Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D2295244	06/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Men's Health	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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory Qualigen Individualized Quality Control Plan (IQCP), calibration and quality control (QC) records, and confirmed in interview, the laboratory failed to follow their own policy for performing quality control following calibration for six of twelve calibrations performed in 2024. Findings Included: 1. During a tour of the laboratory on 06/18/2024 at 11:15 AM, the surveyor observed one Qualigen Immunoassay analyzer (Serial Number: 02187) currently in use for patient testosterone testing. 2. Review of laboratory's Qualigen testosterone IQCP (Approved by the Laboratory Director on 02/2024) revealed the following: "Quality Control Plan ...QC is still performed at the time of opening a new shipment of FastPacks, after calibration or maintenance, if improper storage is suspected, or a patient test result appears to be questionable." Further review of the IQCP revealed the following: "If QC results are in range, and the overall risk of the lab is manageable, QC frequency is reduced to once per week and after each calibration." 3. Review of calibration and QC records revealed the following days calibrations were performed on the Qualigen FastPack testosterone analyte, and QC was not documented following calibration in 2024: Calibration performed on: a. 02/23/2024; No testosterone QC documented b. 03/11/2024; No testosterone QC documented c. 03/19/2024; No testosterone QC documented d. 04/03/2024; No

	testosterone QC documented e. 05/24/2024; No testosterone QC documented f. 06/07 /2024; No testosterone QC documented The surveyor requested QC documentation for the above days calibrations were performed on 06/18/2024 at 11:45 AM, and none were provided. 4. In an interview on 06/18/2024 at 12:05 PM, the laboratory owner confirmed the laboratory failed to follow their own policy for performing quality control following calibration for six of twelve calibrations performed in 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory Qualigen FastPack Testosterone verification study, and confirmed in interview, the laboratory failed to have documentation of verifying its patient population reference range for one of one analyte performed in 2024. Findings Included: 1. During a tour of the laboratory on 06 /18/2024 at 11:15 AM, the surveyor observed one Qualigen Immunoassay analyzer (Serial Number: 02187) currently in use for patient testosterone testing. 2. Review of laboratory Qualigen FastPack Testosterone verification study performed in January 2024 revealed the following: "Installation and Method Validation Method validation is performed for each test being used per system serial number and consists of the following: ...Identifying your Reference Ranges In this step you are identifying the reference range that is appropriate for your patient population." Directly under this statement was a provided table with the header, "Your Reference (Normal) Ranges". The table had no documentation for the laboratory's reference range. The surveyor requested documentation of the laboratory verifying its patient population reference range on 06/18/2024 at 11:48 AM, and none was provided. 3. In an interview on 06/18 /2024 at 12:05 PM, the laboratory owner confirmed the laboratory failed to have documentation of verifying its patient population reference range for one of one analyte performed in 2024.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, environmental records (01/22/2024-06/18/2024), corrective action log, and confirmed in interview, the laboratory failed to have documentation of corrective actions for out of range refrigerator temperatures for 104 of 108 days in 2024. Findings Included: 1. During a tour of the laboratory on 06/18/2024 at 11:15 AM, the surveyor observed one

Qualigen Immunoassay analyzer (Serial Number: 02187) currently in use for patient testosterone testing. Further observation of the laboratory revealed a refrigerator (SN: AA0138) storing six boxes of Qualigen FastPack Testosterone testing kits (Lot Number: 2402010-8; Expiration Date: 09/19/2024). Printed on each testing kit was the required storage temperature range, "2-8 C (35-46 F)". 2. Review of manufacturer's instructions, "Qualigen FastPack System" (Revision 010 (09/22)) revealed the following: "Storing Test Supplies ...If storage temperatures are too cold or too warm, testing supplies could be damaged. Be sure to record the temperature of the refrigerator, where these items are stored, on a daily basis and enter this reading in Environmental Log. Adjust temperatures that are out of range and include any remedial action in the Corrective Action Log." 3. Review of laboratory environmental records from (01/22/2024-06/18/2024), revealed the following days the laboratory refrigerator temperature was out of range (35-46 F): Date; Temperature recorded a.01/22/2024; 50.6 F b.01/23/2024: 49.9 F c.01/24/2024; 50.6 F d.01/25/2024: 49.5 F e.01/26/2024; 52.1 F f.01/29/2024; 50.5 F g.01/30/2024; 51.6 F h.01/31/2024; 50.5 F i.02/01/2024; 49.3 F j.02/02/2024; 48.3 F k.02/05/2024; 47.3 F l.02/06/2024; 50.2 F m.02/07/2024; 48.3 F n.02/08/2024; 47.9 F o.02/09/2024; 52.8 F p.02/12/2024; 49.6 F q.02/13/2024; 52.4 F r.02/14/2024; 51.2 F s.02/15/2024; 50.2 F t.02/16/2024; 49.9 F u.02/19/2024; 49.0 F v.02/20/2024; 50.1 F w.02/21/2024; 49.6 F x.02/22/2024; 48.5 F y.02/23/2024; 50.0 F z.02/26/2024; 50.2 F aa.02/27/2024; 51.4 F bb.02/28/2024; 52.0 F dd.03/01/2024; 51.2 F ee.03/04/2024; 47.6 F ff.03/05/2024; 50.2 F gg.03/06/2024; 51.3 F hh.03/07/2024; 51.7 F ii.03/08/2024; 49.4 F jj.03/11/2024; 53.3 F kk.03/12/2024; 47.8 F ll.03/13/2024; 53.7 F mm.03/14/2024; 51.2 F nn.03/15/2024; 49.4 F oo.03/18/2024; 51.0 F pp.03/19/2024; 50.6 F qq.03/20/2024; 50.1 F rr.03/21/2024; 52.3 F tt.03/25/2024; 48.6 F uu.03/26/2024; 52.4 F vv.03/27/2024; 48.7 F ww.03/28/2024; 52.9 F xx.03/29/2024; 46.7 F yy.04/01/2024; 48.4 F zz.04/02/2024; 50.2 F aaa.04/03/2024; 51.3 F bbb.04/04/2024; 49.6 F ccc.04/05/2024; 47.1 F ddd.04/08/2024; 49.9 F eee.04/09/2024; 49.3 F fff.04/10/2024; 49.2 F ggg.04/11/2024; 50.2 F hhh.04/12/2024; 48.2 F iii.04/15/2024; 48.5 F jjj.04/16/2024; 53.6 F kkk.04/17/2024; 50.6 F lll.04/18/2024; 51.3 F mmm.04/19/2024; 50.2 F nnn.04/22/2024; 53.3 F ooo.04/23/2024; 46.9 F ppp.04/24/2024; 46.7 F qqq.04/25/2024; 50.2 F rrr.04/26/2024; 49.6 F sss.04/29/2024; 46.5 F ttt.04/30/2024; 52.0 F uuu.05/01/2024; 51.4 F vvv.05/02/2024; 48.6 F xxx.05/06/2024; 50.2 F yyy.5/07/2024; 47.8 F zzz.05/08/2024; 49.6 F aaaa.05/09/2024; 53.4 F bbbb.05/10/2024; 52.1 F cccc.05/13/2024; 49.1 F eeee.05/15/2024; 47.7 F ffff.05/16/2024; 49.7 F gggg.05/17/2024; 48.7 F hhhh.05/20/2024; 49.5 F iiii.05/21/2024; 49.7 F jjjj.05/22/2024; 49.3 F kkkk.05/23/2024; 50.2 F llll.05/24/2024; 47.3 F mmmm.05/28/2024; 50.0 F nnnn.05/29/2024; 49.6 F oooo.05/30/2024; 50.4 F pppp.05/31/2024; 50.1 F qqqq.06/03/2024; 49.5 F rrrr.06/04/2024; 50.7 F ssss.06/05/2024; 50.4 F tttt.06/06/2024; 51.4 F uuuu.06/07/2024; 50.9 F vvvv.06/10/2024; 50.6 F wwww.06/11/2024; 49.3 F xxxx.06/12/2024; 47.5 F yyyy.06/13/2024; 47.1 F zzzz.06/14/2024; 49.6 F aaaaa.06/17/2024; 48.6 F bbbbb.06/18/2024; 49.1 F 4. Review of corrective action logs (January-June 2024) revealed the following: "This log is to be used to record any problems or abnormalities that have occurred in your laboratory and to list the actions taken to correct them. Fill in the date the problem occurred. Describe the problem, the resolution and any corrective action that has taken place to ensure the problem does not occur again." Further review of the corrective action log revealed no corrective actions documented for the above out of range temperatures. The surveyor requested documentation of corrective actions for the recorded temperatures, on 06/18/2024 at 11:28 AM, and none was provided. 5. Random review of patient reports in 2024 revealed the following patients tested for testosterone using the Qualigen Fastpack testosterone testing kits stored at the above temperatures with no corrective actions documented: Performed: 06/17/2024 a. Patient 1 (See attached Patient Alias List) b. Patient 2 c. Patient 3 d. Patient 4 Performed on 06/14/2024 e. Patient 5 f.

	Patient 6 g. Patient 7 h. Patient 8 i. Patient 9 j. Patient 10 k. Patient 11 l. Patient 12 m. Patient 13 n. Patient 14 Performed on 06/13/2024 o. Patient 15 6. In an interview on 06 /18/2024 at 12:05 PM, the laboratory owner confirmed the laboratory failed to have documentation of corrective actions for out of range refrigerator temperatures for 104 of 108 days in 2024.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, verification studies, quality control (QC) records, laboratory environment records, monthly quality assurance (QA),and confirmed in interview, the laboratory failed to ensure an effective QA program was in place to monitor, assess, and correct problems in the laboratory for the analytical phase of testing for 104 of 108 patient testing days in 2024. Findings Included: 1. Review of laboratory policy, "Monthly QA Assessment" (Approved by the laboratory director on 01/2024) revealed the following: "Write one of the following notations for each item: Y (YES); N (NO); or N/A (Not Applicable)\ Our Quality Control (QC) policies were performed as specified: Each day, all environmental elements are checked, logged and are within normal ranges. Each QC event, two levels of quality control were tested and were within acceptable ranges before patients were tested. ... Our Quality Assurance Program is monitored for compliance: The above information has been reviewed to determine whether errors that occurred this month could have been prevented by changing policies and/or procedure. ...If you answered "No" to any item, use the Corrective action Log to explain the problem and how it was resolved ... Describe any corrective actions taken and how changes have improved the quality of the testing process." 2. The laboratory failed to follow their own policy for performing quality control following calibration for six of twelve calibrations performed in 2024. Refer to D5401. 3. The laboratory failed to have documentation of verifying its patient population reference range for one of one analyte performed in 2024. Refer to D5421. 4. The laboratory failed to have documentation of corrective actions for out of range refrigerator temperatures for 104 of 108 days in 2024. Refer to D5779. 5. Review of laboratory Monthly QA Assessments in 2024 revealed the laboratory QA assessments failed to document the above issues. The surveyor requested documentation of the laboratory's QA program correcting problems found in the analytic phase of testing on 06/18/2024 at 11:48 AM, and none was provided. 6. In an interview on 06/18/2024 at 12:05 PM, the laboratory owner confirmed the laboratory failed to ensure an effective QA program was in place to monitor, assess, and correct problems in the laboratory for the analytical phase of testing for 104 of 108 patient testing days in 2024.