Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469999	02/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Clinic Primary Care W Guy & Gen Surg	415 W Guy Ave, Pauls Valley, 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 02/04/2026. Standard-level deficiencies were cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure a proficiency testing attestation statement had been signed and dated by the laboratory director or designee for one of three Hematology events reviewed in 2025. Findings include: (1) A review of the first, second, and third 2025 Hematology proficiency testing records identified the following for one of three events: (a) Third 2025 Event - The attestation statement had not been signed and dated by the laboratory director or designee. (2) The findings were reviewed with the technical consultant who stated on 02/04/2026 at 12:20 pm the attestation statement had not been signed and dated by the laboratory director or designee.
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 and testing person

	#1, the laboratory failed to ensure expired materials were not available for use. Findings include: (1) Observation of the supply room on 02/04/2026 at 10:22 am, identified the following expired supplies that were available for use: (a) Ten BD Vacutainer Trace Element Serum tubes - lot 4222030, expired 08/31/2025; (b) Ten BD Vacutainer Trace Element Serum tubes - lot 4344147, expired 12/31/2025; (c) Ten BD Vacutainer Sodium Fluoride Potassium Oxalate tubes - lot 4257307, expired 01/31/2026. (2) Interview with the technical consultant and testing person #1 on 02/04/2026 at 10:25 am confirmed the expired materials were available for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for one of one analyzer reviewed from January 2025 through the current date. Findings include: (1) On 02/04/2026 at 10:10 am, the technical consultant stated the laboratory performed CBC (WBC (White Blood Cell), RBC (Red Blood Cell), Hgb (Hemoglobin), Hct (Hematocrit), Plt (Platelet)) testing using the Sysmex XP-300 analyzer; (2) On 02/04/2026, a review of the manufacturer's maintenance log showed the following required maintenance procedure: (a) Weekly: (i) Clean SRV Tray (3) A review of maintenance logs from January 2025 through the current date identified the weekly maintenance had not been documented as performed as follows: (a) Between 01/24/2025 and 02/06/2025 (b) Between 04/25/2025 and 05/05/2025 (c) Between 06/24/2025 and 07/10/2025 (d) Between 10/23/2025 and 11/04/2025 (e) Between 12/24/2025 and 01/08/2025 (4) The records were reviewed with the technical consultant who stated on 02/04/2026 at 02:39 pm, the weekly maintenance procedure had not been documented as performed as stated above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. 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 control procedures that monitored the accuracy and precision of the complete analytic process for two of five months reviewed for the testing performed using the Sysmex XP-300 analyzer. Findings include: (1) On 02/04/2026 at

	10:10 am, the technical consultant stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (b) Three levels of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing. (2) A review of records from July 2025 through December 2025 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e., biases, shifts, or trends) for the period of October 16, 2025 through December 29, 2025; (3) Interview with the technical consultant on 02/04/2026 at 02:50 pm confirmed that QC data to include Levey-Jennings graphs and cumulative statistical data had not been printed and reviewed for the period stated above.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure competency evaluations for moderate complexity testing had been performed at least two times (semiannually) during the first year of testing for one of one testing person. Findings include: (1) On 02/04/2026, a review of personnel records for one of one person performing moderate complexity testing identified the following: (a) Testing Person #5 - The initial training was completed on 01/20/2025 and the first competency evaluation was completed on 06/16/2025. The second competency evaluation was not performed until 02/02/2026; (2) Interview with the technical consultant on 02/04/2026 at 11:20 am confirmed that the second competency evaluation had not been completed during the first year of patient testing.