

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521750	(X3) Date Survey Completed 08/09/2018
Name of Provider or Supplier Intermountain Pediatric Clinic	Street Address, City, State 7722 W Ustick Road, Boise, 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 an interview with the laboratory director, an observation of the laboratory, and a record review, the laboratory failed to follow the manufacturer's instructions for the differentiation of Group A streptococci in throat cultures since the last survey on October 14, 2016. Findings: 1. An observation of the laboratory on August 9, 2018 at 1:35 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 Select Strep agar. 2. A record review of patient results from December 19 and 27, 2017, revealed the laboratory failed to follow the manufacturer's instruction for identifying presumptive Group A streptococci by using bacitracin discs or other serological tests. 3. An interview with the laboratory director on August 9, 2018 at 2:00 PM, confirmed the laboratory does not use bacitracin discs for the presence of Group A streptococci.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory director and a record review, the laboratory failed to identify the temperature ranges for the incubator used for performing throat and urine cultures since October 14, 2016. Findings: 1. A record review of temperature logs revealed the laboratory failed to indentify the temperature range for performing urine and throat cultures on pediatric patients using Select Strep agar and Trypticase Soy Agar with 5% sheep blood and MacConkey. 2. An interview on August 9, 2018, at 1:50 PM, with the laboratory director, confirmed the laboratory failed to identify the temperature ranges for the incubator since the last survey.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on an interview with the laboratory director and a record review, the laboratory failed to establish the quality control plan (QCP) portion of the Individualized Quality Control Plan (IQCP) for the microbiology media used in throat and urine cultures since the last survey on October 14, 2016. Findings: 1. A review of the IQCP for the microbiology media, Trypticase Soy agar with 5% sheep blood/MacConkey and Select Strep agar, revealed the laboratory failed to establish the QCP. 2. An interview on August 9, 2018 at 1:45 PM, with the laboratory director, confirmed the laboratory failed to write the QCP for the microbiology media for urine and throat cultures.