

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0301526	(X3) Date Survey Completed 11/05/2020
Name of Provider or Supplier R Joe Teague Md	Street Address, City, State 1 Independence, Suite 315, Birmingham, AL	
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 a review of the test menu, a review of the 2018 - 2019 proficiency testing and quality assurance records, a lack of documentation of enrollment for 2019 - third event of 2020, a review of the policy and procedure for Proficiency Testing (PT), and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the laboratory failed to enroll in PT for Chemistry (Routine and Endocrinology). This affected 2019 and most of 2020. The findings include: 1. During the tour of the laboratory on 11/05/2020 at 9:45 AM, TP #1 stated the laboratory uses the Immulite 1000 and the Ace Alera to perform Chemistry testing. At this time, TP #1 stated the laboratory had not enrolled in proficiency testing in 2019, due to the loss of an employee, who had been responsible for all laboratory processes. 2. A review of the proficiency testing records revealed the laboratory was enrolled with Medical Laboratory Evaluation (MLE) PT provider in 2018; but had no documentation of enrollment for 2019. The laboratory did not timely enroll in PT to receive the usual testing events, until Event # 2020. The laboratory analyzed specimens for remedial events 68 R and 69 R in 2020 and self-evaluated the results. 3. In a quality assurance note, the laboratory documented an eighteen months lapse in PT enrollment. 4. The laboratory's PT policy and procedure indicated the following: "...GENERAL</p>

COMPLIANCE *Enroll in PT for every regulated analyte performed in-house..." 5. On 11/5/2020 at 4:15 PM, the surveyor discussed the concerns of the survey with TP #1 and the TC, who joined via telephone. The TC and TP #1 expressed understanding of the CLIA requirement to maintain PT enrollment for all testing the laboratory seeks recertification.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, a lack of documentation, a review of the PT policy and procedure, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the surveyor determined the laboratory failed to self-evaluate results of the Thyroglobulin, which was not graded by API for Chemistry Event #3, 2020. This affected one of five testing events reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed API did not grade the Thyroglobulin results (specimens TM 11 and 12) for Event #3, 2020. The laboratory failed to self-evaluate the results, when they were returned by API without a grade /score. 2. A review of the PT policy and procedure revealed the following: "... ASSESSMENT OF THE PROFICIENCY TESTING REPORT *Evaluate all ungraded responses and perform a self-evaluation to verify the accuracy of analytes that are not graded or that are scored 100 % due to non-consensus or lack of peer group..." 3. In an interview on 11/05/2020 at 4:15 PM, the surveyor discussed the lack of documentation of a self-evaluation, with TP #1 and the TC (via the telephone). The TC stated it was an oversight.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the proficiency testing records, a lack of documentation of corrective actions, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the surveyor determined the laboratory failed to implement and document corrective actions for a PTH (Parathyroid Hormone) score of 50 % (fifty percent) for Chemistry Event #3, 2018. This affected one of five testing events reviewed by the surveyor. The findings include: 1. A review of the MLE (Medical Laboratory Evaluation) proficiency testing records revealed the laboratory was enrolled and participated in PTH testing (PTH is a non-regulated analyte, which requires accuracy verification at least twice/annually) in 2018. The laboratory scored 50 % for the PTH for Chemistry MLE M3. The laboratory did not implement and document corrective actions for this failing score. 2. The laboratory documented the loss of the laboratory technologist responsible for the laboratory and the possibility some of the documents were left at her home. 3. During an interview on 11/05/2020 at 4:15 PM, TP #1 and the TC confirmed the above noted findings.

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 a review of the calibration verification records for the Immulite 1000 and Ace Alera Chemistry analyzers, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the laboratory failed to perform the calibration verifications at least every six months, as required for all Chemistry analytes routinely calibrated with less than three standards. This affected 2019, one of three years of calibration data reviewed by the surveyor. The findings include: 1. A review of the calibration records for the Immulite 1000 revealed the verifications were performed on 4/13/2018, 3/27/2020, exceeding a six month timeframe, and 9/19/2020. The laboratory failed to perform calibration verifications in 2019. 2. A review of the calibration records for the Ace Alera revealed the verifications were performed on 4/10/2018, 3/29/2020, exceeding a six month timeframe, 5/08/2020 and 9/19/2020. The laboratory failed to perform calibration verifications in 2019. 3. During an interview on 11/05/2020 at 4:15 PM, the surveyor discussed with the TC (on the telephone) and TP #1, the CLIA requirement to perform calibration verifications on Chemistry analytes routinely calibrated using less than three standards. TP #1 and the TC confirmed the verifications had not been done in 2019, due to the loss of an employee, who had been responsible for all laboratory processes.

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 a review of the test menu, a review of the 2018 - 2019 proficiency testing

and quality assurance records, a review of the job descriptions, a lack of documentation of enrollment for 2019 - third event of 2020, a review of calibration verification records, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the Laboratory Director failed to ensure the laboratory enrolled in Proficiency Testing (PT) for Chemistry (Routine and Endocrinology). This affected 2019 and most of 2020. The LD further failed to ensure the testing personnel performed the calibration verifications at least every six months. The findings include: Refer to D6015. Refer to D6023.

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 a review of the test menu, a review of the 2018 - 2019 proficiency testing and quality assurance records, a lack of documentation of enrollment for 2019 - third event of 2020, a review of the job descriptions, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure the laboratory enrolled in Proficiency Testing (PT) for Chemistry (Routine and Endocrinology). This affected 2019 and most of 2020. The findings include: 1. During the tour of the laboratory on 11/05/2020 at 9:45 AM, TP #1 stated the laboratory uses the Immulite 1000 and the Ace Alera to perform Chemistry testing. At this time, TP #1 stated the laboratory had not enrolled in proficiency testing in 2019, due to the loss of an employee, who had been responsible for all laboratory processes. 2. A review of the proficiency testing records revealed the laboratory was enrolled with Medical Laboratory Evaluation (MLE) PT provider in 2018; but had no documentation of enrollment for 2019. The laboratory did not timely enroll in PT to receive the usual testing events, until Event #3, 2020. The laboratory analyzed specimens for remedial events 68 R and 69 R in 2020 and self-evaluated the results. 3. In a quality assurance note, the laboratory documented an eighteen months lapse in PT enrollment. 4. A review of the job description for the LD indicated the following: "GENERAL DUTIES AND RESPONSIBILITIES: 1. Administers and supervises the technical and scientific operation of the clinical laboratory... c. Ensures that the laboratory participates in an approved Proficiency Testing program for all regulated analytes and reviews the performance in this program..." 5. On 11/5/2020 at 4:15 PM, the surveyor discussed the concerns of the survey with TP #1 and the TC, who joined via telephone. The TC and TP #1 expressed understanding of the CLIA requirement to maintain PT enrollment for all testing the laboratory seeks recertification.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on a review of calibration verification records, a review of the job descriptions, and an interview with Testing Personnel (TP) #1 and the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure the testing personnel performed the calibration verifications at least every six months. This affected 2019, one of three years of calibration data reviewed by the surveyor. The findings include: 1. A review of the calibration records for the Immulite 1000 revealed the verifications were performed on 4/13/2018, 3/27/2020, exceeding a six month timeframe, and 9/19/2020. The laboratory failed to perform calibration verifications in 2019. 2. A review of the calibration records for the Ace Alera revealed the verifications were performed on 4/10/2018, 3/29/2020, exceeding a six month timeframe, 5/08/2020 and 9/19/2020. The laboratory failed to perform calibration verifications in 2019. 3. During an interview on 11/05/2020 at 4:15 PM, the surveyor discussed with the TC (on the telephone) and TP #1, the CLIA requirement to perform calibration verifications on Chemistry analytes routinely calibrated using less than three standards. TP #1 and the TC confirmed the verifications had not been done in 2019, due to the loss of an employee, who had been responsible for all laboratory processes. 4. A review of the job description for the LD revealed the following: "GENERAL DUTIES AND RESPONSIBILITIES: 1. Administers and supervises the technical and scientific operation of the clinical laboratory... b. Oversees preventative maintenance and calibration verification programs on all instrumentation..."