

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520357	(X3) Date Survey Completed 03/12/2021
Name of Provider or Supplier Pocatello Children's Clinic	Street Address, City, State 1151 Hospital Way Bldg F, Pocatello, ID	
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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on a random review of laboratory temperature logs and an interview with the technical supervisor (TS) on 3/12/2021, the laboratory failed to document corrective actions taken when specimen and reagent storage temperatures are outside of the acceptable ranges for the laboratory refrigerator and freezer. The findings include: 1. A random review of laboratory temperature logs identified that the laboratory failed to document corrective actions for the freezer used to store BD Taxo A Bacitracin Discs (-20 to 8C) and Piccolo CRP calibrators (-15C or less) when it was not within the established range of -15 to -20C for 25 of 25 days in January 2020 and 24 of 24 days in February 2020. 2. A random review of laboratory temperature logs identified that the laboratory failed to document corrective actions for the refrigerator used to store patient samples, Piccolo CRP reagents(2-8C), Piccolo Direct Bilirubin reagents (2-8C) and Medonic Boule CON-DIFF tri-level controls (2-8C) when it was not within the established range of 2-8C for 6 of 25 days in January 2020 and 11 of 24 days in February 2020. 3. An interview with the TS on 3/12/2021 at 12:20 pm confirmed that the laboratory failed to document corrective actions for the freezer and refrigerator when they were not within the established ranges. 4. The laboratory reports performing 24,835 tests annually.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification,</p>

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of laboratory patient reports and an interview with the technical supervisor (TS) on 3/12/2021, the laboratory failed to identify the name and address of the reference laboratory performing the reported tests. The findings include: 1. A review of laboratory patient test reports identified that the laboratory failed to include the name and address of the the performing laboratory when patient testing was sent to and performed by Portneuf Medical Center. 2. An interview with the TS on 3/12 /2021 at 12:41 pm confirmed that the patient report did not contain the name and address of their reference laboratory, Portneuf Medical Center, when they are the performing laboratory.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of training documentation and competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview on 3/12/2021 with the Technical Supervisor (TS), the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1451(b)(7)(8). The findings include: 1. A review of competency assessment records identified that one (1) of four (4) testing personnel listed on the CMS 209 failed to have documentation of the TS evaluating competency for 2019 and (1) of four (4) testing personnel listed on the CMS 209 failed to have documentation of the TS evaluating competency for 2020. 2. A review of competency assessment records identified that the TS failed to have the laboratory director evaluate the TS testing competency assessment for 2019. 3. An interview with the TS on 3/12/2021 at 9:20 am confirmed that the TS was not the individual that evaluated all of the testing personnel's competency. 4. The laboratory reports performing 24,835 tests annually.