

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2170478	(X3) Date Survey Completed 06/14/2022
Name of Provider or Supplier Quest Diagnostics Health Services	Street Address, City, State 1845 Cherry Street 2nd Floor Lab, Montgomery, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Quality Control (QC) records and an interview with the Laboratory Supervisor, the laboratory failed to retain the manufacturers' assay information sheets for quality control material in 2020 and 2021, two of three years of QC reviewed. The findings include: 1. A review of the QC records revealed the laboratory failed to retain the manufacturer's QC assay sheets in 2020 and 2021. 2. During an interview at 2:42 PM on 6/14/2022, the Laboratory Supervisor confirmed the above noted findings. .</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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</p>

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 and an interview with the Laboratory Supervisor and Testing Personnel #2, the laboratory failed to perform and document calibration verification every six months on analytes calibrated with less than three calibrators, as per CLIA requirements. The laboratory failed to perform one of two calibration verifications due in 2020 on eight out of fourteen assays run on the Beckman Coulter AU-480 Chemistry analyzer. The findings include: 1. A review of the Beckman Coulter AU-480 Chemistry analyzer records revealed no documentation of calibration verification data the first half of 2020 on the following analytes calibrated with less than three calibrators: A. Albumin (Alb) B. Aspartate Aminotransferase (AST) C. Total Bilirubin (TBil) D. Total Protein (TP) E. Sodium (Na) F. Potassium (K) G. Chloride (Cl) H. Glucose (Glu) 2. During an interview with the Laboratory Supervisor and Testing Personnel #2 at 1:00 PM on 6/14/2022, TP #2 confirmed not all 2020 calibration verifications were performed. SURVEYOR ID#32558 Licensure and Certification Surveyor