

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0910599	(X3) Date Survey Completed 08/01/2023
Name of Provider or Supplier Afs, Pc	Street Address, City, State 401 Lowell Drive Suite 24, Huntsville, AL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Sperm Motility records, American Association of Bioanalysts (AAB) proficiency testing records, Quality Assurance records, and an interview with the Technical Consultant, the laboratory failed to verify the accuracy of Sperm Motility at least twice annually. This was noted on two of two AAB events reviewed in 2022. The findings include: 1. A review of the Sperm Motility records revealed a lack of documentation of accuracy verification being performed twice annually for the year 2022. 2. A review of the AAB proficiency testing records revealed the laboratory did not add Sperm Motility until April 2023. 3. A review of the Quality Assurance Program page 9 under Proficiency Testing, "analytes... are tested twice per year to verify accuracy using the split-sample method." 4. During an interview on August 1, 2023, at 12:05 PM, the Technical Consultant confirmed the above findings.</p>