Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D2169538	**(X3) Date Survey Completed** 01/06/2020
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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**
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's review of the hematology quality Control (QC) records and an interview with the laboratory technical consultant, the laboratory failed to discontinue the use of expired hematology quality control materials. FINDINGS: 1. On January 6, 2020 at approximately 11:00 AM, the technical consultant confirmed surveyor's findings that the laboratory used 3 levels of expired QC for hematology testing. Lot numbers: 068300, 078300 and 088300 expired 12/16/19 for Quality controls low, normal and high respectively from 12/17/19 through 12/18/19. 3. Approximately 40 patients were tested for hematology using the expired quality control materials during the above time frames.
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 review of the calibration records and interview with the technical consultant, the laboratory failed to perform and document calibration on the DXI 600 analyzer at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzers. FINDINGS: 1. The technical consultant confirmed on 1 /6/2020 at approximately 11:30 AM the surveyor's review of calibration records finding that the laboratory failed to perform calibration on the DXI 600 analyzer for the endocrinology analytes from October 21, 2019 through the survey date. 2. Approximately 200 patient samples were tested and reported for endocrinology during the above time frame.
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 lack of calibration verification records and an interview with the technical consultant, the laboratory failed to perform calibration verification at least once every six months for chemistry and immunology testing on the AU 480 analyzer from May 8, 2019 up to survey date. FINDINGS: 1. At approximately 11:30 AM on January 6, 2020, the technical consultant confirmed that the laboratory had not performed calibration verification on the AU 480 analyzer for all the chemistry and immunology analytes after the initial calibration verification on November 7, 2018. The AU 480 analyzer was therefore out of calibration verification from May 8, 2019 through the date of this survey. Calibration Verification is required because the chemistry and immunology analytes on the AU 480 analyzer have less than three point calibrators. 2. Approximately 1500 patients were tested during this time period.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology quality control (QC) records and an interview with the technical consultant, the laboratory failed to ensure that hematology QC test results were within acceptable range prior to testing patient specimens. Findings Include: 1) Based on review of QC records and confirmed by the technical consultant on January 6, 2020 at approximately 11:30 AM, three out of three hematology control materials were out of acceptable range for multiple analytes from 10/9/19 through 12/18/19 and remediation was not performed. 2) Approximately 100 patient specimens were tested and results reported for hematology testing during this time period.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the laboratory director, the laboratory director failed to provide overall management of the laboratory. Findings: The laboratory director failed to ensure that the laboratory maintained the laboratory's QC and calibration program for chemistry, endocrinology, immunology and hematology. Refer to D6020.
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 a surveyor's review of QC and calibration records and confirmed in an interview with the technical consultant at the time of this survey, the laboratory director failed to ensure that the QC and calibration program for chemistry, endocrinology, immunology, and hematology testing was maintained to assure the quality of laboratory services. Refer to: D5417, D5437, D5439, D5481