Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661910	(X3) Date Survey Completed 06/10/2024
Name of Provider or Supplier Ascension Wisconsin Laboratory, Inc	**Street Address, City, State** 2323 N Lake Dr, Milwaukee, WI	
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	A complaint survey was conducted on June 10, 2024. The following condition-level findings were noted: D5300 493.1240 Preanalytic Sytems D5800 493.1290 Postanalytic Sytems D6076 493.1441 Laboratory Director
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory manager, staff A, the laboratory did not monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed. Findings include: 1. The laboratory did not ensure the test requisition solicited the date and time of specimen collection. See D5305.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory

	results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory manager, staff A, the laboratory did not ensure the test requisition solicited the date and time of specimen collection for five of eight test requisitions reviewed. Findings include: 1. Review of test requisitions for patient 1 showed no date and time of specimen collection for five of the eight test requisition provided for the patient between May 11, 2024, and May 12, 2024. 2. Interview with staff A on June 10, 2024, at 10:14 AM confirmed the laboratory did not ensure the test requisitions solicited the date and time of specimen collection.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory manager, staff A, the laboratory did not monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed. See D5813 Findings include: 1. The laboratory failed to ensure that notification of authorized personnel of the test results that indicated an imminently life-threatening condition, or panic or alert value. 2. The laboratory did not follow the "Critical Result Reporting" procedure, which outlined the policy for notifying authorized personnel of test results that indicated an imminently life-threatening condition, or panic or alert values.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on survey review of laboratory records and procedures, interview with the laboratory manager, staff A, and email with the laboratory director, staff B, the

	laboratory did not follow the procedure for calling critical values and did not document notification of the test result to the authorized personnel when the test resulted indicated an imminently life-threatening condition, or panic or alert values for two of five critical values reviewed. Findings include: 1. Review of laboratory records for patient 1 showed the following: Potassium value on 05/11/2024 at 10:42 AM: 6.5 millimoles/Liter (mmol/L) with a comment of "Critical K result called to and read back by TRIED CALLING 3 TIMES-NO ANSWER." Potassium value on 05/11 /2024 at 12:46 PM: 7.7 mmol/L with a comment of "Critical K result called to and read back by TRIED CALLING 3 TIMES-NO ANSWER." 2. Review of the "Critical Result Reporting" procedure stated the following: "B. When contact cannot be established with an authorized personnel or responsible licensed caregiver, repeat the call. Note: It is recommended the associate wait no longer than 5 minutes between attempts to ensure timely communication. C. If successful contact cannot be established after this repeat call or authorized personnel/responsible licensed caregiver will note take the result, communicate the results to the on-call nurse/house manager /supervisor. D. If successful contact cannot be established with the nurse/house supervisor after multiple attempts (three), notify the on-call physician for that department/specialty (i.e. hospitalist, OB, etc ...) E. If successful contact cannot be established with the on-call hospitalist or they will not take the result, notify the hospital department chair/medical director for help identifying the right clinician who can triage the issue to the ER or another clinical environment. NOTE: If a phone number is not available for the hospital department chair, notify the on-call administrator. F. If the department chair is not available, escalate to the VPMA and/or Chief of Staff of the hospital for help identifying the right clinician who can triage the issue to the ER or another clinical environment. G. If none of these individuals respond, then call the Chief Medical Officer for help identifying the right clinician who can triage the issue to the ER or another clinical environment." 3. Further review of the "Critical Result Reporting" procedure stated the following: "1. Records must show prompt notification of a critical value or test to the appropriate, authorized personnel or responsible licensed caregiver. 2.All attempts for notification will be documented." 4. Interview with staff A on June 10, 2024, at 10:20 AM stated testing personnel, staff C, tried to call the critical value to the authorized personnel three times and was unable to reach a staff member on the phone. The laboratory decided to deliver the laboratory results to the patient care staff via pneumatic tube to the floor the patient resided. 5. Email correspondence with staff C on June 10, 2024, at 1:17 PM confirmed the results were delivered via pneumatic tube to the floor the patient resided. 6. Further interview with staff A on June 10, 2024, at 2:20 PM confirmed testing personnel did not follow the procedure for critical value reporting and the laboratory has no documentation of sending the test results via the pneumatic tube and of who received the results and what time the results were viewed by the authorized personnel responsible for using the test results.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory manager, staff A, the laboratory director failed to ensure the quality assessment (QA)

	programs established for preanalytic, postanalytic, and competency assessment identify failure as they occur. See D6082 Findings include: 1. The QA program failed to identify incomplete test requisitions prior to testing patient specimens and identify failure to follow downtime protocol . See D5300, D5305 and D6175 2. The QA program failed to identify the untimely reporting of panic values and identify failures to follow 'alert' protocols. See D5800 and D5813 3. The QA program failed to identify issues with timely competency assessment of testing personnel. See D6120
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory manager, staff A, the laboratory director did not ensure that testing systems developed and used for each of the test performed in the laboratory provided quality laboratory services for all aspects of test performance. Findings include: 1. The QA program failed to identify incomplete test requisitions prior to testing patient specimens and identify failure to follow downtime protocol. See D5300, D5305 and D6175. 2. The QA program failed to identify the untimely reporting of panic values and identify failures to follow 'alert' protocols. See D5800 and D5813. 3. The laboratory director did not ensure the technical supervisor performed competency assessment annually as required. See D6120.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of competency assessment records and interview with the laboratory manager, staff A, the technical supervisor did not evaluate semiannual and annual competency for one of one testing personnel reviewed. Findings include: 1. Review of competency assessment records for testing personnel, staff C, showed initial training and competency in December of 2022. Further review showed competency assessment in April 2024 with no additional competency assessment in 2023. 2. Interview with staff A on June 10, 2024, at 11:25 AM confirmed the technical supervisor did not evaluate semiannual and annual competency for staff C in 2023.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1)

	Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the laboratory manager, staff A, testing personnel did not follow the laboratory's procedures for specimen handling and processing for five of eight test requisitions reviewed. 1. Review of the "General Downtime Policy" stated "Ensure that Demographic /Collection/Patient location information has been completed on the downtime form. 2. Review of test requisitions for patient 1 showed no date and time of specimen collection for five of the eight test requisition provided for the patient between May 11, 2024, and May 12, 2024. Further review showed no documentation that the information was requested by testing personnel to complete the form. 3. Interview with staff A on June 10, 2024, at 10:14 AM confirmed testing personnel did not follow the laboratory's procedure for specimen handling and processing and did not solicit the date and time of specimen collection on the test requisitions.