

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2016974	(X3) Date Survey Completed 11/27/2019
Name of Provider or Supplier Lamar Family Medicine	Street Address, City, State 45020 Hwy 17, Vernon, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2017 - 2019 API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with the Testing Personnel, the laboratory failed to print survey evaluation results and document reviews for two out of seven surveys, and failed to document investigation and corrective actions for two out of seven surveys with results less than 100 % (percent). The findings include: 1. A review of the Hematology Proficiency Testing records revealed the laboratory failed to print the API evaluations / scores for 2017-Event #3 (performed 11/27/2017) and 2018-Event #3 (performed 11/20/2018). Thus, there was no evidence of review and on-site assessment of the laboratory's performance for these two surveys. 2. A further review of the API PT records revealed the following: A) 2017-Event #2: 80% for Platelets; Granulocyte and Lymphocyte % with scores of 80% each, resulting in a score of 87% for the White Blood Cell (WBC) Differential An "Unsatisfactory Proficiency Investigation Report" was included with the survey, however it was incomplete; the survey event, unsatisfactory scores, or the reason for the results less than 100% were not specified in the report. B) 2019-Event #2: Granulocyte % with a score of 80%, resulting in a score of 93% for the WBC Differential; the Technical Consultant had signed the report, however there was no documentation of investigation or corrective action. 3. In an interview on 11/27/2019 at 11:40 AM, the Testing Personnel reviewed and confirmed the above noted findings, stating she had written the incomplete "Unsatisfactory Proficiency Investigation Report" for 2017-Event #2. She did not know why the Technical Consultant had not implemented corrective actions for the analytes with scores less than 100%. Thus, the above noted findings were confirmed. .</p>

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 reviews of the Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual, calibration records, and an interview with the Testing Personnel (TP), the surveyor determined the laboratory failed to follow the manufacturer's instructions in the performance frequency of calibrations in 2019. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual on page 6-3 revealed the following instructions, "When to Calibrate...At least every six months...". 2. A review of the Hematology records revealed the following: A) 7/30/2018: Documentation of a satisfactory calibration B) 3/19/2019: Documentation of a calibration performed seven and a half months after the previous calibration, and no documentation of a second calibration in 2019. 3. During an interview and review of these records on 11/27/2019 at 10:55 AM, the Testing Personnel confirmed the laboratory had missed performing a second calibration in 2019. The Cell Dyn calibrator was "just ordered", and the laboratory was expecting delivery. The surveyor then reviewed the calibration procedure which required calibration every six months, and asked if the laboratory had performed a calibration in January 2019. The Testing Personnel answered "No", and confirmed the laboratory had not performed the 2019 calibrations every six months as per manufacturer's instructions. .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of laboratory records and an interview with the Testing Personnel, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of the "Corrective Action Log" revealed the laboratory documented problems and the resolutions as their main quality assurance activity, however this was inadequate to discover and correct problems noted in the following areas: A) Failure to print survey evaluation results and document reviews and on-site assessment of the laboratory's performance, and failure to document investigation and corrective actions for surveys with results less than 100

% (percent). (Refer to D5221.) B) Failure to calibrate the Abbott Cell Dyn Emerald Hematology analyzer every six months as per manufacturer's instructions. (Refer to D5437.) 2. During the exit summation on 11/27/2019 at 1:05 PM, these concerns were reviewed and confirmed with the Testing Personnel.. SURVEYOR ID #32558
Licensure and Certification Surveyor