Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469999	04/27/2022
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 initial survey was performed on 04/27/2022. The findings were reviewed with the technical consultant and the regional point of care coordinator at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on an interview with the technical consultant, the laboratory failed to have a written employee competency policy that explained each component of a required competency for moderate complexity testing. Findings include: (1) On 04/27/2022 at 10:20 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer. (2) An interview with the technical consultant on 04/27/2022 at 01:55 pm revealed a competency assessment policy had not been written.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 an interview with the technical consultant, the laboratory failed to have written CBC (Complete Blood Count) policies and procedures. Findings Include: (1) On 04/27/2022 at 10:20 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer. (2) An interview with the technical consultant on 04/27/2022 at 01:55 pm revealed CBC policies and procedures had not been written.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #1, the laboratory failed to ensure materials were stored as required by the manufacturer for nine of nine months. Findings include: (1) On 04/27/2022 at 10:20 am, the technical consultant stated the following: (a) Blood collection tubes were stored at the draw station and used for the following: (i) Routine CBC (Complete Blood Count) testing performed on the Sysmex XP-300 analyzer. (2) A review of the manufacturer's environmental requirements for the blood collection tubes required a room temperature 4-25 degrees C (Celsius). The following were examples of blood collection tubes stored at the draw station: (i) Vacutte Tubes K2 EDTA (28 tubes). (3) A review of laboratory temperature records from July 2021 through the day of the survey (04/27/2022) revealed for nine of nine months, room temperatures had not been documented for the draw station; (4) The records were reviewed with testing person #1. Testing person #1 stated on 04/27/2022 at 12:00 pm the laboratory failed to ensure materials were stored as required by the manufacturer as indicated above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 follow the manufacturer's instructions for weekly maintenance procedures for four of seven months. Findings include: (1) On 04 /27/2022 at 10:20 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer. (2) A review of the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Weekly: (i) Clean SRV Tray (3) A review of

	maintenance records for seven months (July 2021 through January 2022) revealed the following: (a) There was no evidence the weekly maintenance had been performed (i) Between 07/16/2021 and 08/06/2021 (ii) Between 08/12/2021 and 09/01/2021 (iii) Between 09/08/2021 and 10/05/2021 (iv) Between 12/10/2021 and 01/05/2022 (4) The records were reviewed with the technical consultant who stated on 04/27/2022 at 02:20 pm, the maintenance had been performed but not documented.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to verify the stated value of control materials before they were put into use for three of three lot numbers. Findings include: (1) On 04/27/2022 at 10:20 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing performed on the Sysmex XP-300 analyzer; (b) Three levels of manufacturer control materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records for three control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for three of three lot numbers as follows: (a) Low control lot #21100710, Normal control lot # 21100711 and High control lot #21100712 used from 04/25/2022 through the day of the survey (04/27/2022). (3) The findings were reviewed with the technical consultant who stated on 04/27/2022 at 02:55 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the

	laboratory director failed to ensure enrollment and participation in a proficiency testing program for one of one event. Findings include: (1) On 04/27/2022, a review of proficiency testing records revealed no evidence the laboratory was enrolled in proficiency testing for hematology testing for one of one event (2021 third hematology event); (2) On 04/27/2022 at 11:30 am, the technical consultant stated the following: (a) The laboratory performed hematology testing using the Sysmex XP-300 beginning 06/14/2021. (3) During an interview on 04/27/2022 at 12:20 pm, the technical consultant stated the specific enrollment was not available. A phone call to the proficiency testing provider at 12:25 pm confirmed the laboratory had not enrolled for hematology testing events until 11/08/2021.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for 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 technical consultant failed to ensure a semiannual evaluation for moderate complexity testing was performed for two of two testing persons. Findings include: (1) On 04/27/2022 at 10:20 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer. (2) A review of 2021 and 2022 personnel records for two persons requiring a semiannual competency for the above testing, revealed the following: (a) Testing Person #1 - The initial training had been documented as performed on 04/15/2021. There was no evidence the semiannual competency had been performed (due 10/2021); (b) Testing Person #2 - The initial training had been documented as performed on 04/15/2021. There was no evidence the semiannual competency had been performed (due 10/2021). (3) The findings were reviewed with the technical consultant who stated on 04/27/2022 at 01: 45 pm the semiannual competency had not been performed as indicated above.