

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0919258	(X3) Date Survey Completed 05/30/2024
Name of Provider or Supplier American Scientific Laboratory	Street Address, City, State 8744 Shermer Rd, Niles, IL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory and proficiency testing (PT) records and interview with the laboratory director (LD); the laboratory failed to have PT samples tested by two of four testing personnel (TP) who routinely perform Neisseria gonorrhoeae (GC), Chlamydia trachomatis (CT), and Trichomonas vaginalis (TV) testing on the BD Max analyzer (Serial Number: 1080) for 14 of 14 events in 2022 through the survey date of 05/30/2024. Findings include: 1. Review of the Laboratory Personnel Report (signed by the LD on 05/30/2024) and laboratory competency documents revealed four TP authorized to perform GC, CT, and TV testing on the BD Max analyzer. 2. Review of the College of American Pathologists (CAP) PT attestation statements for the three testing events per calendar year of regulated analytes GC and CT in 2022 through event two of 2024 found TP #2 performed seven out of eight GC and CT PT events. Year Event TP 2022 1 2 2022 2 2 2022 3 2 2023 1 2 2023 2 2 2023 3 3 2024 1 2 2024 2 2 3. Review of the College of American Pathologists (CAP) PT attestation statements for the two testing events per calendar year of non-regulated analyte TV in 2022 through event one of 2024 found TP #2 performed four out of five TV PT events. Year Event TP 2022 1 2 2022 2 2 2023 1 2 2023 2 3 2024 1 2 4. On survey date 05/30/2024, at 1:13 pm the LD confirmed the above findings.</p>