Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2275119	10/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Limitless Male Medical Clinic	20 Power Drive #5, Council Bluffs, IA	

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 initial survey was completed 10/27/2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 CFR 493.1212 Condition: Endocrinology 42 CFR 493.1403 Condition: Moderate Complexity Laboratory Director 42 CFR 493.1409 Condition: Technical Consultant - Moderate Complexity 42 CFR 493.1421 Condition: Laboratory Testing Personnel
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on lack of proficiency testing records and an Individualized Quality Control Plan (IQCP); review of Frend operator manual, quality control (QC) records, QC manufacturer's package insert; observations made during the survey and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory failed to: twice annually verify the accuracy of the analyte, testosterone, refer to D5217; include all the necessary policies and procedure for performing testosterone testing, refer to D5403; ensure the laboratory director approved, signed and dated all policies and procedures, refer to D5407; complete an IQCP plan for performing testosterone QC and perform electronic QC each day of patient testing, refer to D5445; perform external testosterone QC each day of patient testing, refer to D5449; and take corrective action when QC fell outside of the manufacturer's established ranges, refer to D5783.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of proficiency testing records, observations made during the survey, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:25 pm on 10/25/2023, the laboratory failed to verify the accuracy of the analyte, testosterone twice annually for two out of two time periods from 1/17/23 - 10 /25/2023. The findings include: 1. The laboratory began performing testosterone testing on patient specimens on 1/17/2023. 2. The laboratory personnel confirmed the laboratory did not enroll in proficiency testing for testosterone and had not verified the accuracy for the analyte, testosterone since starting testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 2:30 pm on 10/25 /2023, the laboratory failed to have the following policies and procedures: requirements for patient preparation, specimen collection and labeling criteria, specimen processing, criteria for specimen acceptability and rejection, and the step-by-step procedure for performing testosterone testing on the Frend test system. The findings include: 1. The laboratory used the Frend operator manual as the procedure manual. 2. The Frend operator manual did not include the above listed policies and procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of the Frend operator manual and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) and 2:30 pm on 10/25/2023, the laboratory director failed to approve, sign and date all laboratory policies and procedures. The findings include: 1. The laboratory used the Frend test system to perform testosterone testing. 2. The laboratory intended to use the Frend operator manual as the procedure manual. 3. At the time of the survey, the laboratory director had not approved, signed or dated the Frend operator manual.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of the Frend operator manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:31 pm on 10/25/2023, the laboratory failed to have a completed Individualized Quality Control Plan (IQCP) for the Frend test system. The findings include: 1. The laboratory used the Frend test system to perform testosterone testing. 2. The Frend operator manual contained an IQCP plan for the test system. The laboratory needed to complete portions of the IQCP in order for it to be effective and allow the laboratory to perform quality control less than each day of patient testing. 3. At the time of the survey, the laboratory had not completed the IQCP nor had the laboratory director approved the IQCP. B. Based on review of the Frend operator manual and quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:31 pm on 10/25/2023, the laboratory failed to perform electronic quality controls as directed by the manufacturer for six out of 32 days of patient testing from 6/1/2023 - 10/25/2023. The findings include: 1. The laboratory used the Frend test system to perform testosterone testing. 2. The Frend operator manual stated the laboratory must perform an electronic QC cartridge each day of patient testing. 3. The laboratory performed patient testosterone testing on the following dates: *6/1/2023 - 2 patients *6/8/2023 - 1 patient *6/14/2023 - 1 patient *6/16/2023 - 1 patient *6/19/2023 - 1 patient *8/23/2023 - 1 patient 4. The laboratory did not perform the electronic QC cartridge for the above dates of patient testing.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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--At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on lack of an Individualized Quality Control plan, review of the Frend operator manual and quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:31 pm on 10/25/2023, the laboratory failed to perform two levels of external QC each day of patient testing for the analyte, testosterone for 26 out of 28 days of patient testing from 6/1/2023 - 10/25/2023. The findings include: 1. The laboratory used the Frend test system to perform testosterone testing. 2. The Frend Operator Manual stated external QC must be performed monthly, with each new shipment and/or lot number of test cartridges, and with untrained operators. The laboratory needed to complete the IQCP in order to perform the less frequent external QC. 3. Refer to D5445, the laboratory did not complete the IQCP plan. 4. The laboratory performed testosterone testing for 30 patients on the following dates in 2023: 6/1, 6/8, 6/14, 6/16, 6/19, 6/21, 6/23, 6/28, 6/30, 7/5, 7/6, 7/10, 7/13, 8/16, 8/21, 8/23, 8/30, 9/1, 9/8, 9/13, 9/15, 9/25, 10/9, 10/12, 10/23, 10/25. 5. The laboratory did not have documented external QC for the dates listed.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) package insert, QC records and confirmed by laboratory personnel identifier #1 (refer the Laboratory Personnel Report) at 1:31 pm on 10/25/23, the laboratory failed to take and document corrective action when the testosterone QC fell outside of the manufacturer's expected ranges for one out of five days from 6/1/2023 - 10/25/2023. The findings include: 1. The QC package insert for Level 1 (Lot 2008122, exp 10/31/23) testosterone stated the expected range as 86.08 - 300.83 ng/dL. 2. On 6/23/2023 the laboratory ran Level 1 testosterone and received a value of 80.35 ng/dL. 3. At the time of the survey, the laboratory did not take corrective action with Level 1 testosterone QC fell outside of the manufacturer's established range.
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 lack of proficiency testing records, an Individualized Quality Control Plan

	(IQCP) and personnel records; review of Frend operator manual, quality control (QC) records, QC manufacturer's package insert, observations made during the survey and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure a quality control program is established and maintained, refer to D6020; ensure a quality assessment program is established and maintained, refer to D6021; ensure that prior to testing patient specimens personnel are qualified and trained, refer to D6029; and ensure the laboratory has all of the necessary policies and procedures, refer to D6030.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Frend operator manual and QC records and confirmed by laboratory personnel, identifier #1 (refer to the Laboratory Personnel Report) at 1:31 pm on 10/25/2023, the laboratory director failed to ensure the laboratory established and maintained an effective quality control program from 6/1/2023 - 10/25/2023. The findings include: 1. The laboratory did not have an Individualized Quality Control Plan, refer to D5445. 2. The laboratory did not perform the electronic QC cartridge each day of patient testing, refer to D5445. 3. The laboratory did not perform external QC each day of patient testing, refer to D5447. 4. The laboratory did not take corrective action when the QC fell outside the manufacturer's established ranges, refer to D5783.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of quality assessment policy and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 2:30 pm on 10/25/2023, the laboratory director failed to ensure the laboratory established and maintained a quality assessment program. The findings include: 1. The laboratory did not have a quality assessment policy. 2. At the time of the survey, the laboratory had not performed any quality assessment activities.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)

	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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:15 pm on 10/25/2023, the laboratory director failed to ensure that prior to performing patient testing laboratory personnel identifier #1 met the educational requirements and had appropriate training documented. The findings include: 1. Laboratory identifier #1 did not have educational qualifications for performing testosterone testing. Refer to D6063 2. Laboratory identifier #1 did have have initial training for performing testosterone testing. Refer to D6065.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at 2:30 pm the laboratory director failed to ensure the laboratory had all of the necessary policies and procedures. The findings include: 1. The laboratory intended to use the Frend operator manual as the procedure manual. 2. The Frend operator manual did not have all of the required procedures. Refer to D5403.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

	Based on lack of an Individualized Quality Control Plan (IQCP) and personnel records; review of Frend operator manual, quality control (QC) records, QC manufacturer's package insert, observations made during the survey and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) the technical consultant failed to establish and maintain a quality control program, refer to D6024 and ensure initial training for laboratory personnel, refer to D6045.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the Frend operator manual and QC records and confirmed by laboratory personnel, identifier #1 (refer to the Laboratory Personnel Report) at 1:31 pm on 10/25/2023, the technical consultant failed to ensure the laboratory established and maintained an effective quality control program from 6/1/2023 - 10/25/2023. The findings include: 1. The laboratory did not have an Individualized Quality Control Plan, refer to D5445. 2. The laboratory did not perform the electronic QC cartridge each day of patient testing, refer to D5445. 3. The laboratory did not perform external QC each day of patient testing, refer to D5447. 4. The laboratory did not take corrective action when the QC fell outside the manufacturer's established ranges, refer to D5783.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (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 lack of training records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:15 pm on 10/25/2023, the technical consultant failed to ensure initial training for one out of one individual performing testosterone testing. The findings include: 1. Laboratory personnel identifier #1 started performing testosterone testing using the Frend test system effective 9/1/2023. 2. At the time of the survey, the laboratory did not have training records for laboratory personnel identifier #1.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on lack of laboratory personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform moderate complexity, refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on lack of laboratory personnel records and confirmed by laboratory personnel identifier #1 at approximately 1:15 pm on 10/25/2023, the laboratory failed to have educational documentation to qualify 1 out of 1 testing personnel who performed testosterone testing using the Frend test system. The findings include: 1. Testing personnel identifier #1 started performing testosterone testing effective 9/1/2023. 2. At the time of the survey, the laboratory did not have a copy of the educational diploma and/or transcripts for testing personnel identifier #1.