

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0522334	(X3) Date Survey Completed 02/25/2019
Name of Provider or Supplier Benewah Community Hospital	Street Address, City, State 229 S 7th St, Saint Maries, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on the Siemens Dimension prostate-specific antigen (PSA) reagent instructions, patient test report review, and an interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions to include the test method for PSA on the patient's test reports since the last survey on February 27, 2017. Findings: 1. A review of the Siemen TPSA reagent instruction sheet revealed the laboratory failed to include the identity of the PSA assay to physicians for patient's PSA test results. 2. The laboratory performs approximately 325 PSA tests a year. 3. An interview on February 25, 2019 at 11:10 AM, with the laboratory manager, confirmed the identity of the PSA assay was not included on patient test reports.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test</p>

system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification procedures for D-dimer tests since July 2018 and blood gas analytes at least once every 6 months since May 2018. Findings: 1. A record review revealed the laboratory failed to perform and document calibration verification procedures for blood gas assays performed on the I-Stat and D-dimer assays performed on the Siemens Stratus. 2. The laboratory performs approximately 40 blood gas tests and approximately 150 D-Dimer tests a year. 3. An interview on February 25, 2019 at 1:05 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration verification procedures.

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 record review and an interview with the laboratory manager, the laboratory failed to establish the number, type, and frequency of quality control testing materials used to monitor and detect immediate errors for D-dimer tests performed on the Siemens Stratus test system since the last survey on February 27, 2017. Findings: 1. A review of the laboratory's Individualized Quality Control Plan (IQCP) for D-dimer tests performed on the Stratus revealed the laboratory failed to identify the number, type, and frequency of quality control testing materials used to monitor the performance of the tests over time. 2. The laboratory performs approximately 150 D-Dimer tests a year. 3. An interview on February 25, 2019 at 1:00 PM, with the laboratory manager, confirmed the laboratory failed to establish and identify the number, the type, and the frequency of quality control testing materials for D-dimer in the IQCP.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

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 the source of microbiology culture specimens on the patient's final report from the time reviewed between December 2018 and February 2019. Findings: 1. A review of patient #348859 for a gram stain revealed the report failed to include the source of the specimen on the final report. 2. A review of 2 out of 2 patient test records for microbiology cultures referred to a reference laboratory, revealed the source of the specimen was not indicated either in the laboratory information system or on the patient's final report. 3. The laboratory performs approximately 40 gram stains per year and refers approximately 100 cultures out per year to a reference laboratory. 4. An interview on February 25, 2019 at 12:15 PM, with the laboratory manager, confirmed the patient's final microbiology results failed to include the source of the specimen in the laboratory information system or on the reference laboratory's final report.