

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310135	(X3) Date Survey Completed 07/31/2018
Name of Provider or Supplier Chattanooga Diagnostic Associates Llc	Street Address, City, State 2205 Mc Callie Avenue, Chattanooga, TN	
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
D0000	<p>493.51 Notification requirements for laboratories issued a certificate of compliance (Rev.140, Issued: 5/29/15, Effective: 5/29/15, Implementation: 5/29/15) (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. Based on review of testing menu during on-site survey 7/31/18 and interview with Practice Manager, determined the laboratory had failed to notify HHS within 6 months of deletion of 5 of 7 specialties in November of 2017 as issued under their Certificate of Compliance. The findings include: 1. Review of test menu during on-site survey 7/31/18 disclosed deletion of Mycology, Parasitology, Urinalysis, Endocrinology and Hematology testing as of November 2017. 2. The laboratory failed to notify HHS within a 6 month period upon deletion of 5 specialties in November of 2017. 3. Interview at approximately 4:30 p.m. July 31, 2018 with the Practice Manager confirmed the laboratory had failed to notify HHS of deletion of 5 of 7 specialties in November of 2017 as issued under their Certificate of Compliance.</p> <p>=====</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p> <p>===== Based on review of 2017 and 2018 Proficiency Testing (PT) attestation sheets and interview with the 2 blood gas testing personnel, determined the PT samples were not tested by all 4 of 4 testing personnel and 3 attestation sheets were not signed by director. The findings include: 1. Review of the 2017 and 2018 PT attestation sheets revealed only 1 of 4 testing personnel</p>

attested to performing all events of proficiency testing. 2. Review of 2017 and 2018 PT attestation sheets revealed 3 of 8 (AQ-A2018, AQ-B and SO-B 2017) attestation sheets were not signed by director. 2. Interview with the 2 blood gas testing personnel at approximately 4:00 p.m. July 31, 2018 confirmed only 1 of 4 testing personnel had performed PT testing for all events in 2017 and 2018 and 3 of 8 attestation sheets were not signed by director. =====

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 review of the blood gas laboratory procedure manual which lacked pertinent procedures and interview with the 2 blood gas testing personnel, determined the procedure manual was substantially lacking in written procedures for testing and reporting of blood gas analytes. The findings include: 1. Review of the blood gas procedure manual revealed lack of procedures for: a. Specimen collection, processing and specimen rejection; b. Normal patient ranges and critical values; c. Reporting patient results and critical value reporting; d. Remedial action to be taken when controls or calibration values out of range; e. Course of action to be taken if test system becomes inoperable. 2. Interview with the 2 blood gas testing personnel at approximately 4:00 p.m. July 31, 2018 confirmed that procedure manual was lacking in written procedures as required for 2018. =====

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
===== Based on lack of director review for the Blood Gas Laboratory procedure manual and interview with the 2 blood gas

testing personnel, determined the laboratory director failed to sign and date the current procedure manual. The findings include: 1. Lack of director review for the Blood Gas Laboratory Procedure manual upon survey date of 7/31/18. 2. Interview at approximately 4:00 p.m. July 31, 2018 with the 2 blood gas testing personnel confirmed the procedure manual lacked documentation of review by laboratory director. =====

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

===== Based on observation of reagent refrigerator thermometer, lack of re-verification documentation and interview with the 2 blood gas testing personnel, the laboratory failed to re-verify the thermometer since 2016. The findings include: 1. Observation of reagent refrigerator thermometer with expired certification. 2. Lack of verification documentation since 2016. 3. Interview with the 2 blood gas personnel at approximately 4:00 p.m. July 31, 2018 confirmed the reagent refrigerator thermometer's certification had expired and had not been re-verified since 2016. =====

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 review of Blood Gas Analyzer calibration verification records for 2017 and 2018, lack of calibration verification every 6 months and interview with the 2 blood gas testing personnel, determined the laboratory failed to perform calibration verification at least every 6 months for the 2 year period. The findings include: 1. Review of the Blood Gas Analyzer calibration verifications for 2017 and 2018 revealed one performed 8/11/17. 2. Lack of calibration verification documentation at 6 month intervals between February 2017 and February 2018. 3. Interview with the 2 blood gas testing personnel at approximately 4:00 p.m. July 31, 2018 confirmed calibration verifications were not performed every 6 months between 2017 and 2018.
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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 lack of a written Quality Assessment (QA) plan and interview with the 2 blood gas testing personnel, determined the laboratory director failed to ensure a Quality Assessment plan was established and maintained for monitoring pre-analytic, analytic and post-analytic laboratory functions for 2017 and 2018. The findings include: 1. Lack of a written QA plan for monitoring pre-analytic, analytic and post-analytic laboratory functions. 2. Interview at approximately 4:00 p.m. July 31, 2018 with the 2 blood gas testing personnel confirmed there was no written Quality Assessment plan for 2017 and 2018. =====

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 ===== Based on review of annual competencies for 4 of 4 blood gas testing personnel, lack of competency for testing personnel number 3 of 4 since 2016, lack of Technical Consultant review for all competencies and interview with the 2 blood gas testing personnel, determined the Technical Consultant failed to evaluate the competencies of all testing personnel for 2016 and 2017. The findings include: 1. Review of annual competencies for 4 of 4 blood gas testing personnel revealed testing personnel 1 and 2 performed competencies on each other and on testing personnel number 4. 2. Lack of competency documentation since 2016 for testing personnel number 3 of 4. 3. Lack of

Technical Consultant review for all testing personnel competencies since 2016. 4. Interview at approximately 4:00 p.m. July 31, 2018 with the 2 blood gas testing personnel confirmed that annual competencies for 1, 2 and 4 testing personnel were performed by testing personnel 1 and 2 and competencies were not available for testing persone number 3 since 2016. =====