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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>13D0969818 | <b>(X3) Date Survey Completed</b><br><br>06/03/2019 |
| <b>Name of Provider or Supplier</b><br><br>Idaho Falls Pediatrics  | <b>Street Address, City, State</b><br><br>3067 Eagle Dr, Ammon, 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>  |
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| <b>D2015</b>              | <p>TESTING OF PROFICIENCY TESTING SAMPLES<br/>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:<br/>Based on a review of proficiency testing records and an interview with the laboratory manager, the laboratory failed to maintain the American Proficiency Institute (API) Attestation Statements for Microbiology, events 2 and 3 in 2018. This is a repeat deficiency from the last survey on July 8, 2017. Finding: 1. A PT review from API and laboratory documents revealed the laboratory failed to maintain the Attestation Statement forms for Microbiology events 2 and 3 of 2018. 2. The laboratory performed approximately 1500 throat cultures on Strep Selective agar in 2018. 3. An interview with the laboratory manager on June 3, 2019, at 1:15 PM, confirmed the laboratory failed to retain the API PT Attestation Statements for events for 2 and 3 of 2018 for throat cultures.</p> |
| <b>D5411</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed</p>  |

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.

This STANDARD is not met as evidenced by:

Based on a record review, an observation, and an interview with the laboratory manager, the laboratory failed to follow HealthLink Strept Select Agar instructions for differentiation and reporting of Group A streptococci on throat cultures since the last survey on July 18, 2017. Findings: 1. An observation of the laboratory on June 3, 2019 at 1:55 PM, revealed the laboratory did not have bacitracin discs or other serological tests for the differentiation of Group A streptococci of positive throat cultures performed on HealthLink Select Strep agar. 2. A record review of patient throat culture results revealed the laboratory failed to follow the manufacturer's instruction for reporting presumptive Group A streptococci by observing a zone of inhibition around the bacitracin discs or other serological tests since the last survey. 3. 2. The laboratory performs approximately 1500 throat cultures per year. 4. An interview with the laboratory manager on June 3, 2019 at 2:00 PM, confirmed the the laboratory does not use bacitracin discs for the presumptive identification of Group A streptococci since the last survey.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a procedure review, document reviews, and an interview with the laboratory manager, the laboratory director failed to ensure the quality assessment program for the laboratory was established and monitored for the general, pre-analytic, analytic, and post-analytic phases for throat cultures since the last survey on July 18, 2019. Findings: 1. A record review revealed the laboratory director failed to establish and write a policy or procedure for a system to monitor, assess, and correct problems in the pre-analytic, analytic, and post-analytic phases of testing throat cultures. Refer to D5411. 2. A review of the procedure manual revealed the laboratory failed to have a written procedure for the review and evaluation of proficiency testing requirements. Refer to D3037. 3. An interview with the laboratory manager on June 3, 2019 at 1:15 PM, confirmed the laboratory director failed to establish and write policies and procedures for a system to monitor all quality assessments activities for the laboratory's test performance in throat cultures.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on testing personnel competency assessment reviews, a procedure manual review, and an interview with laboratory manager, the laboratory director failed to ensure that a policy or procedure was established for the performance and monitoring of competency assessment for pre-analytic, analytic, and post-analytic phases of testing throat cultures since 2017. This is a repeat deficiency from the last survey on July 18, 2017. Findings: 1. A review of competency assessments revealed the laboratory director failed to perform and document assessments for 4 out of 4 medical providers performing throat cultures since 2017. 2. A review of the procedure manual revealed the laboratory failed to have a procedure for monitoring and performing competency assessments of testing personnel performing throat cultures. 3. The laboratory performs approximately 1500 throat cultures a year. 4. An interview with the laboratory manager on June 3, 2019, at 2:35 PM, confirmed the laboratory director failed to establish a written policy or procedure for monitoring and performing competency assessments for throat cultures performed by the providers since the last survey.