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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>53D0662169  | <b>(X3) Date Survey Completed</b><br>11/15/2018 |
| <b>Name of Provider or Supplier</b><br>Wyoming Public Health Laboratory  | <b>Street Address, City, State</b><br>208 S College Drive, Cheyenne, WY |   |
| 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>   |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of competency documentation and staff interview, the technical consultant failed to have a competency evaluation performed prior to performing evaluations on other staff members in 1 of 1 years evaluated. Findings include: 1. Review of competency documentation revealed the Technical Supervisor was hired on March 1, 2018, and performed competency evaluations on testing personnel prior to being assessed for competency. 2. In an interview conducted on November 14, 2018 at approximately 11:00 AM, the Laboratory Manager confirmed the technical supervisor hired on March 1, 2018 had not been assessed for competency but did perform competency assessments on other employees.</p> |
| <b>D6106</b>              | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the test method procedures and staff interview, the current laboratory director failed to approve all test method procedures. Findings include: 1. Review of the procedure manual in Bacteriology revealed the current laboratory director failed to approve 3 of 7 test method procedures. 2. Review of the procedure</p>  |

manual in Immunology revealed the current laboratory director failed to approve 1 of 11 test method procedures. 3. In an interview conducted on 11/15/2018 at approximately 12:00, the Laboratory Administrator and Technical Supervisor stated they were unaware these procedure were not signed by the current laboratory director.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on review of competency documentation and staff interview, the laboratory failed to perform annual competency evaluations on 3 of 14 employees in 2017. Findings include: 1. Review of competency documentation revealed 3 employees had not received their annual competency evaluation in 2017 in Immunology. For each of these three employees, the 2016 competency was performed in November 2016. Competency was next performed and documented on these employees in February 2018. 2. In an interview conducted on November 14, 2018 at approximately 2:00 PM, the Technical Supervisor confirmed competency evaluations were not performed on three employees in 2017.