Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2295849	02/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Optimal Man, Pllc	1270 25th St. Place, Suite 1, Hickory, NC	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of proficiency testing (PT) records, review of the laboratory's Proficiency and Split Sample policy, and an interview with the Lab Director (LD) on 2/26/26, the laboratory failed to enroll in a proficiency testing program for Testosterone. Findings: 1. Review of PT records revealed no documentation of proficiency testing or blind split sample testing since 4/17/25. 2. Review of the laboratory's Proficiency and Split Sample policy revealed an effective date of 2/25/26. There were no other policies or procedures that addressed proficiency testing for regulated analytes. 3. During an interview at approximately 11:30 a.m., the LD confirmed there were no proficiency or split sample testing records available for 2025 or 2026. The LD stated proficiency had not been ordered since her employment on 4/17/25 and confirmed the Proficiency and Split Sample policy was established on 2/25/26.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including

	instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's 2025 and 2026 analytic systems records, review of the NanoEnTek FREND Testosterone reagent package insert (PI), absence of records, and interview with Testing Personnel #2 (TP2) and the Laboratory Director (LD) on 2/26/26, the laboratory failed to retain analytic systems records. Findings: 1. Review of 2025 and 2026 QC and instrument maintenance records revealed documentation of external quality control for 1 out of 11 months (July 2025) and no instrument maintenance records 11 out of 11 months. 2. Review of the NanoEnTek Testosterone reagent PI revealed, "Unopened materials are stable until the expiration date on the label when stored at the specified temperature." The PI listed Testosterone cartridges under "Refrigerator temperature (2-8 degrees Celsius)." There were no refrigerator temperature records between 4/17/25 and 12/17/25. 3. During an interview at approximately 12:15 p.m., TP2 stated the QC records for April, May, and June 2025 were stored on a thumb drive that malfunctioned, deleting all records. TP2 explained there were no external QC records after July 2025 due to the QC being on backorder. The LD confirmed there were no maintenance records or refrigerator temperature records available prior to 12/18/25.
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 review of the laboratory's Test Menu Reportable Ranges policy, review of the NanoEnTek FREND System performance specification validation records, and an interview with the Laboratory Director (LD) on 2/26/26, the laboratory failed to verify the reportable range for Testosterone results reported by the NanoEnTek FREND System. Findings: 1. Review of the laboratory's Test Menu Reportable Ranges policy revealed, "The reportable range for this quantitative test has been...established by the manufacturer as 20 ng/dL - 1500 ng/dL (nanograms per deciliter). 2. Review of the NanoEnTek FREND System's performance specification validation records revealed an EP Evaluator Accuracy report for Testosterone that stated, "...Testosterone was analyzed on F10U210204-032 over a range of 227.8 to 780.6 ng/dL. Reportable Range was not verified." The record was signed by the LD on 5/28/25. 3. During an interview at approximately 1:25 p.m., the LD confirmed there were no other records indicating the laboratory's validation of the analyzer's reportable range.
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 review of the NanoEnTek FREND analyzer user manual, the absence of external quality control (QC) records, absence of an Individualized Quality Control Plan (IQCP), and interviews with the Lab Director (LD) on 2/26/26, the laboratory failed to test two levels of external QC material each day of patient testing per regulatory requirements. Findings: 1. Review of the NanoEnTek FREND Testosterone assay sheet revealed the following statement on page 7, under External Quality Control Testing, "It is recommended that a minimum of two levels of controls be run at least once per month or once for each new lot, whichever comes earlier. However, controls should be run according to the local requirements for each laboratory." 2. Review of the 2025 and 2026 quality control records revealed external quality control results in July 2025. External quality control records were not available for 10 of the 11 months reviewed. There was no IQCP available for review. 3. During an interview at approximately 11:30 a.m., the LD confirmed the lab was following the manufacturer's instructions, performing external quality control once per month. The LD also confirmed there was no established IQCP to indicate the acceptable performance of less stringent manufacturer quality control instructions.
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 review of a patient Electronic Medical Record (EMR), review of the NanoEnTek analyzer patient result printout, and interview with the Lab Director (LD) on 2/26/26, the laboratory failed to include normal values (reference intervals) and units of measurement on the patient test reports. 1. Review of a patient's EMR laboratory report revealed the absence of both normal values (reference intervals) and units of measurement (nanograms per deciliter or ng/dl) for Testosterone. 2. Review of the corresponding NanoEnTek analyzer report revealed the absence of normal values (reference intervals) and the presence of units of measurement (nanograms per deciliter or ng/dl) for Testosterone. 3. During an interview at approximately 2:15 p.m., the LD confirmed that the EMR patient reports are missing normal ranges and units of measurements for Testosterone.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on absence of proficiency testing records, review of laboratory policies, review of the NanoEnTek FREND analyzer performance validation records, review of test reports, review of corrective actions, and interview with the Lab Director (LD) on 2/26 /26, the lab director failed to provide effective direction over the operation of the laboratory. Findings: 1. Absence of proficiency testing records revealed the laboratory was not enrolled in an appropriate proficiency testing program as required for regulated analytes. Review of the laboratory's Proficiency and Split Sample policy revealed the Proficiency and Split Sample policy was effective 2/25/26. See D2000 2. Review of the NanoEnTek FREND analyzer performance validation records revealed the analyzer's reportable range was not verified. See D5421. 3. Review of patient test reports revealed the absence of normal values (reference intervals) and units of measure for Testosterone. See D5807 4. Review of the Quality Assessment policy revealed an effective date of 2/26/26. 5. Review of documented corrective actions revealed no corrective actions were taken for D2000, D5421, or D5807, although patient testing had been performed since 4/17/25. 5. During an interview at approximately 2:20 p.m., the LD confirmed their duties began on 4/17/25 when the Certificate of Registration became effective.