

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0676492	(X3) Date Survey Completed 02/03/2022
Name of Provider or Supplier Min No Aya Win Human Services Center	Street Address, City, State 927 Trettel Lane, Cloquet, MN	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish a written procedure for correcting test result reporting errors. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 02/03/22. 2. A written procedure for correcting test result reporting errors was not found in laboratory documents. 3. The laboratory was unable to provide a procedure for this process upon request. 4. The laboratory performed approximately 8736 tests annually as indicated on the Clinic</p>

Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 5. In an interview at 2:00 p.m. on 02/03/22, the LD confirmed the above finding. .

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to retain the original test result information when a corrected report was generated. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, and Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:05 a.m. on 02/03/22. 2. A written procedure for correcting test result reporting errors was not found in laboratory documents. See D5403. 3. The laboratory performed approximately 8736 tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 4. In an interview at 2:00 p.m. on 02/03/22, the LD indicated the original test result information was not retained when an test report error was corrected.