

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0471998	<b>(X3) Date Survey Completed</b>  05/19/2021
<b>Name of Provider or Supplier</b>  Mercy Hospital Tishomingo, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 05/17,18,2021. The findings were reviewed with the laboratory director, laboratory manager, and testing person #9 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for verifying morphology flags for four of 67 patient reports. Findings include: (1) On 05 /17/2021 at 11:15 am, the laboratory manager stated that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) The surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Thrombocytopenia - "Verify RBC morphology on slide" (3) The surveyor randomly reviewed 67 patient records which contained morphology flags from CBC testing performed between 04/01/2021 through 04/29/2021. For four of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the four records were: (a) Testing was performed on 04/14/2021 at 06:11 am, with a Thrombocytopenia flag obtained; (b) Testing was performed on 04/15/2021 at 05:31 am, with a Thrombocytopenia flag obtained; (c) Testing was performed on 04/16/2021 at 05:51 am, with a Thrombocytopenia flag obtained; (d) Testing was performed on 04/18/2021 at 06:14</p>

am, with a Thrombocytopenia flag obtained; (4) The surveyor reviewed the records with the laboratory manager, who stated on 05/18/2021 at 12:49 pm that the flags obtained for the above four patients had not been verified as indicated above.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

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 and interview with the laboratory manager, the laboratory failed to demonstrate the reportable ranges 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: **REPORTABLE RANGES NOT DEMONSTRATED** (1) On 05/17/2021 at 11:30 am, the laboratory manager stated to the surveyor 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 on 01/06/2021; (2) The surveyor reviewed the performance specification records for the new test system and identified the following: (a) There was no documentation to prove the laboratory had demonstrated the reportable ranges for each analyte; (3) The surveyor reviewed the findings with the laboratory manager, who stated on 05/17/2021 at 05:10 pm, the laboratory had not demonstrated the reportable ranges as stated above. **REPORTABLE RANGES NOT UTILIZED** (1) On 05/17/2021 at 11:30 am, the laboratory manager stated to the surveyor the laboratory began using the iSTAT 1 analyzer and the EG6+ cartridge to perform Blood Gas (pH, pCO2, pO2) testing on 07/25/2020; (2) The surveyor reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable ranges for pCO2, pO2, and pH: (a) pCO2 - 20.0 - 88.1 (b) pO2 - 60 - 429 (c) pH 6.528 - 7.889 (3) The surveyor reviewed the following manufacturer's reportable ranges: (a) pCO2 - 5 - 130 (b) pO2 - 5 - 800 (c) pH 6.50 - 8.20 (4) The surveyor asked the laboratory manager to explain the reportable ranges in use. On 05/17/2021 at 04:50 pm, the laboratory manager stated the laboratory was using the manufacturer's reportable ranges; (5) The surveyor reviewed the findings with the laboratory manager, who stated on 05/17/2021 at 05:05 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or

baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to follow their function check protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) On 05/17/2021 at 11:25 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed urine sediment examinations and the specimens were processed in the Drucker 642 VES centrifuge at a speed of 1700 rpm (Revolutions Per Minute) and a time of five minutes; (b) The laboratory performed routine chemistry testing and the specimens were processed in the Drucker DASH centrifuge at a speed of 3200 rpm for two to five minutes; (c) The laboratory performed Immunohematology (ABO/Rh, Antibody Screens, and Compatibility) testing using the tube method and the specimens were processed in the Clay Adams Serofuge at a speed of 3500 rpm for 15 seconds, 30 seconds, and 60 seconds. (2) On 05/18/2021, the surveyor asked the laboratory manager to explain how often function checks (speed and timer checks) were performed on the centrifuge. The laboratory manager stated on 05/18/2021 at 01:45 pm it was the laboratory's policy to check the speed and timer of the centrifuges annually; (3) The surveyor reviewed the centrifuge function check records that had been performed in 2018, 2019, 2020, and to date (05/18/2021). The centrifuge's speed and time had not been checked between 11/30/2018 and 01/19/2021; (4) The surveyor reviewed the records with the laboratory manager and asked if the speed and timer had been checked for the above centrifuges according to the laboratory's policy. On 05/18/2021 at 04:37 pm, the laboratory manager stated the centrifuge speed and time check had not been performed as indicated above.

**D5559**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of written policies and interview with the laboratory manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for one of eight units of packed red blood cells. Findings include: (1) On 05/17/2021 at 11:45 am, the laboratory manager stated to the surveyor the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) The surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "Transfusion of Blood or Blood Products Policy" under the section titled, "ii Assess, obtain vital signs, and monitor for signs and symptoms of transfusion reaction:", stated: (a) "1. Within 10 -15 minutes

after the start of the transfusion"; (3) The surveyor then reviewed records for eight units of PRBCs (Packed Red Blood Cells) that had been transfused on 09/15/2020, 09/29/2020, 11/20/2020, 01/29/2021, and 04/05/2021 for five patients, and identified the following: (a) Vitals signs within 10 -15 minutes after the transfusion started (i) Patient #131491312- Transfused with 1 unit PRBCs (unit # W091020361603) on 09/29/2020. The transfusion started at 04:33 pm and the first vital was documented at 04:56 pm (23 minutes later). (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated on 05/18/2021 at 10:12 am the written policy and procedure for blood administration had not been followed as indicated above.

**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 records and interview with the laboratory manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP's for urine drug testing and Troponin I testing; MEDTOX PROFILE V (1) On 05/17/2021 at 11:30 am, the laboratory manager stated the following to the surveyor: (a) Urine drug screen testing was performed using the MedTox Profile V; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 05/19/2016), The QA (Quality Assessment) portion of the IQCP's did not include a schedule for evaluating the QCP's (Quality Control Plan) to ensure they continued to provide accurate and reliable results; (3) The surveyor reviewed the records with the laboratory manager and asked if the QA plan addressed how the laboratory will evaluate the QCP's, including the frequency of the reviews. The laboratory manager stated on 05/17/2021 at 03:07 pm, the QA plan did not include an evaluation of the QCP's, and the frequency of the reviews for the MedTox Profile V urine drug testing. TROPONIN I (1) On 05/17/2021 at 11:30 am, the laboratory manager stated the following to the surveyor: (a) Troponin I testing was performed using the iSTAT 1 analyzer (S/N# 373980) and Troponin I cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 08/18/2016), The QA (Quality Assessment) portion of the IQCP's did not include a schedule for evaluating the QCP's (Quality Control Plan) to ensure they continued to provide accurate and reliable results; (3) The surveyor reviewed the records with the laboratory manager and asked if the QA plan addressed how the laboratory will evaluate the QCP's, including the frequency of the reviews. The laboratory manager stated on 05/17/2021 at 03:20 pm, the QA plans did not include an evaluation of the QCP's, and the frequency of the reviews for the Troponin I testing.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
 Based on a review of records and interview with the laboratory manager, the laboratory failed to make appropriate reference ranges available for two of two reagent lot number changes. Findings include: (1) On 05/17/2021 at 11:35 am, the laboratory manager stated the following to the surveyor: (a) PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) were performed using the Stago analyzer; (b) PT reagent - Neoplastine CI Plus lot #256761 had been put into use on 02/04/2021; (c) PTT reagent - STA PTT lot#256873 had been put into use on 02/04/2021. (3) The survey reviewed the PT and PTT reagent implementation records and identified the following: (a) The laboratory had verified a PT normal reference interval of 12.5 - 16.0 seconds; (b) The laboratory had verified a PTT normal reference interval of 27.0 - 39.0 seconds. (4) The surveyor then reviewed patient PT and PTT reports with the following identified: (a) Patient PT report dated 05/13/2021 at 09:11 pm included a normal reference interval of 11.8-14.4 seconds; (b) Patient PTT report dated 05/15 /2021 at 08:04 am included a normal reference interval of 24.4-37.0 seconds. (4) The surveyor surveyor reviewed the findings with the laboratory manager who stated on 05 /18/2021 at 01:59 pm that, although the laboratory had established a PT normal reference interval and PTT normal reference interval with the reagent lot changes, the laboratory had not implemented the changes into the laboratory's computer information system.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
 Based on a review of records and interview with the laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 4 of 32 events. Findings include: (1) On 05/17/2021 the surveyor reviewed 2019, 2020, and 2021 proficiency testing records. It was identified for 4 of 32 events, the attestation statements had been signed approximately 2-4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Immunology Second event of 2019 - The samples had been tested on 08/14/2019 and the attestation statement had not been signed by the laboratory director until 10/22 /2019; (b) Immunology First event of 2020 - The samples had been tested on 05/13 /2020 and the attestation statement had not been signed by the laboratory director until 07/14/2020; (c) Immunology Second event of 2020 - The samples had been tested on 08/11/2020 and the attestation statement had not been signed by the laboratory director until 10/20/2020; (d) Immunology Third event of 2020 - The samples had been tested on 12/09/2020 and the attestation statement had not been signed by the laboratory director until 04/20/2021. (2) The surveyor reviewed the findings with the laboratory manager and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the

same manner as patient specimens. On 05/17/2021 at 01:45 pm the attestations were not signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens as indicated above.