Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2176590	09/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rps Shergill, Md Pllc	5401 E Mayflower Lane, Wasilla, AK	

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
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 lack of documentation and an interview with the laboratory director, the laboratory failed to have a written procedure for Complete Blood Count (CBC) on the Sysmex pocH-100i analyzer. Findings include: 1. A request was made to review the procedure for the Complete Blood Count (CBC) on the Sysmex pocH-100 I analyzer and documentation could not be provided. 2. An interview conducted on September 29, 2023 at approximately 11:30 AM with the laboratory director confirmed the laboratory did not have written procedure for CBCs. 3. The laboratory reports performing approximately 300 CBCs annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a lack of documentation and an interview with the laboratory director, the laboratory failed to verify the performance specifications for accuracy, precision, reportable range, and reference range for the Complete Blood Count (CBC) on the Sysmex pocH-100i analyzer received in January 2023 prior to reporting patient test results. Findings include: 1. A request was made to review the verification of performance specifications for the Complete Blood Count (CBC) on the Sysmex pocH-100i analyzer received in January 2023, and documentation could not be provided. 2. The laboratory started testing patients on March 10, 2023. 3. An interview conducted on September 29, 2023 at approximately 11:30 AM with the laboratory director confirmed the laboratory did not have the verification studies for accuracy, precision, reportable range and reference range for the CBCs on the Sysmex pocH-100i. 4. The laboratory reports performing approximately 300 CBCs annually.