Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2321237	01/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Vessel Mens Health Llc	201 W Broad St, Boise, 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	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 a review of the Qualigen FastPack IP instrument verification for testosterone testing and an interview with the laboratory owner on 1/28/2026, the laboratory failed to verify precision prior to performing patient testing on 5/2/2025. The findings include: 1. A review of the Qualigen FastPack IP testosterone performance specification verification documentation identified that the laboratory failed to verify precision variance over time prior to beginning patient testing on 5/2/2025. 2. An interview with the laboratory owner on 1/28/2026 at 12:08 pm confirmed that there was no additional verification documentation. 3. The laboratory reports performing 960 testosterone tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to

	verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Qualigen FastPack IP instrument user manual, calibration verification documents and an interview with the laboratory owner on 1/28/2026, the laboratory failed to verify the reportable range at least once every six (6) months for testosterone testing in 2025. The findings include: 1. A review of the instrument user manual for the Qualigen FastPack IP identified that calibration for testosterone testing included one calibrator performed in duplicate every 15 days. 2. A review of Qualigen FastPack IP instrument documents for calibration verification identified that the laboratory performed calibration verification on 4/29/2025 and 12/10/2025 verifying that the laboratory failed to perform verifications of the reportable range for testosterone at least once every six (6) months in 2025. 3. An interview with the laboratory owner on 1/28/2026 at 12:08 pm confirmed that there was no additional documentation for calibration verification for testosterone testing. 4. The laboratory reports performing 960 testosterone tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on a review of the Qualigen FastPack Testosterone individualized quality control plan (IQCP), quality control (QC) records, calibration records, patient reports and an interview with testing personnel 1 (TP1) on 1/28/2026, the laboratory failed to successfully perform QC as written in their IQCP for 53 days from May 2025 to December 2025. The findings include: 1. A review of the Qualigen FastPack Testosterone IQCP signed by the laboratory director on 6/4/2025 stated "two levels of quality control (C1 and C2) will be assayed with each new lot, each new shipment, after calibration, and weekly." 2. A review of the testosterone QC records identified that the laboratory failed to perform weekly QC five (5) of five (5) weeks in July 2025, two (2) of four (4) weeks in August 2025, two (2) of five (5) weeks in

	September 2025, one (1) of four (4) weeks in October 2025 and one (1) of five (5) weeks in December 2025. 3. A review of the calibration records, QC records and patient reports identified that the laboratory failed to perform QC after calibration and prior to performing patient (pts) testosterone testing for the following dates: Cal date QC date pts reported 6/4/2025 6/9/2025 18 6/18/2025 6/23/2025 11 7/7/2025 8/4/2025 80 8/12/2025 8/18/2025 22 9/15/2025 9/22/2025 23 10/7/2025 10/13/2025 19 11/11 /2025 11/25/2025 74 12/10/2025 12/11/2025 3 4. An interview with TP1 on 1/28 /2026 at 11:21 am confirmed that QC had not been performed after calibrations prior to testing patients. 5. The laboratory reports performing 960 testosterone tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of Qualigen FastPack IP testosterone instructions for use (IFU), the laboratory's test report, references listed on the laboratory test report and an interview with the laboratory owner on 1/28/2026, the laboratory failed to establish normal rages for testosterone results for 18 and 19 year old patients prior to performing testing on 5/2/2025. The findings include: 1. A review of the Qualigen FastPack IP testosterone IFU revealed normal ranges for males 20-49 years old and males >50 years old. 2. A review of the laboratory's patient test report identified a normal range for testosterone of 250-1100 ng/dL for males greater than and equal to 18 years old, with the following references: J Clin Invest 1974;53:819-828 and J Clin Endocrionl Metab 1973;36:1132-1142. 3. A review of the documents referenced on the laboratory's patient report: J Clin Invest. 1974 Mar;53(3):819-828. Hypophyso-Gonadal Function in Humans during the First Year of Life and J Clin Endocrinol Metab. 1973 Jun;36(6):1132-42. Total and unbound testosterone levels in the newborn and in normal and hypogonadal children: use of a sensitive radioimmunoassay for testosterone, identified that the laboratory failed to establish an acceptable normal range for 18 and 19 year old patients. 4. An interview with the laboratory owner on 1 /28/2026 at 12:08 pm confirmed that normal ranges had not been verified prior to patient testing. 5. The laboratory reports performing 960 testosterone tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Qualigen FastPack IP instrument verification records, Qualigen FastPack Testosterone individualized quality control plan (IQCP), calibration records, quality control (QC) records, monthly quality assurance (QA) plan review records and an interview with testing personnel 1 on 1/28/2026, the laboratory director failed to ensure that new instrument verifications were adequate, that

	calibrations and quality control were performed to provide accurate and reliable patient results and that there was an adequate QA plan in place to identify quality failures. See D6013, D6120
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the Qualigen FastPack IP instrument verification and an interview with the laboratory owner on 1//28/2026, the laboratory director failed to ensure that the verification of testosterone performance specifications were adequate prior to beginning patient testing on 5/2/2025. The findings include: 1. A review of the new instrument verification for the Qualigen FastPack IP identified that the laboratory director failed to review and approve the verification results for accuracy, precision, and reportable range to ensure that they were adequate for testosterone testing prior to beginning patient testing on 5/2/2025. 2. An interview with the laboratory owner on 1/28/2026 at 1:21 pm confirmed that the laboratory director failed to review and approve the verification prior to patient testing beginning. 3. The laboratory reports performing 960 testosterone tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review the Qualigen FastPack testosterone individualized quality control plan (IQCP), calibration records, quality control (QC) records, patient reports, monthly quality assurance (QA) plan review records and an interview with testing personnel 1 (TP1) on 1/28/2026, the laboratory director failed to ensure that QC was performed prior to patient testing for seven (7) of eight (8) months in 2025 and that there was an adequate QA program to identify and correct the quality failures. The findings include: 1. A review of the Qualigen FastPack Testosterone IQCP signed on 6 /4/2025 stated "two levels of quality control (C1 and C2) will be assayed with each new lot, each new shipment, after calibration, and weekly" and "QC results, timely calibrations, and maintenance documentation will be reviewed on a monthly basis a part of the ongoing QA Plan." 2. A review of calibration records, QC records and patient reports for testosterone testing identified that the laboratory director failed to ensure QC was performed weekly and after performing calibrations prior to performing patient testing impacting 250 patients from June 2025 through December 2025. See D5445 3. A review of the monthly QA plan reviews performed by testing personnel and the laboratory director identified that the laboratory director failed to identify the QC failures and ensure that corrective actions were performed. 4. An interview with TP1 on 1/28/2026 at 11:21 am confirmed that she had discussed the 12

	/10/2025 calibration without QC prior to patient testing with the laboratory director and that no corrective action had been performed. 5. The laboratory reports performing 960 testosterone tests annually.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training documentation, calibration documents, quality control (QC) documents an interview with the laboratory owner on 1/28/2026, the technical consultant (TC) failed to ensure that three (3) of three (3) testing personnel had training to accurately perform and report patient testing. The findings include: 1. A review of the CMS 209 identified three (3) testing personnel performing testosterone testing from April 2025 to January 2026. 2. A review of calibration and QC records identified eight (8) occurrences where calibrations were performed and patient testing was performed prior to QC affecting 250 patients. A review of calibration and QC records identified that three (3) of three (3) testing personnel performed calibrations and tested patients prior to performing QC which identified that the TC failed to recognize training needs to ensure testing personnel were performing and reporting accurate patient results. 3. An interview with the laboratory owner on 1/28/2026 at 1: 30 pm identified that the TC performed training remotely. 4. The laboratory reports performing 960 testosterone tests annually.