Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2120557	08/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Stillwater Medical Plaza Laboratory	1201 S Adams St, Stillwater, 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 08/20/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
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 establish a written policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person. Findings include: (1) On 08/20/2025, a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical consultant based on the position responsibilities, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of August 2023 through the current date identified, although competencies, based on the position responsibilities, had been performed for one of one person listed as the technical consultant on 06/10/2025, the assessment policy was not available for review; (3) The findings were reviewed with the technical consultant who stated on 08/20/2025 at 12:10 pm, a written policy was not available, although competencies had been performed for the position as stated above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the hematology policy and procedure manual, and interview with the technical consultant, the laboratory failed to have complete written procedures for one of one procedure reviewed. Findings include: (1) On 08/20/2025 at 10:50 am, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i hematology analyzer; (2) A review of the procedure titled, "Sysmex XS-1000i (Complete Blood Count)" identified the procedure did not include the normal reference intervals for the laboratory's patient population; (3) The findings were reviewed with the technical consultant who stated on 08/20/2025 at 02:30 pm, the CBC procedure did not include all of the required information.
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 and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Sysmex XS-1000i analyzer during the review period of January 2025 through July 2025. Findings include: (1) On 08/20 /2025 at 10:45 am, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i hematology analyzer; (2) A review of the operator's manual titled "XS-1000i/XS-800i Instructions for Use" under "chapter 9-Cleaning/Maintenance" showed the following required maintenance procedures: (a) Monthly: (i) Run the shutdown process (automatically rinse the detector chamber and dilution line) (3) A review of maintenance records from January 2025 through July 2025 identified monthly maintenance had not been documented as performed prior to 04/01/2025; (4) Interview with the technical consultant on 08/20

	/2025 at 01:09 pm confirmed the maintenance procedures had not been documented as performed as stated above.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. 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 reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 08/20/2025 at 10:50 am, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i hematology analyzer; (2) Review of two patient CBC reports (the first report was for an adult female patient with the testing performed on 01/06/2025 at 15:43 pm and the second report was for an adult male patient with the testing performed on 01/13/2025 at 10:59 am) identified both reports included the same reference intervals for the following CBC parameters: (a) WBC (White Blood Cell) count - 5.5-17.5 (10^3/mL); (b) RBC (Red Blood Cell) count - 4.50-5.40 (10^6/mL); (c) Hemoglobin - 12.0-16.0 g /dL; (d) Hematocrit - 34.0-40.0 %; (e) Platelets - 130-400 (10^3/mL). (3) The reports were reviewed with the technical consultant who stated on 08/20/2025 at 02:00 pm, the patient reports did not include gender specific reference ranges for WBC, RBC, Hemoglobin, Hematocrit, and Platelets.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually 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 personnel performing moderate complexity testing had been evaluated at least annually for one of three testing persons during the review period of August 2023 through the current date. Findings include: (1) On 08/20/2025, a review of personnel records for three persons performing moderate complexity testing during January 2023 to date in 2025 identified no evidence an annual competency evaluation had been performed for one of three persons as follows: (a) Testing person #3 - Initial training had been completed on 01/23/2023, a semi-annual competency had been performed on 07/21/2023, and an annual competency had not been performed until 03/27/2025; (2) The records were reviewed with the technical consultant who stated on 08/20/2025 at 11:42 am, the annual evaluations had not been documented as performed.