Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2173412	(X3) Date Survey Completed 04/17/2025
Name of Provider or Supplier Mercy Emergency Department-Edmond I-35 South	**Street Address, City, State** 2301 W I-35 Frontage Rd, Edmond, 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 validation survey was performed on 04/17/2025. The findings were reviewed with the laboratory director, director of laboratory services, manager of laboratory services/technical consultant, supervisor of laboratory services, and manager of laboratory quality and compliance during an exit conference performed at the conclusion of the survey.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, records, and interview with the technical consultant, the laboratory failed to follow the written policy for alarm system checks for the blood bank refrigerator during the review period of June 2023 through the current date. Findings include: (1) On 04/17/2025 at 11:45 am, the technical consultant stated units of packed red blood cells were routinely maintained in the blood bank refrigerator for emergency patient transfusions; (2) Policy review revealed a policy for performing manual alarm checks quarterly for the blood bank refrigerator; (3) A review of records revealed there were no blood bank alarm checks documented from 06/01/2023 through 02/17/2025; (3) Interview with the technical consultant on 04/17/2025 at 11:45 am confirmed the laboratory failed to follow the policy for performing manual alarm checks for blood product storage.
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, policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written procedure for peforming Platelet Poor Plasma checks during the review period of January 2024 through the current date. Findings include: (1) On 04/17/2025 at 02:45 pm, the technical consultant stated the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the Stago Satellite analyzer; (b) Patient specimens were processed using two Hettich Zentrifugen EBA 280 centrifuges (denoted by the laboratory as "20191545" and "20191546"). (2) A review of the procedure titled, "OKLC I35 Lab Platelet Poor Plasma" stated, "This procedure will be performed twice a year and whenever service is done on the centrifuge or if the centrifuge is replaced"; (3) A review of records for Platelet Poor Plasma checks performed from January 2024 through the current date identified the checks had not been performed on centrifuge 20191545 and centrifuge 20191546 prior to 11/12/2024; (4) The findings were reviewed with the technical consultant who stated on 04/17/2025 at 03:20 pm the laboratory had not followed their written procedure. 48517 Based on observation, review of policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written protocol for centrifuging urine samples for microscopic exam during the review period of June 2023 through the current date. Finding include: (1) On 04/17/2025 at 10:00 am, the technical consultant stated the following: (a) Urine sediment examinations were performed by the laboratory; (b) The specimens were processed in a Horizon 642 VES centrifuge at a speed of 1700 rpm (revolutions per minute) for three minutes; (2) A review of the procedure titled, "OKLC I35 Lab and microscopic urinalysis and culture criteria" stated, "Place ten milliliters (ml) of a well mixed urine into a labeled urine tube. Cap the tube and place it in the centrifuge at 400 RCF (Relative Centrifugal Force) for five minutes"; (4) The records were reviewed with the technical consultant, who stated on 04/17/2025 at 10:00 am, the laboratory had not followed their policy for centrifuging for five minutes.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) 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. This STANDARD is not met as evidenced by: Based on observation, and interview with the technical consultant, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 04/17/2025 at 09:30 am, identified the following expired supplies were available for use: (a) One gallon of methyl alcohol, lot #125384, expired 12/31/2024. (2) Interview with the technical consultant on 04/17/2025 at 09:30 am confirmed the expired reagent was available for use.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(b) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months for two of two iSTAT test systems during the review period of January 2024 through the current date. Findings include: (1) On 04/17/2025 at 10:15 am, the technical consultant stated the following were performed using two iSTAT 1 analyzers (Serial Number 410507 and Serial Number 410538): (a) BUN (Blood Urea Nitrogen), Chloride, CO2 (Carbon Dioxide), Creatinine, Glucose, Potassium, and Sodium testing using the Chem 8+ cartridge; (b) Blood Gas (pH, pCO2, pO2) testing using the EG6+ cartridge; (c) BNP (B-Type Natriuretic Peptide) testing using the BNP cartridge; (d) Troponin I testing using the cTnI cartridge. (2) A review of records from January 2024 through the current date identified calibration verification had not been performed at least once every six months as follows: (a) Chem 8+ Cartridge - Not performed on iSTAT 1 Serial Numbers 410507 and 410538 prior to 09/04/2024; (b) EG6+ Cartridge - Not performed on iSTAT 1 Serial Numbers 410507 and 410538 prior to 09/04/2024; (c) BNP Cartridge - Not performed on iSTAT 1 Serial Numbers 410507 and 410538 prior to 09/20/2024; (d) Troponin I Cartridge - Not performed on iSTAT Serial Numbers 410507 and 410538 prior to 09/05/2024. (3) The records were reviewed with the technical consultant who stated on 04/17/2025 at 02:55 pm, calibration verification procedures had not been performed every six months as shown above.
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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the

	laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers for three of three test systems reviewed from January 2024 through the current date. Findings include: (1) On 04/17/2025 at 10:15 am, the technical consultant stated BUN (Blood Urea Nitrogen), Chloride, CO2 (Carbon Dioxide), Creatinine, Glucose, Potassium, and Sodium testing were performed using the following test systems: (a) Roche Cobas c501 analyzer; (b) iSTAT 1 analyzer (Serial Number 410507) and the Chem 8+ cartridge; (c) iSTAT 1 analyzer (Serial Number 410538) and the Chem 8+ cartridge. (2) A review of records from January 2024 through the current date identified no evidence the relationship between the analytes tested on three test systems had been evaluated twice annually prior to 02/07/2025 as follows: (a) 04/16/2024 - Although the above analytes tested on the iSTAT 1 Serial Number 410538 had been evaluated with the Roche Cobas c501 analyzer, an evaluation with iSTAT 1 Serial Number 410507 had not been included; (b) 10/08/2024 - Although the above analytes tested on the iSTAT 1 Serial Number 410507 had been evaluated with the Roche Cobas c501 analyzer, an evaluation with iSTAT 1 Serial Number 410538 had not been included. (3) The records were reviewed with the technical consultant who stated on 04/17/2025 at 01:00 pm, the relationship between the three test systems had not been evaluated twice annually as stated above.
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 and interview with the technical consultant and director of laboratory services, the laboratory failed to ensure patient test reports included the name, as stated on the CLIA certificate, of the laboratory location where the testing was performed for four of four reports reviewed. Findings include: (1) A review of the following four patient reports identified the laboratory name was listed as "Mercy Laboratory Service-Edmond I35 ED" (the name on the CLIA certificate was "Mercy Emergency Department-Edmond I35 South"): (a) Quantitative HCG (Human Chorionic Gonadotropin) testing resulted on 04/16/2025; (b) Arterial Blood Gas (pH, pCO2, pO2) testing resulted on 07/30/2024; (c) PT/INR (Prothrombin Time /International Normalized Ratio) testing resulted on 03/02/2025; (d) Troponin I testing resulted on 03/04/2025. (2) The findings were reviewed with the technical consultant and director of laboratory services. Both stated on 04/17/2025 at 03:30 pm, the laboratory name, as stated on the CLIA certificate, had not been included on the patient test reports.