Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522371	08/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bonner General Health	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory manager on 8/13/2025, the laboratory failed to follow written procedures to assess testing personnel competency in 2024 and 2025. The findings include: 1. The CMS 209 identified 46 testing personnel (TP) performing moderate and high complexity testing of which 28 are only performing point of care (POC) testing. 2. A review of laboratory procedures identified that the laboratory established a procedure to assess TP initial training, semiannual and annual competency. 3. A review of training and competency assessment records identified that the laboratory failed to have initial training for six (6) POC TP in 2024 and three (3) POC TP in 2025. 4. A review of training and competency assessment records identified that the laboratory failed to have six month competency assessments for five (5) POC TP in 2024 and one (1) POC TP in 2025. 5. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for two (2) POC TP in 2024. 6. An interview with the laboratory manager on 8/13/2025 at 10:04 am confirmed that the above training and competencies were missing for TP performing testing on the EPOC instrument. 7. The laboratory reports performing 707,003 tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a random record review of Quality Control (QC) documentation, patient test records and an interview with the laboratory manager on 8/14/2025, the laboratory failed to successfully perform two levels of QC daily for chemistry in 2024. The findings include: 1. A random record review of QC from the two OrthoVitros XT 7600 analyzers identified that the laboratory failed to perform QC on 7/20/2024 for one of two analyzers for chemistry analytes. 2. A review of patient test records for 7 /20/2024 identified two patients for which the laboratory failed to perform QC prior to reporting results. Sample ID BG025477 had a complete metabolic panel and troponin results released and sample ID BG025476 had troponin results released. 3. An interview with the laboratory manager on 8/14/2025 at 3:08 pm confirmed that the laboratory failed to have acceptable chemistry QC for one of two Vitros analyzers on 7 /20/2025 prior to reporting patient test results. 4. The laboratory reports performing 457,679 chemistry tests annually.