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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 13D0056658 | (X3) Date Survey Completed 02/07/2023 |
| Name of Provider or Supplier Boundary Community Hospital | Street Address, City, State 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 |
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| D5429 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of maintenance records for the Sysmex CS-2500 and an interview with the laboratory manager on 2/7/2023, the laboratory failed to perform instrument maintenance as required by the manufacturer. The findings include: 1. A review of maintenance records for the Sysmex CS-2500 identified that the laboratory failed to complete daily maintenance which included rinsing the probe, discarding used cuvettes and waste and checking and discarding trap chamber fluid for four (4) of 24 days in October 2022, eight (8) of 30 days in November 2022, 12 of 31 days in December and eight (8) of 31 days in January 2023. 2. A review of maintenance records for the Sysmex CS-2500 identified that the laboratory failed to complete weekly maintenance which included cleaning the instrument and rinsing the rinse tank for one (1) of four (4) weeks in December 2022 and one (1) of four (4) weeks in January 2023. 3. A review of maintenance records for the Sysmex CS-2500 identified that the laboratory failed to complete the monthly maintenance of cleaning the filter for December 2022. 4. An interview with the laboratory manager on 2/7/2023 at 10:40 am confirmed the above findings. 5. The laboratory reports performing 930 prothrombin time and partial thromboplastin time tests on the Sysmex CS-2500 annually.</p> |
| D5449 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p> |

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of BioFire quality control (QC) documents and an interview with the laboratory manger on 2/6/2023, the laboratory failed to have positive and negative controls for all analytes tested. The findings include: 1. A review of QC documents for the BioFire Pneumonia Panel identified that the laboratory failed to have a negative control for the 33 targets tested since the last inspection (3/11/21). 2. An interview with the laboratory manager on 2/6/2023 at 3:30 pm confirmed that the laboratory failed to test negative controls for the BioFire Pneumonia Panel. 3. The laboratory reports performing 16 BioFire Pneumonia Panels annually.