Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2333025	04/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Providence Medical Group- Southgate	3017 Paxson Street, Suite A, Missoula, MT	

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 Montana CLIA Program conducted an initial survey on April 27, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements. However, the following standard-level deficiencies were identified during the survey.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS1), the laboratory failed to verify the normal reference ranges were appropriate for the laboratory's patient population for two of two testing platforms prior to reporting patient test results from January 23, 2026, to April 27, 2026. Findings: 1. The laboratory failed to provide verification studies to confirm the normal reference ranges for complete blood count (CBC) testing with a five part differential, performed on the Sysmex XN-450, were appropriate for the laboratory's patient population prior to patient testing from January 23, 2026, to April 27, 2026. 2. The laboratory failed to provide verification studies to confirm the normal reference ranges for the Abbott i-STAT System using Chem8+ cartridges were appropriate for the laboratory's patient population prior to patient testing from January 26, 2026, to April 27, 2026. 3. A review of the Test Volume Sheet revealed the laboratory performed CBC testing with a five part differential on the Sysmex XN-450 for 600 patients and performed Chem8+ testing on

	the i-STAT System for nine patients. 4. During an interview on April 27, 2026, at 10: 15 AM, TS1 confirmed the laboratory had not verified the normal reference ranges were appropriate for the laboratory's patient population for the Sysmex XN-450 and the Abbott i-STAT System prior to reporting patient test results from January 23, 2026, to April 27, 2026.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) (b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS1), the laboratory failed to include a verification study in its Individualized Quality Control Plan (IQCP) to support the quality control (QC) practices for one of one cartridge used by the laboratory on the Abbott i-STAT System from January 26, 2026, to April 27, 2026. Findings: 1. A review of the "iSTAT Blood Analyzer" IQCP summary for the Chem 8+ cartridge states, "Two levels of external Quality Control to be performed every 30 days and with each new shipment/cuvette lot number change of CHEM8+ cartridges." No records of a quality control verification study to support its quality control practices were available for review. 2. A review of the Test Volume Sheet showed nine patient samples were tested using the Chem8+ cartridge on the Abbott i-STAT System from January 26, 2026, to April 27, 2026. 3. An interview with the TS1 on April 27, 2026, at 10:30 AM, confirmed the laboratory failed to perform a verification study to support its quality control practices outlined in its IQCP for the i-STAT Chem8+ cartridge from January 26, 2026, to April 27, 2026.