

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2295244	(X3) Date Survey Completed 03/06/2026
Name of Provider or Supplier Alpha Men's Health	Street Address, City, State 231 W Southlake Blvd Suite 120, Southlake, TX	
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
D0000	An announced routine recertification survey of the laboratory was completed on 03/02/2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, review of the American Proficiency Institute (API) Performance Summary, review of the laboratory's proficiency testing (PT) records, and confirmed in interview, the laboratory failed to retain a copy of all Endocrinology PT records for three of three events in 2025. Findings include: 1. Review of the CASPER Report 155 determined the laboratory was enrolled in PT for the specialty of Endocrinology for Testosterone in 2025. 2. A review of the laboratory's PT records in 2025 determined the laboratory failed to retain a copy of all Endocrinology PT records for Testosterone for three of three events in 2025: API original forms Test records Attestation statements 3. The clinic owner confirmed the laboratory failed to retain a copy of all PT records during an interview on 03/06/2026 at 1025 hours in the office.</p>

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Performance Summary, review of the laboratory's proficiency testing (PT) records, and confirmed in interview, the laboratory failed to have documentation of evaluation of a zero score for nonparticipation in the speciality of Endocrinology for Testosterone for one of three PT events in 2025 (Event 2). Findings include: 1. Review of the API performance summary determined the laboratory received a zero score for nonparticipation for Testosterone for one of three events in 2025 (Event 2). 2. A review of the laboratory's PT records in 2025 determined the laboratory failed to have documentation of evaluation of a zero score for nonparticipation for Testosterone for one of three PT events in 2025 (Event 2). The surveyor requested documentation of evaluation of a zero score for nonparticipation for Testosterone for Event 2 of 2025. No documentation was provided. 3. The clinic owner confirmed the findings in an interview on 03/06/2026 at 1025 hours in the office.