

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0641837	(X3) Date Survey Completed 04/06/2021
Name of Provider or Supplier Providence Valdez Medical Center	Street Address, City, State 911 Meals Avenue, Valdez, AK	
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
D0000	The laboratory is in substantial compliance with the CMS Interim Final Rule (CMS-3401-IFC) on Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) effective August 25, 2020. No deficiencies were cited.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) results and technical supervisor interview, the laboratory failed to document the acceptability of PT results when these results were not evaluated or scored by the PT provider for all non-scored analytes in the 2020 Hematology/Coagulation and Microbiology surveys. Findings include: 1. The laboratory subscribes to the American Proficiency Institute (API) for proficiency testing. 2. In the Hematology/Coagulation surveys the following samples were not scored and did not have documented review for acceptability: a. 2020 first event: Educational Blood Cell ID (DIF-01), Fecal Leukocytes (FW-01) b. 2020 second event: Educational Blood Cell ID (DIF-02, ECI-06, ECI-07, ECI-08, ECI-09, ECI-10) c. 2020 third event: Educational Blood Cell ID (DIF-03, ECI-11, ECI-12, ECI-13, ECI-14, ECI-15) and Urine Sediment (US-06) 3. In the Microbiology surveys the following samples were not scored and did not have documented review for acceptability: a. 2020 first event: Educational Susceptibility (ES-01), Blood Culture MIC/Interpretation (BL-01) b. 2020 second event Educational Susceptibility (ES-02),</p>

Urine Culture MIC/Interpretation (UR-06) c. 2020 third event: Educational Susceptibility (ES-03), Urine Culture MIC/Interpretation (UR-11) 4. The technical consultant confirmed these findings on 4/6/21 at 11:00 am.

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 procedure review and technical supervisor interview the laboratory did not have a written procedure for the analysis of urine sediment. Findings include: 1. The laboratory performs approximately 350 urine sediment analyses annually. 2. The technical supervisor confirmed the laboratory did not have a written procedure for performing urine sediment analysis 4/6/2021 at 11:30 am.

D5551

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

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 review of blood bank testing records and Technical Supervisor interview, the laboratory failed to perform ABO grouping and Rh typing on one of five (1/5) records reviewed for compatibility transfusion testing. Findings include: 1. The laboratory procedure titled "Compatibility Testing" states "Full forward and reverse ABO and Rh typing must be completed on the patient sample, containing two patient identifiers and blood bank ID ban number (BBID), and obtained within 72 hours of transfusion." 2. Patient record (MRN 1078519) did not have documentation of ABO and Rh testing on the sample used for compatibility testing. 3. The laboratory performs approximately 100 Immunohematology tests annually 4. The technical supervisor confirmed these finding on 4/6/21 at 11:00 am.

D5555

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

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and

blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of Immunohematology refrigerator temperature records and Technical Supervisor interview, the laboratory failed to check and document the immunohematology refrigerator alarm on a regular basis. Findings: 1. The laboratory stores blood, blood products, and reagents in the immunohematology refrigerator. 2. There was no documentation in 2019 or 2020 verifying the temperature at which the audible alarm system will alert or sound was checked. 3. The laboratory performs approximately 100 immunohematology tests annually. 4. The technical consultant confirmed these findings on 4/6/21 at 11:00 am.