

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>52D2218240</p>	<p><b>(X3) Date Survey Completed</b></p> <p>11/15/2024</p>
<p><b>Name of Provider or Supplier</b></p> <p>Ascension Wisconsin Hospital</p>	<p><b>Street Address, City, State</b></p> <p>N88 W14275 Main St, Suite 100, Menomonee Falls, WI</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D0000</b></p>	<p>A validation survey was completed on November 15, 2024, the laboratory was found out of compliance with the CLIA regulations. The condition not met: D5024 - 42 C.F.R. 493.1215 Condition: Hematology</p>
<p><b>D5024</b></p>	<p>HEMATOLOGY 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 procedures, the Center for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form 209), test records, and manufacturer's instructions, and interview with the Laboratory Director, the laboratory did not meet the requirements specified in 493.1251, 493.1252, and 493.1283. Findings include: 1. Procedures did not provide step-by-step instructions for evaluation of hematology results identified as 'Positive' by the Sysmex XN-430 analyzer and included instructions for specimen and result manipulation that were not applicable at this laboratory. See D5403. 2. Testing Personnel who processed patient samples did not evaluate 'Positive' flagged hematology results but physician staff responsible for evaluating the results prior to result reporting were not identified as testing personnel on Form 209. See D5411. 3. The laboratory did not document the identity of the person responsible for review of 'Positive' flagged hematology results. See D5787.</p>
<p><b>D5403</b></p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 surveyor review of procedures and interview with the Laboratory Director, one of one Complete Blood Count (CBC) procedure reviewed did not provide step-by-step instructions for the review of 'Positive' flagged results from the Sysmex XN-430 analyzer and directed testing personnel to perform procedures that are not applicable to this laboratory. Findings include: 1. The 'CBC on Sysmex XN-430' procedure included steps the testing person should take after processing a sample with the Sysmex analyzer. In Section III. Operating Procedure, when the analyzer analysis is complete and the sample tube has been removed, the testing person is to review results in the IPU (information-processing unit) to determine whether repeat or reflex testing is required. Section VIII, Limitations of Procedure, C. Flagging and Action Messages, identified four flagging and action messages including suspect flags with a 'Positive' notation, error codes, user-defined flags, and action messages. The procedure referred the user to the "Sysmex XN-L Series Automated Hematology Systems Flagging Interpretation Guide" for additional information on flagging. Section VII, "Reporting Abnormal Results to Physicians" stated, "Abnormal results will be handled on a case-by-case basis based on the judgment of the emergency room physician. It is acceptable to rerun specimens, if indicated. If result verification is desired, samples may be sent to a reference lab for repeat testing." The procedure did not identify the specific steps required when handling results that the analyzer identified as 'Positive' and provided no specific instructions defining when or how the physician is notified of 'Positive' results. 2. Further review of the 'CBC on Sysmex XN-430' procedure revealed references to diluting samples and making blood smears in Section III Operating Procedure, 2. Patient Sample Processing A. Manual Analysis. Section V Procedural Notes and Calculations included, "If making a dilution of a patient specimen and running in XN-L Whole Blood mode, multiply the parameters by the dilution factor." The procedure also provided direction for recalculating and correcting indices when the HGB (hemoglobin) or HCT (hematocrit) results required correction due to interfering substances. 3. Interview with the Laboratory Director on November 15, 2024, at 11:30 AM confirmed the procedure did not provide step-by-step instructions for handling 'Positive' results from the Sysmex analyzer and confirmed testing personnel at this laboratory do not have the supplies or training to produce blood smears. Further email correspondence with the Laboratory Director on November 18, 2024, at 10:01 AM confirmed testing personnel at this site do not

perform dilutions or recalculate and correct results.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on surveyor review of manufacturer instructions and the Center for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CLIA) (Form 209) and interview with the Laboratory Director, the laboratory has not followed the manufacturer's instructions for the review of analyzer flags prior to result report from the laboratory. Findings include: 1. The manufacturer's 'Sysmex XN-L Series Flagging Interpretation Guide' stated, "All analyzer flags, error messages and results must be interpreted together and in consideration of the patient's clinical condition prior to results being reported from the laboratory." 2. Interview with the Laboratory Director on November 15, 2024, at 10:30 AM revealed a testing person who processed a patient sample with the Sysmex XN-430 would not evaluate abnormal results identified as 'Positive' by the analyzer. Further interview revealed the laboratory's process for 'Positive' flagged results required the testing person to provide the printed Sysmex analyzer results to the physician for evaluation. 3. Review of Form 209 submitted by the laboratory for this survey and signed by the Laboratory Director on November 13, 2024, showed no physicians listed as testing personnel. 4. Interview with the Laboratory Director on November 15, 2024, at 10:45 AM confirmed the director did not include physicians that evaluated hematology results with analyzer flags as testing personnel on the submitted Form 209. Further email correspondence with the Laboratory Director on November 18, 2024, at 10:01 AM revealed the physician review of the results to determine whether to order a smear review or additional testing was typically completed before the results from the analyzer were accepted and reported.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the Laboratory Director, the laboratory did not document the identity of the personnel who evaluated results flagged as 'Positive' by the Sysmex XN-430 hematology analyzer for a complete blood count (CBC) to determine whether the results were acceptable in one of one patient case reviewed. Findings include: 1. Interview with the Laboratory Director on November 15, 2024, at 10:30 AM revealed a testing person who

processed a patient sample with the Sysmex XN-430 analyzer for a CBC would not evaluate abnormal results identified as 'Positive' by the analyzer. Further interview revealed the laboratory's process for 'Positive' flagged results required the testing person to provide the printed Sysmex analyzer results to the physician for evaluation. 2. Review of laboratory records including analyzer records, the Laboratory Information System, and the Electronic Medical Record for a patient with a Sysmex 'Positive' flag showed no record of the evaluation of the flagged results, the records did not show who evaluated the results to determine whether they were acceptable or if the sample required additional testing prior to result release. 3. Interview with the Laboratory Director on November 15, 2024, at 11:00 AM confirmed the laboratory had not maintained a record system that identified who evaluated 'Positive' flagged results from the Sysmex hematology analyzer to determine whether the results were acceptable.