

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521880	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Southwest Idaho Ear Nose And Throat Pa	Street Address, City, State 900 N Liberty St #400, 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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical supervisor, the laboratory failed to establish the number, type and frequency of reagent controls used in the identification of microbiological organisms since the last survey on September 23, 2016. Findings: 1. A review of the laboratory 's Individualized Quality Control Plan (IQCP) revealed the quality control plan failed to include the number, type, and frequency of quality control reagents used to perform the identification of microorganisms from the nasal and throat specimens to include: optochin disks, bacitracin disks, and Dade Microscan Pluronic panel since the last survey. 2. An interview on June 5, 2018 at 1:50 PM, with the technical supervisor, confirmed the IQCP for reagents used in the identification of microorganisms failed to establish the number, type, and frequency of control reagents to detect immediate errors in the test system since the last survey.</p>