Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0469999	**(X3) Date Survey Completed** 02/01/2024
Name of Provider or Supplier Mercy Clinic Primary Care W Guy & Gen Surg	**Street Address, City, State** 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 02/01/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the director of ambulatory laboratory services, regional point of care coordinator, and pratice manager during an exit conference performed at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) 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 AAFP (American Academy of Family Physicians) and WSLH (Wisconsin State Laboratory of Hygiene) proficiency testing records and interview with the technical consultant the laboratory failed to ensure proficiency testing attestation statements had been maintained or signed by the laboratory director or designee and testing person(s) for four of six events reviewed. Findings include: (1) A review of 2022 and 2023 Hematology proficiency testing (PT) records identified the following for four of six events: (a) AAFP third 2022 event - The attestation statement had not been signed by the laboratory director or designee and testing person(s); (b) WSLH first 2023 event - The attestation statement had not been signed by the laboratory director or designee and testing person(s); (c) WSLH second 2023 event -

	The attestation statement had not been maintained by the laboratory; (d) WSLH third 2023 event - The attestation statement had not been signed by the laboratory director or designee and testing person(s). (2) The findings were reviewed with the technical consultant who stated on 02/01/2024 at 12:35 pm, the attestation statements had not been maintained or signed as stated above.
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 a review of records, written policies and procedures, and interview with the technical consultant, the laboratory failed to follow their policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person serving as technical consultant during the review period of May 2022 through the current date. Findings include: (1) A review of the laboratory policy titled "Laboratory Staff Competency Assessment Policy" required competencies for the technical consultant based on job responsibilities be performed annually; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed from May 2022 through the current date identified competencies, based on job responsibilities, had not been documented as performed after 05/18/2022 for one of one person listed as technical consultant; (3) The findings were reviewed with the technical consultant who stated on 02/01/2024 at 10:50 am, the competencies for the technical consultant had not been performed as stated above.
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 a review of records, policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for six of 12 lot numbers used during the review period of April through December 2023. Findings include: (1) On 02/01/2024 at 12:45 pm, 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; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the Laboratory Procedure Manual titled "Complete Blood Count (CBC) on the Sysmex XP-300", section IV- Calibration, Part C - Starting A new Lot of Control, stated "Parallel test new assayed controls by analyzing the three levels of control once a day for 1 to 5 days prior to expiration of the previous lot. Ensure each time they are

	run, all values are within assayed ranges. The new lot may be placed into production and patient samples tested. The new lot has then been validated prior to the expiration." (3) A review of records for nine control lot numbers used from April through December 2023 identified no documentation to prove six of the 12 lot numbers had been implemented per policy: (a) Lot #31650710, 31650711, and 31650712 used from 06/22/2023 through 09/20/2023; (b) Lot #32490710, 32490711, and 32490712 used from 09/21/2023 through 12/12/2023. (4) The findings were reviewed with the technical consultant who stated 01/04/2024 at 1:45 pm, the laboratory did not follow their written policy.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure the manufacturer's operator manual was available for use in the laboratory. Findings include: (1) On 02/01/2024 at 12:45 pm, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (2) On 02/01/2024 at 01:15 pm, the surveyor requested the manufacturer's operator manual for the analyzer to ensure laboratory was following manufacturer's requirements; (3) The technical consultant stated on 02/01/2024 at 01:40 pm the manufacturer's operator manual was not available.
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 observation and interview with testing person #2 and the technical consultant, the laboratory failed to ensure the temperatures in the laboratory were documented for four of 12 months reviewed from January through December 2023, and failed to ensure five of five types of blood collection tubes were stored as required by the manufacturer in the supply room. Findings include: LABORATORY: (1) Observation of the laboratory on 02/01/2024 at 12:45 pm, identified multiple BD Vacutainer blood collection tubes stored in the laboratory with a manufacturer's storage requirement of 4 to 25 degrees Centigrade (C); (2) A review of temperature logs for 12 months showed the temperature had not been documented as follows: (a) May 2023 - two of 31 days (b) June 2023 - one of 30 days (c) July 2023 - two of 31 days (d) August 2023 - one of 31 days (3) Interview with technical consultant 02/01

	/2024 at 1:00pm confirmed the laboratory had not documented the temperatures as stated above. SUPPLY ROOM: (1) Observation of the supply room and interview with testing person #2 on 02/01/2024 at 1:00 pm, identified the following: (a) one package of Vacuette 6ml CAT Serum Sep Clot Activator tubes, lot # B231133J, storage temperature of 4-25 degrees (C) Centigrade; (b) one package of Vacuette 4ml K2EDTA tubes, lot # B230735H, storage temperature of 4-25 degrees C; (c) 40 Vacuette 6ml Lithium Heparin tubes, lot # B23053, storage temperature of 4-25 degrees C; (d) 40 BD Vacutainer Trace element K2EDTA 10.8 mg, lot # 2292119, storage temperature of 4-25 degrees C; (e) ten BD Vacutainer Buff. Na Citrate 0.109 M, 3.2%, lot # 32577665, storage temperature of 4-25 degrees C; (2) Interview with testing person #2 and technical consultant on 02/01/2024 at 1:00 pm confirmed the laboratory was not monitoring the temperature of the supply room.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 a review of records and interview with the technical consultant and point of care coordinator, the laboratory failed to ensure control materials were not used beyond the expiration date for six of 12 lot numbers reviewed from January through December 2023. Findings include: (1) On 02/01/2024 at 12:45 pm, 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) On 02/01/2024 at 2:30 pm, the surveyor reviewed records for 12 lot numbers of QC materials used from 01/11/2023 through 12/31/2023. The surveyor identified controls had been used beyond the manufacturer's expiration date for six of 12 lot numbers reviewed as follows: (a) Low control lot #22780710, normal control lot #22780711, and high control lot # 22780712 used from 01/11/2023 through 01/17 /2023. The manufacturer's expiration date was 01/11/2023; (b) Low control lot #23620710, normal control lot #23620711, and high control lot # 23620712 used from 04/03/2023 through 04/28/2023. The manufacturer's expiration date was 04/05/2023. (3) A review of patient records confirmed patient CBC results had been reported on the following dates when the laboratory had used expired QC materials to assess the acceptable performance of the analyzer: (a) January: 12, 13, 16, and 17 of 2023. (b) April: 12, 13, 17,18, 19, 20, 21, 24, 25, 26, 27, and 28 of 2023. (4) The records were reviewed with the technical consultant and point of care coordinator who stated on 02 /01/2024 at 03:00 pm, the controls had been used beyond the expiration date.
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 and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Sysmex XP-300 analyzer during the review period of February 2023 through December 2023. Findings include: (1) On 02/01/2024 at 12:45 pm, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) A review of the "XP-300 Maintenance Log" provided by the manufacturer required the following maintenance procedures: (a) Weekly "Clean SRV tray" (b) Quarterly (or every 4,500 samples) "Clean Sample Rotor Valve (SRV)" (3) A review of maintenance logs from February 2023 through December 2023 identified maintenance had not been documented as performed for the following: (a) Weekly: (i) Between 02/12/2023 and 03/06/2023 (ii) Between 03/22/2023 and 04/05/2023 (iii) Between 04/11/2023 and 05/10/2023 (iv) Between 05/31/2023 and 06/12/2023 (v) Between 07/13/2023 and 08/07/2023 (vi) Between 08/18/2023 and 09/08/2023 (vii) Between 09/08/2023 and 09/29/2023 (b) Quarterly: (i) Between 03/22/2023 and 08/14/2023 (4) The records were reviewed with the laboratory manager who stated on 01/03/2024 at 1:45 pm, maintenance procedures had not been documented as performed as stated above.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. 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 performing calibrations during the review period of May 2022 through December 2023. Findings include: (1) On 02/01/2024 at 12:45 pm, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) A review of the Sysmex Managed Calibration Addendum, section titled, "Precision and Calibration" stated, "Calibration verification should occur at least once every six months or if one of the following occurs: (i) Critical parts or assemblies are replaced. (ii) Controls are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting. (iii) When advise by a Sysmex Representative." (3) A review of records from May 2022 through December 2023 identified no documentation to prove the analyzer had been calibrated before 11/28/2023; (4) Interview with the technical consultant on 02/01/2024 at 02:15 pm confirmed there were no records to prove the analyzer had been calibrated as required by the manufacturer.
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. (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 have control procedures that monitored the accuracy and precision of the complete analytic process for 12 of 12 months reviewed for the testing performed using the Sysmex XP-300 analyzer. Findings include: (1) On 02/01/2024 at 12:45 pm, 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 January 2023 through December 2023 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); (3) Interview with the laboratory manager on 02/01 /2024 at 3:12 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.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director or designee failed to ensure proficiency testing reports were reviewed for four of six Hematology events reviewed in 2022 and 2023. Findings include: (1) A review of 2022 and 2023 Hematology proficiency testing (PT) events identified the "Performance Evaluations" included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following was identified for four of six events: (a) AAFP Third PT event of 2022 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (b)WSLH First PT event of 2023 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (c) WSLH Second PT event of 2023 - There was no evidence the Performance Evaluation had been signed and dated as

	reviewed by the laboratory director or designee; (d) WLSH Third PT event of 2023 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (2) The records were reviewed with the technical consultant who stated on 02/01/2024 at 11:30 am, the graded evaluation, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee.