

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1057951	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Asthma & Allergy Of Idaho	Street Address, City, State 714 W Appleway Ave #200, Coeur D'Alene, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to verify the performance specifications of the Thermo Fisher Phadia 100 before reporting patient total and specific IgE and Immumocap allergen test results when a new analyzer was put into service on November 26, 2018. Findings: 1. A review of laboratory documents revealed the laboratory failed to verify the Phadia's performance specifications for accuracy, precision, and reportable range for the new analyzer before reporting patient test results since November 26, 2018. 2. The laboratory performed approximately 900 total and specific IgE tests since November 2018. 3. An interview on April 2, 2019 at 4:05 PM, with the laboratory manager, confirmed the laboratory failed to verify the performance of the new Phadia 100 prior to reporting patient test results.</p>