

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0056658	<b>(X3) Date Survey Completed</b>  03/11/2021
<b>Name of Provider or Supplier</b>  Boundary Community Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of Proficiency Testing (PT) from the American Proficiency Institute (API) and an interview with the Laboratory Manager on 03/10/2021, the Laboratory Director, or designee, failed to sign PT attestation forms for all events and all specialties and subspecialties in 2020. The findings include: 1. A review of PT attestation forms from API on 03/10/2021 at 12:30 PM, for Events 1,2, and 3 in 2020 revealed that the Laboratory Director, or designee, failed to sign all PT attestation forms for all events and all specialties and subspecialties. 2. An interview with the Laboratory Manager on 03/10/2021 at 12:30 confirmed the above finding. 3. The laboratory reports performing 34,720 moderate and high complexity tests annually. 4. This is a repeat deficiency from the previous survey on 11/14/2018.</p>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on record review of the laboratory's procedure manual, the procedures "Daily Quality Assurance Check" and "Quality Assurance in Laboratory Services," and an interview with the Laboratory Manager on 03/11/2021, the laboratory failed to follow their written policies and document problems identified in the general laboratory system. The findings include: 1. A procedure record review of "Daily Quality Assurance Check" on 03/11/2021 at 10:30 AM, revealed that the laboratory failed to follow their written procedure and document that daily worksheets were crosschecked for errors on a daily interval. 2. A procedure record review of "Quality Assurance in Laboratory Services" on 03/11/2021 at 10:30 AM, revealed that the laboratory failed to follow their written procedure and document their ongoing mechanism to monitor, assess, review and correct problems identified in the analytic system on a monthly, semiannually, and yearly basis. 3. An interview with the Laboratory Manager on 03/11/2021 at 11:00 AM confirmed that the laboratory failed to document these quality assurance reviews. 4. The laboratory reports performing 34,720 moderate and high complexity tests 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 record review of the laboratory's procedure manual and an interview with the Technical Supervisor (TS) on 03/11/2021, the laboratory failed to have a Coagulation test procedure with step-by-step performance of crossover studies when a new lot of Innovin reagent is implemented by the laboratory for Prothrombin Time (PT) patient testing. The findings include: 1. A record review of the laboratory's Coagulation procedure manual revealed that the laboratory failed to have a procedure for Innovin reagent lot crossover studies when a new lot is implemented by the laboratory. 2. An interview with the TS on 03/11/2021 at 9:50 AM confirmed that the

	<p>laboratory did not have a procedure for Innovin reagent lot crossover studies. 3. The laboratory reports performing 761 Prothrombin Time(PT) patients tests annually.</p>
<p><b>D5415</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and an interview with the Technical Supervisor (TS) on 03/11/21, the laboratory failed to label secondary containers with Wright-Giemsa stain contents and other pertinent information required for proper use. The findings include: 1. Based on an observation of the supplies and reagents in the laboratory on 03/11/2021 at 9:00 AM, the laboratory failed to label containers in the hematology area with the identity, preparation and expiration, lot number, or other pertinent information required for proper use. 2. An interview with the TS on 03/11 /2021 at 9:00 AM confirmed that the contents of the unlabeled containers were Wright-Giemsa Stain.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory supplies in the laboratory and phlebotomy blood draw tray, and an interview with the laboratory manager on 03/11/2021, the laboratory failed to maintain blood culture media that had not exceeded the expiration date set by the manufacturer. The findings include: 1. An observation of supplies in the laboratory and phlebotomy draw tray on 03/11/2021 at 9:15 AM, revealed that Becton Dickinson (BD) BACTEC anaerobic blood culture bottles, lot #0125445, used for patient blood culture collection, expired on 02/28/2021. 2. An interview with the laboratory manager on 03/11/2021 at 9:15 AM confirmed that the expired blood culture media bottles were being used for patient blood culture collection. 3. The laboratory reports performing 159 blood cultures annually.</p>
<p><b>D5435</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or</p>

baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on record review of Immunohematology maintenance, observation of laboratory equipment, and an interview with the Laboratory Manager on 03/10/2021, the laboratory failed to document maintenance and function checks critical to Immunohematology test performance. The findings include: 1. A record review of Immunohematology maintenance logs on 03/10/2021 at 4:30 PM revealed that the laboratory failed to document calibration of Immunohematology pipettes and Ortho MTS Gel Card centrifuge since the last survey on 11/14/2018. 2. An observation of Immunohematology pipettes and Ortho MTS Gel Card centrifuge in the laboratory on 03/10/2021 at 4:30 PM, revealed that the laboratory failed to retain documentation of calibration on Immunohematology equipment that is critical to test performance. 3. An interview with the Laboratory Manager on 03/10/2021 at 4:35 PM confirmed the above findings. 4. The laboratory reports performing 113 Immunohematology tests annually.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Quality Control (QC) record review and an interview with the laboratory manager on 03/10/2021, the laboratory failed to document the evaluation of QC results to detect outliers, shifts, and trends in control values in the analytic system. The findings include: 1. Based on record review of routine chemistry QC documents for the Siemens Dimension EXL, the laboratory failed to have a documented mechanism in place to monitor quality control results to detect outliers, shifts, and trends in the analytic system. 2. An interview with the laboratory manager on 03/10/2021 at 2:15 PM confirmed that the laboratory failed to document and monitor QC activities to detect outliers, shifts, and trends in the analytic system. 3. The laboratory reports performing 22, 280 chemistry tests annually.

**D5559**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or

blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 Immunohematology Quality Control (QC) random record review, the laboratory immunohematology patient logbook, and an interview with the Laboratory Manager on 03/10/2021, the laboratory failed to document Immunohematology QC when patient testing occurred. The findings include: 1. A random record review of Immunohematology QC and the laboratory patient logbook on 03/10/2021 at 3:45 PM, the laboratory failed to document QC performed when patient compatibility testing occurred for the following days; 06/15/2020, 06/11/2020, and 02/13/2020. 2. An interview with the Laboratory Manager on 03/10/21 at 3:45 confirmed that the laboratory failed to document QC for the days listed above. 3. The laboratory reports performing 113 Immunohematology tests annually.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on a random record review of temperature charts and an interview with the Technical Supervisor (TS) on 03/10/2021, the laboratory failed to document corrective actions taken for the specimen send-out freezer when the freezer exceeded the laboratory's established temperature range. The findings include: 1. Based on a random record review of the temperature log for the patient specimen send-out freezer on 03/10/2021 at 2:00 PM, the laboratory failed to document corrective action when the temperature was out of the laboratory's established range(-18 C to -28C) for 1 of 31 days in January 2021, 19 of 28 days in February 2021, and 9 of 10 days in March 2021. 2. Based on review of the temperature log for the patient specimen send-out freezer, there was no documented corrective action or supervisor review. 3. An interview with the TS on 03/10/21 at 2:05 PM confirmed the above findings.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to

determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on record review of verification performance and an interview with the Laboratory Manager on 03/11/2021, the Laboratory Director failed to ensure that the verification being used by the laboratory for SARS-CoV-2 patient testing was adequate to determine the accuracy, precision, and other pertinent performance characteristics of the test method. The findings include: 1. A record review of the laboratory's verification performance on 03/11/2021 at 9:15 AM for the BioFire RP2 Respiratory Panel, currently under Emergency Use Authorization (EUA), revealed that the laboratory director failed to approve the verification procedure to ensure the adequacy, and determine the accuracy and precision for SARS-CoV-2 patient testing. 2. An interview with the Laboratory Manager on 03/11/2021 at 9:15 confirmed that the laboratory director failed to sign and approve the BioFire RP2 Respiratory Panel verification procedure prior to testing patient specimens. 3. The laboratory reports performing 691 BioFire Respiratory Panels annually.

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for

proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:  
 Based on review of diplomas and educational documents, testing personnel training records, the CMS-209 form, and an interview with the laboratory manager on 03/10/2021, the laboratory failed to provide documentation of a qualified testing person, performing moderate and high complexity testing, prior to testing patient samples. The findings include: 1. Based on record review of diplomas and educational documentation, and the CMS-209 form, the laboratory failed to provide educational documentation at the time of survey for one of five testing personnel listed on the CMS-209 form. 2. The laboratory manager confirmed on 03/10/21 at 12:15 PM that the educational documentation was not available at the time of survey for one of five testing personnel listed on the CMS-209 form. 3. The laboratory reports performing 34,720 moderate and high complexity tests annually.

**D6181**

**TESTING PERSONNEL RESPONSIBILITIES**  
 CFR(s): 493.1495(b)(6)

Each individual performing high complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:  
 Based on a random record review of temperature charts and an interview with the Technical Supervisor (TS) on 03/10/2021, the laboratory's testing personnel failed to document corrective actions taken for the specimen send-out freezer when the freezer exceeded the laboratory's established temperature range. The findings include: 1. Based on random record review of the temperature log for the patient specimen send-out freezer on 03/10/2021 at 2:00 PM, the laboratory's testing personnel failed to document corrective action when the temperature was out of the laboratory's established range for 1 of 31 days in January 2021, 19 of 28 days in February 2021, and 9 of 10 days in March 2021. 2. Based on review of the temperature log for the

patient specimen send-out freezer, there was no corrective action documented by the laboratory's testing personnel. 3. An interview with the TS on 03/10/21 at 2:05 PM confirmed the above findings.