

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0522371	<b>(X3) Date Survey Completed</b>  07/13/2023
<b>Name of Provider or Supplier</b>  Bonner General Health	<b>Street Address, City, State</b>  520 N Third Ave, Sandpoint, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> 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 lack of quality control (QC) documentation and an interview with the laboratory manager on 7/13/2023, the laboratory failed to perform QC for serum beta-human chorionic gonadotropin (-hCG) testing. The findings include: 1. A review of the qualitative -hCG testing QC logs identified that the laboratory failed to perform serum -hCG testing QC in 2022 and 2023. 2. An interview with the laboratory manager on 7/13/2023 at 10:43 am confirmed the above findings. 3. The laboratory reports performing 357 qualitative serum -hCG tests annually.</p>