Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2141778	10/08/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records and confirmed in an interview with the laboratory director, the laboratory failed to enroll in an approved PT program for the following analyte in the calendar year 2018. FINDINGS: The laboratory director confirmed on October 8, 2019 at approximately 11:00 AM that the laboratory initiated patient testing for IgE testing in January 2018 but did not enroll in a PT program in calendar year 2018 and the first event of 2019.
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 the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the laboratory director, the laboratory

	failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2019 first event: Parathyroid Hormone (PTH) = 0% Vitamin B12 = 33%
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a lack laboratory's proficiency testing (PT) records or twice year verification records and confirmed in an interview with the laboratory director, the laboratory failed to evaluate and verify the accuracy of the of Sex Hormone-Binding Globulin (SHBG) analyte from January 2018 when testing was initiated to the date of this survey, and failed to enroll in PT or evaluate and verify the accuracy of the of respiratory panel initiated on April 4, 2019. Findings: At approximately 11:30 AM on October 8, 2019 the laboratory director confirmed that the laboratory failed to perform PT or twice year verification for SHBG for the year 2018 and up the date of this survey, and failed to perform PT or twice year verification for respiratory panel from April 4, 2019 when testing was initiated to the date of this survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory's equipment maintenance records, laboratory's maintenance policy and an interview with the laboratory director, the laboratory failed to follow the manufacturer's and the laboratory's maintenance policy to calibrate the pipettes annually. Findings: On October 8, 2019 at approximately 11: 30 AM the laboratory director confirmed surveyor's finding that the laboratory failed to follow the manufacturer's and the laboratory's maintenance policy to calibrate the two pipettes (2-20 and 200-1000) used for reagent preparation and specimen sampling in calendar year 2018 and up to survey date.
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 laboratory director, the laboratory failed to perform calibration verification at least once every six months for chemistry and immunology testing on the AU 480 analyzer from July 2018 up to survey date. FINDINGS: 1. At approximately 11:30 AM on October 8, 2019, the laboratory director 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 in January 2018. The AU 480 analyzer was therefore out of calibration verification from July 2018 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 1200 patients were tested during this time period.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's review of Quality Control (QC) records and interview with the laboratory director, the laboratory failed to program the manufacturer expected ranges, as defined on the QC assay sheets, into the Access 2 analyzer and into the AU 480 analyzer from January 2018, when testing was initiated, through the date of this survey. FINDINGS: 1. On October 8, 2019 at approximately 11:00 AM the laboratory director confirmed the surveyor's review of QC records finding that the laboratory failed to program the established QC ranges and expected means into the Access 2 analyzer for endocrinology tests and failed to program the established QC ranges and expected means into the AU 480 analyzer for chemistry and immunology tests performed. 2. Without the established QC limits and without the QC assay sheets the

	surveyor could not determine if the quality control results were within the acceptable ranges for the chemistry, immunology and endocrinology analytes tested. 3. Approximately 2500 patients' specimens were tested and reported for chemistry immunology and endocrinology during this time period. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON JUNE 7, 2018.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of respiratory panel Quality Control (QC) records and an interview with the laboratory director, the laboratory failed to check each run of the respiratory panel for positive and negative reactivity from May 2019 through September 2019. FINDINGS: 1. The laboratory initiated the respiratory panel on the Bio Fire analyzer on April 4, 2019. 2. On October 8, 2019 at approximately 11:30 AM, the laboratory director confirmed the surveyor's findings that the laboratory failed to have documentation of the required positive and negative quality controls for each run from May 2019 through September 2019 3. Approximately 40 patients specimens were tested and reported for respiratory panel 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. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on June 7, 2018; 2. Maintained the laboratory's QC program for chemistry, endocrinology, immunology and bacteriology. Refer to D6020; and, 3. Maintained the laboratory's established QA program for all phases of laboratory testing. Refer to D6021. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON JUNE 7, 2018.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of laboratory records and an interview with the laboratory director, the laboratory failed to enroll in Proficiency Testing (PT) for IgE in calendar year 2018 for the first event 2019. FINDINGS: The laboratory director confirmed on October 8, 2019 at approximately 11:00 AM that the laboratory initiated patient testing for IgE testing in January 2018 but did not enroll in a PT program in calendar year 2018 and the first event of 2019.
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 records and confirmed in an interview with the laboratory director at the time of this survey, the laboratory director failed to ensure that the QC program for chemistry, endocrinology, immunology, bacteriology and virology testing was maintained to assure the quality of laboratory services. Refer to: D5217, D5439, D5469, D5471 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON JUNE 7, 2018.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory Quality Assessment (QA) policy, and interview with the laboratory director, the laboratory director failed to follow their QA procedure for having an effective and on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for chemistry, endocrinology, immunology and bacteriology. Refer to D5211, D5429, D5439 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON JUNE 7, 2018.