Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0056658	11/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Boundary Community Hospital	6640 Kaniksu St, Bonners Ferry, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to enroll in a PT program that covers all testing performed in the specialty of bacteriology since the last survey on March 2, 2017. Findings: 1. A record review of the American Association of Bioanalysts (AAB) PT documents revealed the laboratory failed to properly enroll for all testing performed in the bacteriology laboratory to include: interpretation of gram stains, isolation and identification of aerobic organisms from any source and antimicrobial susceptibility tests. 2. An interview on November 14, 2018 at 9:15 A.M., with the laboratory manager, confirmed the microbiology laboratory failed to enroll for all microbiology testing activities for the isolation and identification aerobic microorganism.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the

	laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record reviews and an interview with the laboratory manager, the laboratory director failed to sign the attestation statements from the American Association of Bioanalysts (AAB) for the specialty of Hematology, Chemistry, Immunohematology, Immunology, Endocrinology, Toxicology, and Bacteriology since last survey on March 2, 2017 Findings: 1. An AAB PT record review from 2017 and 2018, revealed the laboratory director failed to sign the attestation statements for the specialty of Hematology, Chemistry, Immunohematology, Immunology, Endocrinology, Toxicology, and Bacteriology. 2. An interview on November 14, 2018 at 9:45 A.M., with the laboratory manager, confirmed the laboratory director failed to sign the attestation statements from AAB and failed to delegate the responsibility of signing the attestation forms to the laboratory manager who is also the technical supervisor.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review, document reviews, and an interview with the laboratory manager, the laboratory failed to verify the accuracy of Cryptosporidium parvum and Giardia lamblia antigens, blood cultures, respiratory and gastrointestinal pathogens tests performed on the BioFire FilmArray, manual body fluid counts, and Helicobacter pylori stool antigen at least twice annually since the last survey on March 2, 2017. Findings: 1. A record review of proficiency testing from American Association of Bioanalysts and laboratory documents revealed the laboratory failed to document the accuracy of Cryptosporidium parvum and Giardia lamblia antigens, blood cultures, respiratory and gastrointestinal pathogens tests performed on the BioFire FilmArray, manual body fluid counts, and Helicobacter pylori stool antigen at least twice annually since the last survey. 2. An interview on November 14, 2018 at 9:35 A.M., with the laboratory manager, confirmed the laboratory failed to document accuracy at least twice annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to include calibration verification activities in the procedure for beta hydroxybutyrate performed on the Stat Site M Beta Hydroxybutyrate meter since patient testing in October 2018. Findings: 1. A review of the procedure for beta hydroxybutyrate revealed the procedure failed to include the steps to perform calibration verification activities for the meter. 2. An interview on November 14, 2018 at 2:35 P.M., with the laboratory manager, confirmed the laboratory failed to include calibration verification activities in the procedure.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of Individualized Quality Control Plans (IQCPs) and an interview with the laboratory manager, the laboratory director failed to approve, sign, and date the IQCPs since the last survey on March 2, 2017. Findings: 1. A review of 13 Individualized Quality Control Plans (IQCPs) for microbiology media, Alere D-dimer, Syphilis, Illumigene Clostridium difficile, Biofire respiratory and gastrointestinal panels, i-Stat blood gas and troponin, Vitek antimicrobial susceptibility and identification system, Meridian Crypto/Giardia kit, and Rheumatoid Factor test kit, revealed the laboratory director failed to approve, sign, and date the plans. 2. An interview on November 14, 2018 at 5:30 P.M., with the laboratory manager, confirmed the laboratory director failed to approve, sign, and date the IQCPs.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of Individualized Quality Control Plans (IQCPs) and an interview with the laboratory manager, the laboratory failed to establish the number, frequency, and type of control materials used to detect errors and monitor test performance over time since the last survey on March 2, 2017. Findings: 1. A review of the IQCPs revealed the laboratory failed to include the Quality Control Plan (QCP) to include the number, type, and frequency of control materials tested for microbiology media, Alere D-dimer, Syphilis, Illumigene Clostridium difficile, Biofire respiratory and gastrointestinal panels, i-Stat blood gas and troponin, Vitek antimicrobial susceptibility and identification system, Meridian Crypto/Giardia kit, and Rheumatoid Factor test kit. 2. An interview on November 14, 2018 at 5:30 P.M., with the laboratory manager, confirmed the laboratory failed to establish the QCP for the test systems.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by:
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to document lot numbers, the dates kits were opened and expire for the Illumigene molecular assay for Clostridium difficile since the start of patient testing in 2018. Findings: 1. A review of Illumigene worksheets revealed the laboratory failed to document the lot numbers and dates the kits were opened or expired. 2. An interview on November 14, 2018 at 1:35 P.M., with the laboratory manager, confirmed the laboratory failed to document lot numbers and dates of kits opened and expired.
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 a record review and an interview with the testing personnel, the laboratory failed to perform immediate spin compatibility testing to detect IgM antibodies since the last survey on March 2, 2017. Findings: 1. A review of blood bank documents revealed the laboratory failed to perform an immediate spin crossmatch for the detection of IgM antibodies for ABO incompatibilities. 2. An interview on November 14, 2018 at 3:35 P.M., with the testing personnel, confirmed the laboratory testing personnel failed to perform an immediate spin to demonstrate ABO incompatibilities on patient specimens.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient record reviews, proficiency testing (PT) record reviews, and an interview with the laboratory manager, the laboratory failed to maintain test records to include the dates of test performances and the testing personnel who performed routine culture tests in bacteriology such as culture set-up on media, colony description and quantitation, inhibition zone sizes, gram stains, susceptibilities, and identifications since the last survey on March 2, 2017. Findings: 1. A review of the American Association of Bioanalysts bacteriology PT worksheets for bacteriology revealed the laboratory worksheets failed to include: a. the type of media used b. the colony description, quantitation, and morphology c. the person performing each step of testing from streaking of the plate to final sensitivity d. and the lot numbers and dates of each test performance 2. A record review of patient reports revealed the laboratory failed to identify the dates of test performance and the testing personnel performing the tests. 3. An interview on November 14, 2018 at 3:00 P.M., with the laboratory manager, confirmed the laboratory bacteriology worksheets and electronic record of bacteriology test performance failed to contain all dates of testing and the identity of testing personnel.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the laboratory manager, the laboratory failed to establish written procedures or policies for the analytic quality assessment activities for the laboratory since the last survey on March 2, 2017. Findings: 1. A review of 13 Individualized Quality Control Plans (IQCPs) revealed the laboratory failed to establish and follow a written Quality Assessment Plan to monitor the IQCPs effectiveness over time. 2. A review of documents revealed the laboratory failed to write procedures to follow for quality assessment activities for the laboratory since the last survey. 3. An interview on November 14, 2018 at 5:15 P.M., with the laboratory manager, confirmed the laboratory failed to establish written procedures or policies for the quality assessment activities for the laboratory and for the IQCP monitored effectiveness.