017 and 2018 calendar years. 2. The workload form did contain the number of QC and cytology slides that were examined but not the hours spent. Therefore, the surveyor could not verify the

	maximum number slides examined in a specific timeframe for a workload limit of 100 slides per 24 hours.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory records and findings and an interview with the pathologist/laboratory director, the laboratory director failed to fulfill his responsibilities and provide overall management of the laboratory including failure to maintain the Plan of Correction from the January 12, 2017 survey. Refer to D6094.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory QA records,cytology QA policies /procedures and an interview with the pathologist/laboratory director and laboratory supervisor/testing person, the laboratory director failed to follow the established QA policies to identify failures in quality laboratory services. FINDINGS: The laboratory director failed to identify failures as follows: a. calibration of the hematology analyzer D5437 b. calibration verification of both the endocrinology analyzer and the chemistry analyzer D5439 c. failed to record the number of hours spent examining the cytology slides D5645.