

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396895	(X3) Date Survey Completed 10/17/2022
Name of Provider or Supplier Aspirus Stanley Hospital Laboratory	Street Address, City, State 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
D3021	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1)</p> <p>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a general supervisor, the laboratory's evaluation of the alarm system on the refrigerator used to store red blood cell products did not ensure the maintenance of acceptable refrigerator storage temperatures in 2021 and 2022. Findings include: 1. Review of the 'Laboratory Blood Bank Activation Temps' worksheets from March 7, 2021 through September 17, 2022 showed the high temperature set point for the alarm is 7.0 degrees Celsius (C). The records show the alarm triggered at 6.7 - 6.9 C. 2. Interview with a general supervisor (staff A) on October 5, 2022 at 1:00 PM confirmed the 7.0 degree C high alarm set temperature for the refrigerator would not ensure blood products are kept at appropriate storage temperatures (1 - 6 degrees C) to prevent deterioration.</p>
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of blood administration procedures and transfusion records and interview with a general supervisor, the facility did not promptly identify a potential transfusion reaction and did not notify the Food and Drug Administration (FDA) of a fatality that occurred during a transfusion when signs were present of a potential transfusion reaction. Findings include: 1. The policy, 'Guidelines for Blood Administration and Monitoring', revision date November 2018, included a 'Signs and Symptoms to Watch For' section that listed indicators of a potential transfusion reaction; the list includes tachycardia. The policy outlined immediate actions to take when signs and symptoms indicate a potential transfusion reaction. The first action listed is "Stop the transfusion". 2. Review of a 'Blood Transfusion / Blood Bank Products' form showed patient 1 received a unit of blood on January 5, 2022. The record showed the time started was 1400 (2:00 PM). Personnel documented the time the transfusion was stopped as 1515 (3:15 PM), and 'Reaction to Transfusion (No)' is marked 'No'. 3. Review of the vital signs record for patient 1 on January 5, 2022 showed the patient's heart rate was 84 at 2:00 PM, 100 at 2:24 PM, 170 at 2:49 PM and 162 at 2:59 PM. There is no indication the transfusion was immediately stopped when the heart rate increased to 170 at 2:49 PM. 4. The laboratory provided no evidence of an evaluation of the tachycardia that occurred during the transfusion or notification to the FDA of a potential transfusion related fatality. 5. Email communication with a general supervisor (staff A) on October 13, 2022 at 11:28 AM included the following statement, "there was no indication of death related to the transfusion" and on October 17, 2022 at 9:15 AM, "There are no indications of a transfusion reaction or any issues with the blood." Additional documentation provided by staff A showed no evaluation of the tachycardia that occurred during the transfusion to determine whether a transfusion reaction occurred.

D5026

IMMUNOHEMATOLOGY
CFR(s): 493.1217

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on surveyor review of procedures and interview with laboratory personnel, the laboratory has not met the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299 for immunohematology. Findings include: 1. The laboratory did not have a procedure for evaluating and resolving discrepancies between ABO forward and reverse typing results. See D5401. 2. The laboratory did not ensure nursing staff evaluated recipient vital signs to identify a potential transfusion reaction. See D5559. 3. The laboratory did not ensure the relationship between ABO forward and reverse types were in agreement before reporting a patient ABO blood type and transfusing blood products. See D5777. The deficiencies identified in this condition level citation resulted in a finding of immediate jeopardy at the time of the on-site survey. The immediate jeopardy determination has since been removed.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(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.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with a general supervisor, the laboratory did not have a procedure that identified the steps testing personnel take when testing shows a discrepant result between ABO forward (red cell) and reverse (serum or plasma) typing. Additionally, the ABO test procedure did not show the expected forward and reverse results for common blood types. Findings include: 1. Review of laboratory procedures showed no evidence of a procedure for resolving discrepant ABO test results. The Ascension 'ABO/Rh Patient Typing - Gel' procedure, 'Interpretation' section stated, "ABO serum and ABO red cells grouping should always agree. Discrepancies between forward and reverse grouping should be resolved." The interpretation section defined negative and positive results; the procedure did not identify the expected forward and reverse types for common ABO blood types. 2. Interview with a general supervisor (staff A) on October 4, 2022 at 3:40 PM confirmed the laboratory did not have a procedure for resolving ABO blood typing discrepancies.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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 the 'LAB D dimer' procedure and interview with the technical consultant, the laboratory procedure for D dimer did not include requirements for calibration or calibration verification. Findings include: 1. Review of the Ascension 'LAB D dimer' procedure showed no reference to calibration or calibration verification requirements. 2. Interview with a technical consultant (staff A) on October 5, 2022 at 11:35 AM confirmed the 'LAB D dimer' procedure did not include calibration or calibration verification requirements. This is a repeat deficiency, D5403 was cited on February 16, 2021.

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 surveyor review of laboratory records and interview with a technical supervisor and testing personnel, the laboratory used potassium hydroxide (KOH) reagent five months after the expiration date and used two of three hematology stain solutions three months after the expiration dates. 1. Review of 'KOH/Wet Prep Patient and QC Log' showed KOH lot number 96370 expired on February 7, 2022 and testing personnel used the expired reagent for patient testing in April and July 2022. 2. Review of the 'XN-550 Maintenance Log' showed personnel recorded the current stain lot number and expiration dates on the log. The logs showed the following lot numbers and expiration dates were in use in from May to August 2022: May 2022 Log (Solution / lot number / expiration date) Fixative / 107309E / May 2022 Solution A / 114082 / December 2022 Solution B / 107716E / May 2022 June 2022 Log Fixative / 108423E / June 2022 Solution A / 114082 / December 2022 Solution B (no entry) July 2022 Log Fixative / 108423E / June 2022 Solution A / 114082 / December 2022 Solution B (no entry) August 2022 Log Fixative / 107309E (same lot number as used in May, expired May 30, 2022, the expiration date is not shown on log) Solution A / 114082 (expiration not shown) Solution B / 107716E (same lot number as used in May, expired May 30, 2022, the expiration date is not shown on log) 3. Interview with testing personnel (staff B) on October 5, 2022 at 10:45 AM confirmed testing personnel used expired hematology stains for patient testing in July and August 2022. Interview with a technical supervisor (staff A) on October 5, 2022 at 10:00 AM confirmed testing personnel used expired KOH reagent for testing in April and July 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:

Item 1: Based on surveyor review of laboratory records and interview with a general supervisor, the laboratory did not meet the six-month requirement for calibration verification for D dimer testing and performed testing on ten days after calibration verification was due. Findings include: 1. Review of calibration records for the D dimer test on the CA1500 analyzer showed calibration of a new lot of reagents on August 11, 2022 (lot 569X17). Testing personnel performed the previous calibration on January 30, 2022 (lot 569X05). There are no records of a calibration or calibration verification after January 30 and prior to August 11, 2022. 2. Review of quality control testing records showed performance of testing after July 30, 2022 when the calibration verification was due. Personnel performed testing on July 31, 2022, August 1, 3, 4, 5, 6, 7, 8, 10 and 11, 2022 before personnel calibrated and started using the new lot of reagents on August 11, 2022. 3. Interview with a general supervisor (staff C) on October 5, 2022 at 11:35 AM confirmed the laboratory did not perform a D dimer assay calibration or calibration verification within six months of the previous calibration. Item 2: Based on surveyor review of laboratory records and interview with a general supervisor, neither of the two calibration verification events in 2022 included 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 Dimension electrolyte (Sodium, Potassium and Chloride) tests. Findings include: 1. Review of calibration verification records for the Dimension analyzer in 2022 showed the laboratory performed correlations with a second laboratory using low and high patient samples in February and August. Review showed no other calibration verification records for the electrolyte tests on the Dimension analyzer in 2022. 2. Interview with a general supervisor (staff C) on October 5, 2022 at 1:30 PM confirmed the laboratory did not perform calibration verification using 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 at least once every 6 months in 2022. D5439 is a repeat deficiency previously cited on September 8, 2010 and September 21, 2012.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and procedures and interview with a technical consultant, the laboratory did not test two levels of external controls on three days in February 2022 when the laboratory tested fourteen patient troponin tests using the iSTAT system. Findings include: 1. Review of 'ABG & Chemistry Log - Patients' logs from February 2022 showed testing personnel performed troponin testing on the iSTAT analyzer on: Date / number of patient tests February 13 / 4 February 14 / 7 February 15 / 3 2. The 'LAB iSTAT Controls' procedure stated in the 'cTNI Controls' section, "Run level 1 and 3 once per day of patient testing". 3. Review of laboratory procedures showed no evidence of an Individualized Quality Control Plan (IQCP) for

testing performed on the iSTAT analyzer. 4. Interview with a technical consultant (staff A) on October 5, 2022 at 12:15 PM confirmed the laboratory had not developed an IQCP for Troponin tests on the iSTAT analyzer. Further interview confirmed the laboratory used the iSTAT for fourteen patient troponin tests on three days in February without performing two levels of external controls each day of patient testing.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory procedures and records and interview with testing personnel, the laboratory did not test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing for blood gases using the iSTAT EG6+ cartridge in 2021 or 2022. Findings include: 1. The 'LAB iSTAT Controls' procedure stated in the 'Tri controls' section, "EG6+ (gases) all 3 levels run approximately every 5 days or when controls or cartridges expire and / or once per day of patient testing". The laboratory last revised the procedure on January 14, 2021. 2. Review of laboratory documents showed no evidence of an Individualized Quality Control Plan (IQCP) for EG6+ testing on the iSTAT analyzer. 3. Review of quality control (QC) records on May 20, 2022 showed personnel tested three levels of control material with the EG6+ cartridges on the iSTAT analyzer: Lot 301136 at 1:42 AM, lot 311141 at 1:50 AM, and lot 321141 at 2:10 AM. No other QC record documentation was available from May 20, 2022. 4. Review of 'ABG & Chemistry Log - Patients' showed personnel tested patient samples using the EG6+ cartridges on the iSTAT analyzer on May 20, 2022 at 1:30 AM, 10:47 AM, 1:34 PM and 2:24 PM. 5. Interview with testing personnel (staff B) on October 5, 2022 at 2:15 PM confirmed the laboratory had not developed an IQCP for the iSTAT analyzer testing and confirmed personnel did not perform one level of QC testing for the EG6+ cartridge every eight hours of patient testing. This is a repeat deficiency previously cited on July 24, 2014.

D5559

IMMUNOHEMATOLOGY
CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on surveyor review of blood administration procedures and transfusion records and interview with a general supervisor, nursing personnel did not identify tachycardia (increased heart rate) in a patient as a potential indicator of a transfusion reaction and quality review procedures in the laboratory did not ensure potential indicators of transfusion reactions were identified to ensure the safety of individuals being transfused. Findings include: 1. The policy, 'Guidelines for Blood Administration and Monitoring', revision date November 2018, included a 'Signs and Symptoms to Watch For' section that listed indicators of a potential transfusion reaction. The list includes tachycardia. 2. Review of a 'Blood Transfusion / Blood Bank Products' form showed patient 1 received a unit of blood on January 5, 2022. The record showed the time started was 1400 (2:00 PM). Personnel documented the time the transfusion was stopped as 1515 (3:15 PM), and 'Reaction to Transfusion (No)' is marked 'No'. 3. Review of the vital signs record for patient 1 on January 5, 2022 showed the heart rate was 84 at 2:00 PM, 100 at 2:24 PM, 170 at 2:49 PM and 162 at 2:59 PM. There is no indication the transfusion was immediately stopped when the heart rate increased to 170 at 2:49 PM. 4. Email communication with a general supervisor (staff A) on October 17, 2022 at 9:15 AM included the following statement, "There are no indications of a transfusion reaction or any issues with the blood." Additional documentation provided by staff A showed no evaluation of the tachycardia that occurred during the transfusion to determine whether a transfusion reaction occurred.

D5777

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(b)(c)

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory procedures, manufacturer's instructions, and testing records and interview with a general supervisor, the laboratory did not ensure the confirmatory ABO serum (reverse) typing results matched the red blood cell (forward) typing results on two of two days the laboratory performed ABO blood group testing on patient one. Findings include: 1. The 'Blood Bank LAB ABO/RH Patient Typing - Gel' procedure stated in the 'Interpretation' section, "ABO serum and ABO red cells grouping should always agree. Discrepancies between forward and reverse grouping should be resolved." The procedure described the appearance of a positive and negative result in the gel system but did not include instructions for determining the ABO forward or reverse type from the results of the individual tests. 2. The manufacturer's instructions 'ID-Micro Typing System Interpretation Guide, ABO and Rh Card Interpretations' stated, "ABO discrepancies are resolved in the usual manner according to the facility's Standard Operating Procedures (SOPs)." 3. Review of testing records showed patient one had ABO typing performed on December 27, 2021. The results of the cell typing were: Anti A: negative Anti B: 4+ Results of the serum typing were: A1 cells: negative B cells: weak positive The worksheet showed a second testing person repeated the testing with the same results. Both records showed testing personnel interpreted the results as Type B. Further review of records showed patient one had a second ABO typing performed on January

5, 2022. The test results were the same as the results on December 27, 2021. A second testing person repeated the testing and obtained the same results. The record showed both personnel interpreted the result as Type B. The record showed no other testing to resolve the discrepant forward and reverse type results. 4. Interview with a general supervisor (staff A) on October 4, 2022 at 3:40 PM confirmed the reverse typing results for a patient with type B red cells were expected to be positive with A1 cells and negative with B cells. Further interview confirmed the results of the red cell typing and the serum typing did not match for patient one and that the laboratory did not perform additional testing to resolve the discrepant results.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of 'LabLink xL Exception Notes Reports' and interview with testing personnel, the laboratory did not document corrective actions taken when the reports showed results met flagging criteria in three of three months reviewed in 2022. Findings include: 1. Review of January, July, and August 2022 'LabLink xL Exception Notes Reports' showed testing personnel (Staff D) initialed and dated the reports. The reports show no evidence staff D reviewed or evaluated the results that the provider flagged on the report. The reports showed no documented corrective actions. Review of reports from three months in 2022 revealed the provider identified the following: January 2022 Creatine Kinase - MB fraction (CK-MB): The report included thirty-two 'P' and one 'G' flagged results, additionally the report included a total error notification and showed the assay had an SDI (standard deviation index) of -3.44 which is outside the expected range of -2.0 to 2.0. N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP): three P flags July 2022: Total Cholesterol: one 'P' flag Glucose: one 'P' flag Sodium: one 'P' flag and a Total Error notification August 2022: Cholesterol: one 'P' flag Triglyceride: three 'P' flags Lactic Acid: one 'L' flag Aspartase Aminotransferase (AST): one 'L' flag Magnesium: one 'L' flag, Blood Urea Nitrogen: Total Error Notification The reports included the following definitions and notes from the provider: "The flags above are based on the statistical analysis of your data compared to your test system peer and do not necessarily indicate a quality control problem. See Individual Lab Report for additional detail." Flag L: "This value has flagged the laboratory outlier check, which highlights values more than +/- 3 standard deviations from the lab's mean for the month." Flag P: "This value has flagged the Peer Outlier Check, which highlights values more than +/- 3SD from the peer's mean for the month. Flag G: "This value has flagged the Gross Outlier Check, which checks for data points that fall outside of the package insert or peer range." 2. Interview with testing personnel (staff D) on October 5, 2022 at 1:30 PM revealed individual testing personnel in the laboratory were not consistent in documenting corrective action for out-of-range quality control results and staff D confirmed they did not document corrective actions in response to flagged results and total error notifications on LabLink XL exception note reports.

D6069

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(a)

Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and test records and interview with a technical consultant, three testing personnel each performed a potassium hydroxide (KOH) patient test after the procedure was discontinued on March 2, 2022. Findings include: 1. Review of laboratory procedures showed the 'Microbiology Lab KOH' test procedure was in a binder of discontinued microbiology procedures. The binder label showed the procedures were "No Longer in Use" with a discontinuation date of March 2, 2022. 2. Review of 'KOH / Wet Prep Patient and QC Log' showed records of three KOH tests performed after March 2, 2022. Three different testing personnel performed KOH testing on April 5 and 6 and July 7, 2022. 3. Interview with a technical consultant on October 5, 2022 at 10:00 AM confirmed the laboratory discontinued performance of the KOH test as of March 2, 2022 and confirmed three testing personnel performed KOH testing after the laboratory discontinued the test and the test was no longer authorized by the laboratory director.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of procedures, quality control (QC), and patient test records and interview with testing personnel, testing personnel did not perform external quality control testing on the EG6+ cartridge on one of six days of testing in June 2022 on the i-STAT analyzer. Findings include: 1. The 'LAB iSTAT Controls' procedure stated in the 'Tri controls' section, "EG6+ (gases) all 3 levels run approximately every 5 days or when controls or cartridges expire and / or once per day of patient testing". 2. Review of QC records from June 2022 for the i-STAT analyzer EG6+ cartridge showed testing personnel performed external QC testing on June 1, 18, 22, 29, and 30. 3. Review of patient EG6+ test records showed testing personnel performed one patient blood gas test on June 5, 2022 in addition to the five other days when controls were tested. 4. Interview with testing personnel (staff B) on October 5, 2022 at 2:15 PM confirmed testing personnel had not followed the laboratory's procedures and did not perform QC testing for the EG6+ cartridge before performing patient testing on June 5, 2022.

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 proficiency testing and laboratory records and procedure manuals and interview with personnel, the director did not provide overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The director did not ensure proficiency testing results were reviewed to identify unacceptable results and evaluate the laboratory's performance. See D6091. 2. The director did not ensure the maintenance of the quality assurance program through the documented monitoring of laboratory worksheets to ensure testing personnel correctly interpreted testing results and completed testing as required. See D6094. 3. The director did not ensure that appropriate procedures were available for testing personnel and that procedures were approved. See D6106.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on surveyor review of proficiency testing (PT) records and interview with the technical supervisor, the laboratory director did not ensure the laboratory reviewed and evaluated performance to identify problems that required corrective action and the laboratory did not document the evaluation of five of fifteen analytes reviewed that the PT program scored as not acceptable. Findings include: 1. Review of PT records showed no documentation of evaluation of the following PT results with analyte scores less than 100%: 2021 Event one Bacteriology. 75% score on sensitivity testing. Sample UR-01; Clindamycin and Erythromycin were reported for a Methicillin Resistant Staphylococcus in a urine culture when the PT program showed the antibiotics were not appropriate. 2021 Event two Sodium. 80% score, sample CH-09 was unacceptable. 2022 Event one Acetaminophen 80% score, sample CH-04 was unacceptable. Total Iron binding capacity (TIBC) 80% score, sample CH-04 was unacceptable. Serum HCG (human chorionic gonadotropin) 80%, sample HCG-02 was unacceptable. 2. Interviews with the technical supervisor on October 4, 2022 at 10:25 AM and 11:30 AM confirmed the laboratory had not reviewed the five identified unacceptable results.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview with a technical supervisor, the laboratory director had not ensured the quality assessment program was maintained including review of intermediate testing worksheets in the laboratory. Findings include: 1. Review of blood bank worksheets from 2021 and 2022 showed

no documented review to ensure testing personnel completed testing as required and interpreted results appropriately. 2. Interview with the technical supervisor on October 5, 2022 at 1:45 PM confirmed the review of blood bank worksheets was not documented and the quality assessment program was not maintained.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory procedure manuals and interview with a technical supervisor, the laboratory director did not ensure that four of six microbiology procedures were approved by the laboratory director, and one of the six procedures was not applicable to testing performed in the laboratory. Findings include: 1. Review of procedures in the microbiology manual showed a mixture of procedures for Ascension (two procedures) and Aspirus (four procedures) laboratories. There was no evidence of review or approval of the following four Aspirus procedures by the laboratory director: Gram Stain Policy / Procedure (System) Culture Procedures for Initial Setup (System) Blood Culture Subculture and Reporting Policy/Procedure Fecal Leukocytes Policy/Procedure (System) 2. Review of the 'Blood Culture Subculture and Reporting Policy/Procedure' showed the procedure provided instructions for setting up, loading blood culture bottles onto instrumentation, and processing positive blood cultures. The Aspirus Stanley Hospital is identified in the list of sites that the procedure applies to, but the laboratory does not incubate blood cultures or process positive blood culture samples. The procedure showed no evidence of review or approval by the laboratory director. 3. Interview with a technical supervisor on October 5, 2022 at 8:30 AM confirmed the laboratory director had not ensured procedures available to staff applied to testing performed in the laboratory and had not ensured the procedures were approved.