

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395561	(X3) Date Survey Completed 05/18/2023
Name of Provider or Supplier Aspirus Plover Clinic - Plover Road	Street Address, City, State 2401 Plover Rd, Plover, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory supervisor, staff A, the laboratory did not retain the lot and expiration date for the hematology reagent stains used for manual differentials for sixteen of seventeen months reviewed in 2022 and 2023. Findings include: 1. Review of the hematology maintenance log showed no documentation of hematology stain lot or expiration date information from January 1, 2022, until April 20, 2023. 2. Interview with the staff A on May 18, 2023, at 10:20 AM confirmed the laboratory did not retain the lot and expiration dates from the hematology stain used for manual differentials.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory supervisor, staff A, the laboratory did not document the reactivity of the hematology</p>

stain on days of use for hematology manual differential testing for sixteen of seventeen months reviewed in 2022 and 2023. Findings include: 1. Review of the hematology daily maintenance logs for 2022 and 2023 showed no evidence of documentation showing the hematology stain was evaluated for intended reactivity each day of patient use from January 1, 2022, until April 20, 2023. 2. Interview with the staff A on May 18, 2023, at 10:20 AM confirmed the laboratory did not document the reactivity of the hematology stain for hematology manual differential testing on days of patient testing.

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 Basic Metabolic Panel (BMP) test report and laboratory procedures and interview with the laboratory supervisor, staff A, the reference ranges shown on the patient report was not the same as the approved reference ranges for two of eight chemistry analytes reviewed. Findings include: 1. Review of the reference range of the BMP test report from May 18, 2023, in the electronic medical record (EMR) for patient one (an adult female) showed the following expected ranges: Analyte/Reference range Sodium/133-144 milliequivalents /liter (mEq/L) Potassium/3.5-5.0 mEq/L Chloride/95-107 mEq/L Carbon Dioxide/21-32 mEq/L Blood Urea Nitrogen/8-24 milligrams/deciliter (mg/dL) Creatinine/0.5-1.2 mg/dL Glucose/70-100 mg/dL Calcium/8.6-10.4 mg/dL 2. Review of the individual analyte "Xpand" chemistry procedures showed the approved reference ranges for an adult female are: Analyte/Reference range Sodium/133-144 mEq/L Potassium/3.5-5.0 mEq/L Chloride/98-107 mEq/L Carbon Dioxide/21-32 mEq/L Blood Urea Nitrogen/8-24 mg/dL Creatinine/0.5-1.2 mg/dL Glucose/65-100 mg/dL Calcium/8.6-10.4 mg/dL Further review showed the glucose and chloride reference ranges in the procedures did not match the patient's test report. 3. Interview with the staff A on May 18, 2023, at 12:40 PM confirmed the reference ranges in the EMR were not consistent with the approved reference ranges in the procedures.

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:
Item 1 Based on surveyor review of laboratory procedures, Individualized Quality Control Plan (IQCP), quality control (QC) logs and laboratory information system (LIS) test reports and interview with the laboratory supervisor, staff A, testing personnel did not perform and document QC for the serum human chorionic gonadotropin (HCG) qualitative test every thirty days according to the procedure and IQCP from January 8, 2022, through March 17, 2022. Findings include: 1. Review of the "Cardinal hCG Combo Rapid Test Procedure" and IQCP stated testing personnel

must test a positive and negative serum-based control "with each new shipment, new lot, and at a minimum, every 30 days". 2. Review of the "HCG-Plover Lab" QC logs showed: a. QC was performed January 8, 2022, and March 17, 2022, with no additional QC performed between those dates. QC was due to be performed February 8, 2022. 3. Review of patient reports from the LIS showed one patient test was performed on March 9, 2022. 4. Interview with staff A on May 18, 2023, at 11:10 AM confirmed testing personnel did not perform and document quality control for the serum HCG qualitative test every thirty days according to the procedure and IQCP.

Item 2 Based on surveyor review of laboratory procedures, Individualized Quality Control Plan (IQCP), quality control (QC) logs and laboratory information system (LIS) test reports and interview with the laboratory supervisor, staff A, testing personnel did not perform and document QC for the infectious mononucleosis test every thirty days according to the procedure and IQCP from January 8, 2022, through March 17, 2022. Findings include: 1. Review of the "Monospot-OSOM Mono Test" procedure and IQCP stated "Two levels of external controls are to be run with every new lot, new shipment and every 30 days thereafter." 2. Review of the "Mono-Plover Lab" QC logs showed: a. QC was performed January 8, 2022, and March 17, 2022, with no additional QC performed between those dates. QC was due to be performed February 8, 2022. 3. Review of patient reports from the LIS showed one patient test was performed on March 10, 2022. 4. Interview with staff A on May 18, 2023, at 11:10 AM confirmed testing personnel did not perform and document quality control for the infectious mononucleosis test every thirty days according to the procedure and IQCP.