Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471986	10/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Love County	300 Wanda Street, Marietta, 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 10/28,29,30/2025. The laboratory was found in compliance with standard-level deficiencies cited. The laboratory had not been operational from 04/27/2024 through 09/01/2025 due the hospital being destroyed by a tornado on 04/27/2024. A temporary Emergency Department and Laboratory were built in the parking lot until a new hospital could be built, and the laboratory began patient testing in the temporary facility on 09/02/2025. Two new analyzers had been purchased while some of the analyzers were salvageable and reinstated for patient testing.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, observation, and interview with the laboratory manager, the laboratory failed to follow the written policy to ensure that emergency release of blood forms had been signed by the physician for one of one emergency releases reviewed; and failed to follow the written policy for centrifuging urine specimens for microscopic sediment examinations. Findings include: EMERGENCY RELEASE (1) On 10/28/2025 at 10:00 am, the laboratory manager stated the laboratory maintained units of (PRBC's) packed red blood cells in the Helmer refrigerator. The units were to be used for emergency transfusions; (2) A review of the policy titled, "MHLC LAB Emergency Release of Uncrossmatched Blood" stated, "The caregiver will complete an Emergency Transfusion Release Form for the physician's signature. Form should be returned to the lab once signed." (3) A review of documentation of an emergency release

	identified the following for one of one patient record: (a) One unit of O negative packed red blood cells had been released to a patient on 09/10/2025 at 11:02 am. The "Emergency Transfusion Release Form" appeared to be signed by a mid-level provider and not a physician. (4) The documentation was reviewed with the laboratory manager who stated on 10/28/2025 at 02:10 pm, the emergency release had not been signed by a physician. URINE CENTRIFUGE (1) On 10/28/2025 at 11:05 am, the laboratory manager stated microscopic urine sediment examinations were performed in the laboratory and the specimens were processed at a speed of 1500 rpm (revolutions per minute) for five minutes using the Unico centrifuge; (2) Observation of the laboratory on 10/28/2025 at 11:14 am, identified the centrifuge digital display showed it was currently set at 1800 rpm for five minutes; (3) A review of the procedure titled, "MHLC LAB Microscopic Urinalysis" stated, "Place the KOVA tube in a balanced centrifuge and centrifuge at 1500 rpm for five minutes." (4) Interview with the laboratory manager on 10/29/2025 at 11:50 am confirmed the laboratory was not following their procedure for processing urine specimens.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to ensure five of five Vacutainer brand tubes were stored as required by the manufacturer. Findings include: (1) Observation of the laboratory refrigerator and interview with the laboratory manager on 10/28/2025 at 10:40 am, identified the following: (a) Five Vacutainer K2, EDTA tubes, lot # 5169892, storage temperature of 4-25 degrees Celsius. (2) Interview with the laboratory manager on 10/28/2025 at 10:40 am confirmed the tubes were being stored below the manufacturer's stated temperature requirements.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager and testing person #2, the laboratory failed to label three of three containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 10/28/2025 at 09:45

	am, the laboratory manager and testing person #2 stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation of the laboratory on 10/28/2025 at 09:46 am identified three unlabeled Coplin jars, appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with the laboratory manager and testing person #2 who on 10/28/2025 at 09:59 am stated the Coplin jars contained staining materials had not been labeled with the identity, expiration date, and lot numbers.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 utilize the demonstrated reportable range for one of five test systems reinstated for patient testing. Findings include: (1) On 10/28/2025 at 09:30 am, the laboratory manager stated the laboratory reinstated using the Quidel Triage analyzer to perform patient D-dimer testing on 09/02/2025; (2) A review of the performance specification records identified the laboratory had demonstrated a reportable range of 216-3980 ng/ml; (3) Interview with the laboratory manager on 10/28/2025 at 02:55 pm confirmed the laboratory was using the manufacturer's reportable range of 100-5000 ng/ml instead of the reportable range that had been demonstrated by the laboratory. 47979 Based on a review of records and interview with the laboratory manager, the laboratory failed to demonstrate the reportable range and failed to ensure the performance specification data had been evaluated prior to reinstating the Diesse Mini-Cube test system; and failed to utilize the demonstrated reportable ranges for two of six analytes reviewed on the new Sysmex XN-450 test system. Findings include: I. DEISSE MINI-CUBE ESR (1) On 10/28/2025 at 09:55 am, the laboratory manager stated the laboratory reinstated using the Diesse Mini-Cube analyzer to perform ESR (Erythrocyte Sedimentation Rate) testing on 09/04/2025; (2) A review of the performance specification records for the new test system identified the following: (a) No evidence the reportable ranges for the analyte ESR had been demonstrated; (b) No evidence the performance specification data had been signed and dated as approved by the laboratory director prior to putting into use for patient testing. (3) Interview with the laboratory manager on 10/28/2025 at 01:25 pm confirmed there was no documentation to substantiate the reportable ranges had been demonstrated and the data had been signed and dated as approved by the laboratory director prior to beginning patient testing. II. SYSMEX XN-450 (1) On 10/28/2025 at 10:00 am, the laboratory manager stated the laboratory began performing CBC (Complete Blood Count) testing using the Sysmex XN-450 analyzer on 09/02/2025; (2) On 10/29/2025, a review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Hemoglobin: 0.0 - 24.1 g/dL (b) Hematocrit: 0.0 - 68.7% (3) Interview with the laboratory manager on 10/29/2025 at 11:00 am confirmed the laboratory was using the following manufacturer's reportable ranges: (a) Hemoglobin: 0.1 - 26.0 g/dL (b) Hematocrit: 0.0

	- 74.5 % 48517 Based on a review of records and interview with the point of care manager, the laboratory failed to utilize the demonstrated reportable ranges for one of five test systems reinstated for patient testing. Findings include: (1) On 10/28/2025 at 10:15 am, the laboratory manager stated the laboratory reinstated using the iSTAT 1 analyzer (serial #(21)399461 and the CG4+ cartridge to perform Blood Gas (pH, pCO2, pO2) testing on 09/02/2025: (2) On 10/29/2025, a review of the performance specifications records identified the laboratory had demonstrated the following reportable ranges: (a) pCO2 - 16.4-84.0 (b) pO2 - 55-409 (3) Interview with the laboratory manager on 10/09/2025 at 01:30 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) pCO2 - 5-130 (b) pO2 - 15-530
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform a negative and positive control material 27 of 40 days of patient urine drug screen testing reviewed from 09/02/2025 through the current date. Findings include: (1) On 10/28/2025 at 09:50 am, the laboratory manager stated the following: (a) The laboratory reinstated using the Med Tox Scan to perform patient Urine Drug Screen testing on 09/02/2025; (b) Negative and Positive QC (Quality Control) materials were performed weekly; (c) An IQCP (Individualized Quality Control Plan) had not been developed for the test system. (2) On 10/29/2025, a review of QC and patient testing records for testing performed from 09/02/2025 through the current date identified negative and positive QC materials had not been performed each day of patient testing for 27 of 40 days. The specific days were (a) 09/03, 04,05,10,12,16,17,18,19,21,23,24,25,26,30/2025 (b) 10/01, 02,03,05,07,08,09,10,14,22,23,24/2025 (3) The records were reviewed with the laboratory manager who stated on 10/29/2025 at 03:15 pm, negative and positive QC materials had not been performed each day of patient testing;
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform two levels of quality control materials each eight hours of D-dimer testing for one of 30 days of patient testing reviewed from 09/02/2025 through the current date. Findings include: (1) On 10/28/2025 at 09:30 am, the laboratory manager stated the following: (a) The laboratory reinstated using the Quidel Triage analyzer to perform patient D-dimer testing on 09/02/2025; (b) Two levels of QC (Quality Control) materials were performed each eight hours of patient testing. (2) A review of QC and patient records for 30 days of testing performed from 09/02/2025 through the current date identified two levels of QC materials had not been performed each eight hours of patient testing as follows: (a) Two levels of QC

	testing had been performed on 09/23/2025 at 11:12 am (b) A patient test had been performed on 09/23/2025 at 09:33 pm (3) The records were reviewed with the laboratory manager who stated on 10/29/2025 at 01:25 pm two levels of QC materials had not been performed each eight hours of patient testing.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer package insert, and interview with the laboratory manager, the laboratory failed to ensure test reports for Troponin I testing included information required for interpretation for one of one patient report. Findings include: (1) On 10/28/2025 at 09:30 am, the laboratory manager stated the laboratory reinstated using the Quidel Triage analyzer to perform patient D-dimer testing on 09 /02/2025; (2) A review of the manufacturer's instructions contained in the D-dimer assay package insert for the test system on page 2 under "Warnings and Precautions" stated, "The Quidel Triage D-dimer test should not be used as absolute evidence for PE or DVT. As with all in vitro diagnostic tests, the test results should be interpreted by the physician in conjunction with clinical findings and other test results"; (3) A review of one patient report with D-dimer test results reported on 10/27/2025 at 09:24 am identified the report did not include the manufacturer's statement; (4) The findings were discussed with the laboratory manager who stated on 10/28/2025 at 02:58 pm, the patient reports did not include the statement.