

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0858508	(X3) Date Survey Completed 04/18/2024
Name of Provider or Supplier John D Sprandio Md Laboratory	Street Address, City, State 30 Lawrence Road, Suite 201, Broomall, PA	
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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel (TP) #1 the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for platelet (PLT) counts performed on the Sysmex XN L complete blood count analyzer from 10/12/2022 to 04/18/2024. Findings include: 1. Sysmex XN L manufacturer's instruction states "Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid." 2. On the day of the survey, 04/18/2024 at 11:22 am, the laboratory could not provide documentation for the performance specifications established when performing PLT counts using sodium citrate anticoagulant (blue top tube) for 1 of 1 the Sysmex XN L complete blood count analyzer from 10/12/2022 to 04/18/2024. 3. TP #1 confirmed the findings above on 04/18/2024 at 12:30 pm.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

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 observation of the laboratory, lack of documentation, and interview with testing personnel (TP) #1, the laboratory failed to perform and document the maintenance/ function checks for 1 of 1 thermometer used to monitor room temperature used for storage of hematology reagents from 08/21/2020 to the day of survey. Findings Include: 1. On the day of survey, 04/18/2024 at 12:00 pm, the laboratory could not provide maintenance/function check records for the following 1 of 1 thermometer used to monitor room temperature used for storage of hematology reagents from 10/12/2022 to 04/18/2024: - TFA Dostmann : exp: 08/21/2020 2. The following hematology reagents were found to be stored in the laboratory at RT. - Sysmex SLS Sulfolyser (Storage temperature requirements 1-30 degrees Celsius) - 1 of 1 - Sysmex WDF Lysercell (Storage temperature requirements 2-35 degrees Celsius) - 2 of 2 3. The TP #1 confirmed the findings above on 04/18/2024 at 12:30 pm.