Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396895	09/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Stanley Hospital Laboratory	1120 Pine St, Stanley, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory did not test the American Proficiency Institute (API) proficiency testing (PT) samples using the laboratory's routine methods for five of five gram stain samples in June 2024. Findings include: 1. Review of the "Microbiology Log" worksheets showed API PT samples were tested on June 6, 12, 19, 21 and 22, 2024. 2. Review of the "Micro Maintenance Log" stated "Gram Stain QC must be performed WEEKLY and PER DAY of PATIENT TESTING". Further review showed QC testing was performed June 2, 6, and 16, 2024, while QC was not performed on June 12, 19, 21 and 22, 2024, while performing the API PT samples. 3. Interview with the technical consultant on September 4, 2024, at 12:55 PM confirmed the laboratory did not test PT samples using the laboratory's routine methods for gram stains.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by:

	Based on surveyor review of the submitted Centers for Medicare and Medicaid Services (CMS) Form CMS-209 (Laboratory Personnel Report), procedures, laboratory records and competency evaluation records and interview with a technical supervisor, staff A, the laboratory did not follow written policies and procedures to assess the competence for two of two personnel designated as technical consultant, technical supervisor and general supervisor. Findings include: 1. Review of the Form CMS-209 submitted for survey showed one technical consultant, two technical supervisors (the laboratory director is the technical supervisor for immunohematology) and two general supervisors. 2. Review of laboratory procedures related to competency assessment showed the evaluation of the competence of staff A and staff B in performing their delegated responsibilities is to be performed annually by the laboratory director. 3. Review of the laboratory records showed a new laboratory director was assigned to this laboratory on May 1, 2024. 4. Review of the competency evaluation records showed the previous director had performed competency on staff A and staff B for their delegated responsibilities on March 21, 2024. Further review shoed no evidence the new laboratory director evaluated the competence of staff A and B in performing their assigned technical consultant, technical supervisor and technical consultant responsibilities. 5. Interview with staff A on September 4, 2024, at 12:35 PM confirmed the laboratory did not follow written policies and procedures to assess the competence for personnel designated as technical consultant, technical supervisor and general supervisor.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the technical consultant, the laboratory director did not approve, sign and date two of five new Stago Compact Max coagulation procedures prior to patient use. Findings include: 1. Review of verification of performance specifications on the Stago Compact Max showed the go-live date for the analyzer was September 13, 2023. 2. Review of Stago Compact Max coagulation testing procedures showed the following procedures were approved and signed by the laboratory director in November 2022. Prothrombin Time (PT) Policy and Procedure (System) Activated Partial Thromboplastin Time (aPTT) Policy and Procedure (System) STA-Liatest D-Dimer Policy and Procedure (System) Further review showed additional procedures related to the Stago Compact Max were approved and signed by the laboratory director in December 2023. Quality Control Program for Coagulation Testing (Stago Compact Max) Stago Compact Max Maintenance and Consumable Supply Replacement Procedure 3. Interview with the technical consultant on September 4, 2024, at 3:45 PM confirmed the laboratory director did not approve, sign and date new coagulation procedures prior to patient use.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, observation of reagents and interview with the technical consultant, the laboratory used expired reagents to perform gram stains for five of five specimens tested. Findings include: 1. Review of the "Micro Maintenance Log" for June 2024 showed the following: Reagent / Lot / Expiration date Crystal Violet Stain / 3031845 / 8-31-2024 Iodine / 2300388 / 5-31-2024 Decolorizer / 3320105 / 4-30-2025 Safranin Stain / 3297852 / 3-31-2025 2. Review of the "Microbiology Log" showed five American Proficiency Institute (API) proficiency testing (PT) samples were performed on June 6, 12, 19, 21, and 22, 2024. 3. Observation of the microbiology reagents on September 4, 2024, at 12:50 PM showed the following reagents available for use: Reagent / Lot / Expiration date Crystal Violet Stain / 3031845 / 08/31/2024 Iodine / 2300388 / 05/31/2024 Decolorizer / 3320105 / 04/30/2025 Safranin Stain / 3297852 / 03/31/2025 4. Interview with the technical consultant on September 4, 2024, at 12:55 PM confirmed the laboratory used expired reagents to perform gram stain testing. This is a repeat deficiency from October 4-5, 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview a general supervisor, staff B, and the chemistry lead, staff C, the laboratory did not perform calibration verification every six months for three of three chemistry analytes on the Siemens Dimension EXL chemistry analyzer. Finding include: 1. Review of Siemens Dimension EXL calibration verification records showed calibration verification was performed on sodium, potassium and chloride on March 19, 2023, November 25, 2023, and June 20, 2024. Further review showed no additional calibration verifications. 2. Review of quality control testing records showed testing was performed between September 19, 2023, when calibration verification was due, and

	November 25, 2023, and May 25, 2024, when calibration verification was due, and June 20, 2024. 3. Interview with staff B and staff C on September 5, 2024, at 12:35 PM confirmed the laboratory did not perform calibration verification every six months on the Siemens Dimension EXL chemistry analyzer. This is a repeat deficiency from October 4-5, 2022.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on survey review of a patient's chemistry test report and laboratory procedures and interview with the technical consultant, the reference ranges shown on the patient report were not the same as the approved reference ranges for twelve of fourteen chemistry analytes reviewed. Findings include: 1. Review of the reference range of a chemistry test report from September 5, 2024, in the electronic medical record (EMR) for patient 1 (an adult female) showed the following expected ranges: Analyte / Reference range Sodium / 133-144 Milliequivalents/Liter (mEq/L) Potassium / 3.5-8.0 mEq/L Chloride / 95-107 mEq/L Carbon Dioxide / 21-32 mEq/L Blood Urea Nitrogen (BUN) / 8-24 milligrams/deciliter (mg/dL) Creatinine / 0.50-1.2 mg/dL Glucose / 70-100 mg/dL Calcium / 8.6-10.4 mg/dL Aspartate aminotransferase (AST) / 11-41 International units/Liter (IU/L) Alanine transaminase (ALT) / 9-40 IU/L Alkaline Phosphatase / 35-121 IU/L Total Bilirubin / 0.2-1.2 mg/dL Albumin / 3.5-5.2 grams/deciliter (g/dL) Total Protein / 6.2-8.5 g/dL 2. Review of the "Dimension EXL-Specifications" which listed references ranges showed the approved reference ranges for an adult female are: Analyte /Reference range Sodium / 136-145 Milliequivalents /Liter (mEq/L) Potassium / 3.5-5.0 mEq/L Chloride / 98-107 mEq/L Carbon Dioxide / 21-32 mEq/L Blood Urea Nitrogen (BUN) / 7-18 milligrams/deciliter (mg/dL) Creatinine / 0.51-1.17 mg/dL Glucose / 70-99 mg/dL Calcium / 8.5-10.1 mg/dL Aspartate aminotransferase (AST) / 15-37 International units/Liter (IU/L) Alanine transaminase (ALT) / 12-59 IU/L Alkaline Phosphatase / 46-116 IU/L Total Bilirubin / 0.0-1.0 mg/dL Albumin / 3.4-5.0 grams/deciliter (g/dL) Total Protein / 6.4-8.2 g/dL Further review showed the sodium, chloride, BUN, creatinine, glucose, AST, ALT, alkaline phosphatase, total bilirubin, albumin and total protein reference ranges in the procedure did not match the patient's test report. 3. Interview with the technical consultant on September 5, 2024, at 1:35 PM confirmed the reference ranges for twelve analytes in the procedure were not the same as the test report.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 competency assessment records and interview with the technical consultant, the technical consultant did not document competency assessment for nine of nine

	testing personnel responsible for urine microscopy and wet prep testing in the laboratory in 2023. Findings include: 1. Review of competency assessments for the laboratory showed no documentation of competency assessment for urine microscopy testing in the laboratory for 2023. 2. Interview with the technical consultant on September 4, 2024, at 10: 15 AM, confirmed the technical consultant did not document competency assessment for testing personnel performing urine microscopy and wet prep testing in 2023.