

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0471998	(X3) Date Survey Completed 03/10/2023
Name of Provider or Supplier Mercy Hospital Tishomingo, Inc	Street Address, City, State 1000 S Byrd St, Tishomingo, 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 03/08,09,10/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed the laboratory director, hospital administrator, technical consultant #2, technical consultant #4, laboratory manager, testing person #3, and testing person #5 during an exit conference performed at the conclusion of the survey.
D5555	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)</p> <p>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to ensure a policy was in place for regularly inspecting the blood bank temperature alarm system during the review period of June 2021 through the current date. Findings include: (1) On 03/08/2023 at 11:45 am, the laboratory manager stated units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (2) A review of the policy titled, "TISH LABBB Blood Bank Refrigerator Alarm Test Policy" stated, "The Blood Bank refrigerator is used to store blood components, patient samples, and reagents. The alarm system will be checked periodically to confirm the system is working properly and that personnel respond appropriately to the alarm"; (3) Interview with the laboratory manager on 03/08/2023 at 03:35 pm identified the laboratory had not defined "periodically" and did not have defined intervals for performing the alarm checks; (4) A review of alarm check records from June 2021</p>

through the current date identified no consistency in the frequency the alarm checks had been performed. The checks had been performed as follows: (a) 07/16/2021 (b) 11/17/2021 (c) 12/29/2021 (d) 04/01/2022 (e) 04/12/2022 (f) 11/04/2022 (g) 02/24/2023 (4) The records were reviewed with the laboratory manager who stated on 03/08/2023 at 03:47 pm, the laboratory had not defined the frequency alarm checks were to be performed.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Routine Chemistry testing performed using two test methods during the review period of June 2021 through January 2023. Findings include: (1) On 03/08/2023 at 11:10 am, the laboratory manager stated the laboratory performed Sodium, Potassium, Chloride, CO₂, Glucose, BUN, and Creatinine testing using the Roche Cobas c311 analyzer as the primary method and the iSTAT 1 analyzer and Chem 8+ cartridge as the backup method; (2) On 03/09/2023 a review of records from June 2021 through March 2023 identified the relationship between the different test methods had not been evaluated between 09/20/2021 and 03/09/2023; (3) The records were reviewed with the laboratory manager who stated on 03/09/2023 at 01:26 pm, the relationship between the above test methods had not been evaluated at least twice annually during the review period.