Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396895	02/16/2021
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
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant, the laboratory failed to attain satisfactory performance in PT for the Compatibility Testing subspecialty in the Immunohematology specialty for event two in 2020. Findings include: 1. Review of PT records in the federal CASPER reporting system showed the laboratory had unsatisfactory performance for Compatibility Testing subspecialty on event two in 2020. A score of 100% is required for satisfactory performance for compatibility testing. a. Event 2020-2: 80% 2. Review of API PT evaluation report confirmed the unsatisfactory performance for compatibility Testing subspecialty in the Immunohematology specialty for event two in 2020. 3. Interview with the technical consultant on February 15, 2021 at 10:30 AM, confirmed the laboratory did not attain satisfactory performance in PT for the Compatibility Testing subspecialty in the Immunohematology specialty for event two in 2020. This is a repeat deficiency from June 9, 2005.
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 patient and proficiency testing (PT) records and blood bank procedures and interview with the technical consultant, the blood group typing procedures did not provide step-by-step instructions for performing repeat typing on all blood bank specimens. Findings include: 1. Review of the blood bank patient testing log showed the laboratory repeats all blood group typing results for all patient visits. 2. Review of the PT records showed the laboratory repeats blood group typing results for all PT samples. 3. Review of the blood group typing procedures showed no instructions to repeat blood typing results for all patient visits and PT samples. 4. Interview with the technical consultant on February 16, 2021 at 2:15 PM, confirmed the blood group typing procedure did not provide step-by-step instructions for performing repeat blood group typing on all blood bank specimens.