

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520357	(X3) Date Survey Completed 05/12/2022
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, Piccolo quality control (QC) logs and an interview with the laboratory general supervisor (GS) on 5/12/2022, the laboratory failed to perform QC with the frequency required by the manufacturer for direct bilirubin and c-reactive protein (CRP) testing . The findings include: 1. A review of the laboratories Individualized Quality Control Plan ((IQCP) for direct bilirubin and CRP testing on the Piccolo identified that QC must be performed with each new lot and at least every 30 days as per manufacturer. 2. A review of the Piccolo QC logs identified that the laboratory failed to perform direct bilirubin QC in January, February, and April of 2022. 3. A review of the Piccolo QC logs identified that the laboratory failed to perform CRP QC in January and February of 2022. 4. An interview with the GS on 5/12/2022 at 1045 am confirmed the above findings.</p>