

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0656546	(X3) Date Survey Completed 10/18/2021
Name of Provider or Supplier Mercy Hospital Logan County, Inc	Street Address, City, State 200 S Academy Road, Guthrie, OK	
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	The recertification survey was performed on 10/18/2021. The findings were reviewed with the laboratory director, technical consultant #2/general supervisor, testing person #2, laboratory support tech, and director of operations during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to ensure reagents had not exceeded their expiration date for 1 of 1 day of testing. Findings include: (1) On 10/18/2021 at 10:20 am, the general supervisor stated to surveyor #2 Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) Surveyor #2 reviewed quality control and patient testing records for testing performed from 08/08/2020 through 10/17/2021 and identified expired Coombs Control material had been used 1 of 1 day of testing reviewed. The quality control and patient testing had been performed on 11/11/2020 using the expired following reagent: (a) ORTHO Coombs Control lot #K685, expiration date 11/10/2020. (3) Surveyor #2 reviewed the records with the general supervisor who stated on 10/18/2021 at 01:25 pm new reagents had been put into place but not documented on the blood bank log,</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of records, written policies and procedures, and interview with the general supervisor, the laboratory failed to demonstrate the performance specifications for 1 of 2 new test methods; and failed to ensure the reportable ranges were utilized for 1 of 2 new test methods. Findings include: **PERFORMANCE SPECIFICATIONS** (1) On 10/18/2021 at 11:30 am, the general supervisor stated to surveyor #1 the laboratory began using the iSTAT 1 analyzer and the Chem 8+ cartridge to perform Sodium, Potassium, Creatinine, Hemoglobin, Hematocrit, Chloride, BUN, Glucose, Ionized Calcium, and Total CO2 testing in March 2020; (2) Surveyor #1 reviewed the performance specification records for the new test system and identified the following: (a) For Sodium, Potassium, Creatinine, Hemoglobin, Hematocrit there was no documentation to prove the laboratory had demonstrated the reportable ranges for each analyte; (b) For Chloride, BUN, Glucose, Ionized Calcium, and Total CO2 there was no documentation to prove the laboratory had demonstrated the accuracy, precision, and reportable ranges for each analyte. (3) Surveyor #1 reviewed the findings with the general supervisor, who stated on 10/18/2021 at 3:00 pm, the laboratory had not demonstrated the performance specifications as stated above. **REPORTABLE RANGES NOT UTILIZED** (1) On 10/18/2021 at 11:30 am, the general supervisor stated to surveyor #1 the laboratory began using the iSTAT 1 analyzer and the EG6+ cartridge to perform Blood Gas (pH, pCO2, pO2) testing in March 2020; (2) Surveyor #1 reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable ranges for pCO2 and pO2: (a) pCO2 - 20.4-94.3 (b) pO2 - 51-434 (3) Surveyor #1 then reviewed the procedure manual titled, "Point of Care Policies & Procedures" to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following manufacturer's reportable ranges: (a) pCO2 - 5-130 (c) pO2 - 5-800 (4) Surveyor #1 reviewed the findings with the general supervisor, who stated on 10/18/2021 at 1:30 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.