

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2141778	(X3) Date Survey Completed 06/07/2018
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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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>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 immunology testing in the calendar year 2018. FINDINGS: The laboratory director confirmed on June 7, 2018 at approximately 11:30 AM that the laboratory initiated patient testing for immunology testing in January 2018 but did not enroll in a PT program.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory policies and procedures and confirmed</p>

in an interview with the laboratory director at the time of the survey, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components to assess testing personnel's competency at least annually, after the first year.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on surveyor review of the laboratory's procedure manual and interview with the technical supervisor and the general supervisor the laboratory failed to establish a comprehensive policy/procedure manual to include: 1) Procedure for transportation of patients' specimens from the physician office in Farmingdale to the laboratory in Bethpage for testing; 2) Procedure describing laboratory's calibration verification for analytes with less than 3 point calibrators; 3) Procedure for calibration of the pipettes.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:
Based on a surveyor's review of the validation records and an interview with the laboratory director, the laboratory failed to perform and document a complete method validation for Beckman Coulter AU 480 and Access 2 analyzers prior to initiating patient testing in January 2018. Findings: 1. On June 7, 2018 at approximately 11:30

AM the laboratory director confirmed that although there were records indicating that correlation study was performed for the chemistry analytes on Beckman Coulter AU480 analyzer at the time of installation, there was no criteria established for evaluating the acceptance/rejection of the values. 2. The laboratory director confirmed that Correlation study was not performed for the immunology analytes as part of a complete validation of the Beckman Coulter AU480 analyzer prior to patient testing in January 2018. 3. The laboratory director confirmed that Correlation study was not performed for the analytes performed on the Access 2 analyzer as part of a complete validation of the Access 2 analyzer prior to patient testing in January 2018. 4. Approximately 1000 patient specimens were tested and reported for chemistry and approximately 500 patients were tested and reported for endocrinology and immunology when the above analyzers was used for patient testing from January 2018 when testing was initiated up to the survey date.

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 from January 2018, when testing was initiated, through the date of this survey. FINDINGS: 1. On June 7, 2018 at approximately 11:30 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 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 endocrinology analytes tested. 3. Approximately 500 patients' specimens were tested and reported for endocrinology 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.

	<p>This STANDARD is not met as evidenced by: Based on a surveyor's review of chemistry and immunology quality control (QC) records and an interview with the laboratory director, the laboratory failed to ensure that chemistry and immunology QC test results were within acceptable range prior to testing patient specimens. Findings Include: Review of QC records found and it was confirmed with the laboratory director on June 7, 2018 at approximately 11:30 AM during review of QC data that the following levels of control material were out of acceptable range and remediation was not performed: 1. On February 28, 2018, May 18, 21, 22, 23, 2018, June 5, 6, 2018, one out of two controls was out of range for IgA, total protein, triglyceride and Blood Urea Nitrogen (BUN). 2. On March 2, 2018, February 27, 2018, May 25, 29, 30, 31, 2018, June 4, 2018 two out of two controls were out of range for BUN, phosphorus, IgA, total protein and HgbA1C.</p>
<p>D5783</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the chemistry and immunology QC records and an interview with the laboratory director, the laboratory failed to perform and document corrective action when QC results were out of acceptable range and failed to evaluate all patient test results obtained for each unacceptable test run through the last acceptable test run to determine if patient test results were adversely affected. Refer to: D5481</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of laboratory records and interview with the laboratory director, the laboratory director failed to provide overall management and direction for the laboratory and ensure that: 1. The laboratory successfully participate in PT. Refer to D6016; 2. The laboratory maintained the laboratory's QC program for chemistry, endocrinology and immunology. Refer to D6020; 3. The laboratory maintained the laboratory's established QA program for all phases of laboratory testing. Refer to D6021.</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p>

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 chemistry, endocrinology and immunology for the first event 2018. FINDINGS: The laboratory director confirmed on June 7, 2018 at approximately 11:30 AM that the laboratory initiated chemistry, endocrinology and immunology testing in January 2018 but did not enroll in a PT program for the first event of 2018.

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 and immunology testing was maintained to assure the quality of laboratory services. Refer to: D5421, D5469, D5481, D5783

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 surveyor review of the quality assessment (QA) program and confirmed in an interview with the laboratory director at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5209, D5403, D5421