

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0671555	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Monroe County Hospital	Street Address, City, State 2016 South Alabama Ave, Monroeville, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures, a review of the Beckman Coulter AU 480 Chemistry Calibration Verification records, and an interview with the General Supervisor, the laboratory failed to perform and document calibration verification procedures at least once every six months as specified by CLIA requirements. The surveyor noted the laboratory failed to perform and document two out of two calibration verifications due in 2022 on the Beckman Coulter AU 480 chemistry</p>

analyzer. The findings include: 1. A review of the Policies and Procedures revealed the following under "Linearity/Calibration Verification", "...Linearity is performed every six months". 2. A review of Calibration Verification records revealed a lack of documentation for the Calibration Verification of Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP), Amylase, Aspartate Transferase (AST), Creatinine Kinase (CK), and Lipase in 2022 for the Beckman Coulter AU 480 Chemistry Analyzers SN 2016024821 and SN 2019062712. 3. During an interview on 12/7/2022 at 3:30 PM, the General Supervisor confirmed the above findings.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of patient logs, quality control records and an interview with the General Supervisor, the laboratory failed to ensure two levels of controls were performed each day of patient testing for Cerebrospinal Fluid (CSF) Cell Counts. This was noted for three patients in 2022. The findings include: 1. A review of patient logs revealed the laboratory performed CSF Cell Counts on 2/9/2022, 3/14/2022, 11/4/2022. 2. A review of Hematology records revealed no documentation of Body Fluid Cell Count quality controls run on the aforementioned dates. 3. During an interview of 12/7/2022 at 11:15 AM, the General Supervisor confirmed the above findings.