

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D2176590	<b>(X3) Date Survey Completed</b>  08/13/2025
<b>Name of Provider or Supplier</b>  Rps Shergill, Md Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5024</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of Hematology records, lack of documentation, and TP1 interview, the laboratory failed to ensure personnel competency assessments were performed (refer to D5209), failed to ensure proficiency test (PT) results were reviewed and evaluated (refer to D5211), failed to provide a written procedure for performing Complete Blood Counts (CBCs) (refer to D5401), failed to maintain CBC reagents at an acceptable refrigerated temperature (refer to D5413), and failed to ensure the CBC Quality Controls (QC) was regularly reviewed to detect immediate errors or monitored over time (refer to D5441). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the policy entitled 'Quality Assurance Program', lack of documentation, and an interview with TP1, the laboratory failed to follow written</p>

	<p>policies and procedures to assess employee competency for performing complete blood counts (CBCs) on the Sysmex pocH-100i hematology analyzer for one of one testing persons. Findings include: 1. The policy entitled 'Quality Assurance Program' effective 2023, states: a. All new personnel will be properly oriented to the laboratory as according to the Orientation Check List b. All personnel will have a competency evaluation done within the first 30 days of hire, six months after hire, again at the one year date and yearly thereafter. c. Training for all new procedures or new methodologies will be make available to personnel as needed. 2. A request was made to review the orientation check list, training records, and competency assessments for non-waived hematology testing for TP1, hired in June 2024, and documentation could not be provided. 3. On an on-site interview on 8/13/2025 at 11:30 AM, TP1 confirmed there were no documented orientation, training, or competency records. 4. The laboratory reports performing 60 CBCs annually.</p>
<p><b>D5211</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing records, lack of documentation, and an interview with TP1, the laboratory failed to review and evaluate the Proficiency Testing (PT) results obtained from four of four American Proficiency Institute (API) PT events for complete blood counts (CBCs) on the Sysmex pocH-100i hematology analyzer in 2024 and 2025. Findings include: 1. A request was made to review the API PT hematology results and corresponding laboratory PT evaluation and review from the 2024-1, 2024-2, 2024-3, and 2025-1 PT events, and documentation could not be provided. 2. On an on-site interview on 8/13/2025 at 11:30 AM, TP1 confirmed there was no documentation of the PT results, evaluation, or review. 3. The laboratory reports performing 60 CBCs annually.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with TP 1, the laboratory failed to have a written procedure for performing complete blood counts (CBCs) on the Sysmex pocH-100i hematology analyzer. Findings include: 1. A request was made to review the procedure for CBCs on the Sysmex pocH-100i hematology analyzer, and documentation could not be provided. 2. On an on-site interview on 8/13/2025 at 11:30 AM, TP1 confirmed there was no documented procedure for performing CBCs on the Sysmex pocH-100i hematology analyzer. 3. The laboratory reports performing 60 CBCs annually.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b></p>

CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 temperature logs for June and August 2025, and an interview with TP1, the laboratory failed to initiate corrective action or follow up out-of-range temperatures in the refrigerator where CBC controls are stored for 34 of 34 temperature readings. Findings include: 1. A review of refrigerator temperature logs for June and August of 2025 revealed the temperature was documented outside the acceptable range of 36-40 F printed on the log sheets for 34 of 34 temperature readings covering 17 days. 2. On an on-site interview on 8/13/2025 at 11:30 AM, TP1 confirmed there was no documentation of follow-up or corrective actions taken. 3. The laboratory reports performing 60 CBCs annually.

**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.

This STANDARD is not met as evidenced by:

Based on a review of quality control records, a lack of documentation, and an interview with TP1, the laboratory failed to monitor and evaluate quality control (QC) results to detect immediate errors and errors occurring over time, and to verify the accuracy and precision of the testing process for complete blood counts (CBCs) on the Sysmex pocH-100i hematology analyzer for QC performed in 2024 and 2025. Findings include: 1. A request was made to review the laboratory's documentation of quality control evaluation and monitoring, and documentation could not be provided. 2. On an on-site interview on 8/13/2025 at 11:30 AM, TP1 confirmed there was no regular review of CBC QC results on the Sysmex pocH-100i hematology analyzer. 3. The laboratory reports performing 60 CBCs annually.