

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0522371	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Bonner General Health	Street Address, City, State 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review and an interview with the general supervisor, the laboratory failed to document corrective actions for the American Proficiency Institute (API) proficiency testing (PT) unsatisfactory scores in bacteriology and hematology during 2016 and 2017. Findings: 1. An API PT records review revealed the laboratory failed to document the corrective actions for a score of 73% in Bacteriology Susceptibility for the 2017 event 2, and a 50% in Shiga toxin 1 and 2 for 2017 event 1. 2. An API PT records review revealed the laboratory failed to document the corrective actions for a score of 50% in Nucleated Red Bloods cells in the specialty of Hematology for 2017 event 2 and 2016 event 3, and a Reticulocyte Count score of 50% in the specialty of Hematology for 2017 event 2. 3. An API PT records review revealed the laboratory failed to document the corrective actions for a score of 60% in Rheumatoid Factor for 2017 event 1. 4. An API PT records review revealed the laboratory failed to document the corrective actions for a score of 0% in Testosterone in the specialty of Chemistry for 2016 event 1, and 0% for Acetaminophen in the specialty of chemistry for 2016 event 3. 5. An interview on January 10, 2018 at 9:30 AM, with the general supervisor, confirmed that the corrective actions failed to be documented during PT review.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its</p>

ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on an observation, a record review, and an interview with the general supervisor, the laboratory failed to document the sterility, growth, inhibition of growth, and biochemical response for 10 out of 10 media types since the last survey on February 23, 2016. Findings: 1. Based on an observation on January 10, 2018 at 2:30 PM, 10 media types were observed in the microbiology refrigerator which included Trypticase soy agar, Trypticase Soy Agar with w/5% Sheep Blood, Enterococcosel agar, Phenylethyl Alcohol agar 5% Sheep Blood, Sabouraud Dextrose Agar, MacConkey, Martin Lewis agar, Chocolate II, CDC Anaerobic Blood agar, and Oxyrase plates. 2. A review of the microbiology media records failed to show documentation of the sterility, growth, the inhibition of growth, and biochemical response. 3. An interview on January 10, 2018 at 2:45 PM, with the general supervisor, confirmed sterility, growth, the inhibition of growth, and biochemical response was not documented for the 10 types of media.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on competency records review and an interview with the technical supervisor, the technical supervisor who is also the general supervisor, failed to include the review of intermediate test results or worksheets and proficiency testing (PT) results as part of the competency program since the last survey on February 23, 2016. Findings: 1. A review of the personnel documents that were labeled as Skills Checklist Credentialing MT, failed to include the review of PT results and intermediate test results and worksheets for 14 out of 14 testing personnel reported on the CMS-209. 2. An interview on January 10, 2018 at 10:00 AM, with the technical supervisor, confirmed the evaluations of review of test results and PT were not documented for the testing personnel on the checklist.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on competency record review and an interview with the technical supervisor, the technical supervisor who is also the general supervisor, failed to include the review of assessment of test performance through blind testing or proficiency test

(PT) as part of the competency program since the last survey on February 23, 2016. Findings: 1. A review of the personnel documents that were labeled as Skills Checklist Credentialing MT, failed to include the assessment of blind test or PT performance for 14 out of 14 testing personnel reported on the CMS-209. 2. An interview on January 10, 2018 at 10:00 AM, with the technical supervisor, confirmed the evaluations of blind test or PT performance was not documented for the testing personnel on the checklist.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
Based on competency records review and an interview with the technical supervisor, the technical supervisor who is also the general supervisor, failed to include the assessment of problem solving skills as part of the competency program since the last survey on February 23, 2016. Findings: 1. A review of the personnel documents that were labeled as Skills Checklist Credentialing MT, failed to include the assessment of problem solving skills for 14 out of 14 testing personnel reported on the CMS-209. 2. An interview on January 10, 2018 at 10:00 AM, with the technical supervisor, confirmed the assessment of problem solving skills was not documented for the testing personnel on the checklist.