

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D2280165	(X3) Date Survey Completed 01/18/2024
Name of Provider or Supplier Limitless Male Medical Clinic	Street Address, City, State 3721 West 13th Street Suite A, Grand Island, NE	
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 on 1/18/2024. 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
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing records, lack of approved policies and procedures, review of quality control (QC) records, review of instrument patient testing records, review of performance specifications records; interview with testing personnel identifier #1 (refer to the Laboratory Personnel Report) and interview with the technical consultant; the laboratory failed to: twice annually verify the accuracy of the analyte, testosterone (refer to D5217); ensure the laboratory director approved, signed and dated all policies and procedures (refer to D5407); review and evaluate verification data before patient testing (refer to D5421); perform electronic QC each day of patient testing (refer to D5445); and perform external testosterone QC each day of patient testing (refer to D5449).</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on lack of proficiency testing records, observations made during survey, and interview with laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at 12:37 PM on 1/18/2024, the laboratory failed to verify the accuracy of the analyte, testosterone, twice annually for one out of one time period from 6/9/2023 - 1/18/2024. Findings are: 1. The laboratory began performing testosterone testing on patient samples on 6/9/2023. 2. Interview with laboratory personnel, confirmed the laboratory did not verify the accuracy for the analyte, testosterone, since starting testing.

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 interview with laboratory personnel #1 (refer to the Laboratory Personnel Report), at 12:37 PM on 1/18/2024, the laboratory director failed to approve, sign, and date all laboratory policies and procedures. Findings are: 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 time of survey, the laboratory director had not approved, signed or dated, the Frend operator manual. 4. Interview with laboratory personnel #1 (refer to the Laboratory Personnel Report) confirmed the laboratory director had not approved, signed or dated, the Frend operator manual.

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 review of Frend verification report, review of instrument patient testing records, and interview with the technical consultant at, 11:34 AM on 1/18/2024, the laboratory failed to review and evaluate the verification report before patient testing on thirty-two out of seventy-one patients tested from 6/9/2023 - 11/12/2023. 1. Review of the Frend verification report revealed the lab director approved the verification report on 11/12/2023. 2. Review of instrument patient testing records revealed the laboratory tested thirty-two patients before 11/12/2023. Patient testing was performed on the following dates: 6/9/2023, 6/23/2023, 7/13/2023, 7/24/2023, 7/31/2023, 8/24/2023, 8/25/2023, 8/28/2023, 8/31/2023, 9/1/2023, 9/7/2023, 9/8/2023, 9/15/2023, 9/18/2023, 9/25/2023, 10/17/2023, 10/20/2023, 10/26/2023, 10/27/2023, 10

/30/2023, 11/3/2023, 11/7/2023, 11/9/2023, 11/10/2023. 3. Interview with the technical consultant confirmed the laboratory performed patient testing before the verification report was reviewed and evaluated.

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:

Based on review of the Frened operator manual, review of quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at 12:05 PM on 1/18/2024, the laboratory failed to perform electronic quality control as directed by the manufacturer for fourteen out of forty-seven days of patient testing from 6/9/2023 - 1/18/2024. Findings are: 1. The laboratory used the Frened test system to perform testosterone testing. 2. The Frened operator manual stated the laboratory must perform an electronic QC cartridge each day of patient testing. 3. The laboratory failed to perform the electronic QC cartridge on the following dates of testosterone patient testing: - 6/23/2023 - 1 patient - 7/24/2023 - 2 patients - 7/31/2023 - 1 patient - 8/24/2023 - 2 patients - 8/25/2023 - 1 patient - 8/28/2023 - 1 patient - 8/31/2023 - 1 patient - 9/1/2023 - 2 patients - 9/7/2023 - 1 patient - 9/8/2023 - 2 patients - 9/15/2023 - 1 patient - 9/18/2023 - 1 patient - 11/14/2023 - 1 patient - 11/17/2023 - 1 patient 4. Interview with the laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) confirmed the laboratory failed to perform electronic quality control as directed by the manufacturer.

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 review of quality control (QC) records and confirmed by the laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at 12:05 PM on 1/18/2024, the laboratory failed to perform two levels of external QC each day of patient testing for the analyte, testosterone, for forty-one out of forty-seven days of patient testing from 6/9/2023 - 1/18/2024. Findings are: 1. The laboratory used the Frened test system to perform testosterone testing. 2. The laboratory failed to perform two levels of external QC on the following dates of testosterone patient testing: 6/9/2023, 6/23/2023, 7/13/2023, 7/24/2023, 7/31/2023, 8/24/2023, 8/25/2023, 8/28/2023,

	<p>8/31/2023, 9/1/2023, 9/7/2023, 9/8/2023, 9/15/2023, 9/18/2023, 9/25/2023, 10/20/2023, 10/26/2023, 10/27/2023, 10/30/2023, 11/3/2023, 11/9/2023, 11/10/2023, 11/13/2023, 11/14/2023, 11/17/2023, 11/21/2023, 11/24/2023, 11/27/2023, 12/1/2023, 12/4/2023, 12/8/2023, 12/11/2023, 12/12/2023, 12/18/2023, 12/28/2023, 12/29/2023, 1/4/2024, 1/5/2024, 1/8/2024, 1/15/2024, and 1/18/2024. 3. Interview with the laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) confirmed the laboratory failed to perform two levels of external QC each day of patient testing.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing records, review of quality control (QC) records, interviews with the technical consultant and 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); and ensure that an approved procedure manual is available to all personnel (refer to D6030).</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Frennd operator manual, review of quality control (QC) records and interview with the technical consultant, at 11:34 AM on 1/18/2024, at 12:05 PM on 1/18/2024, the laboratory director failed to ensure the laboratory established and maintained an effective quality control program from 6/9/2023 - 1/18/2024. Findings are: 1. The laboratory did not perform electronic QC cartridge each day of patient testing (refer to D5445). 2. The laboratory did not perform external QC each day of patient testing (refer to D5447). 3. Interview with the technical consultant confirmed the laboratory director failed to ensure the laboratory established and maintained an effective quality control program.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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</p>

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 the technical consultant, at 11:34 AM at 1/18/2024, the laboratory director failed to ensure the laboratory established and maintained a quality assessment program. Findings are: 1. The laboratory did not have a quality assessment policy. 2. At the time of survey, the laboratory had not performed any quality assessment activities. 3. Interview with the technical consultant confirmed the laboratory director failed to ensure the laboratory established and maintained a quality assessment program.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with laboratory personnel #1 (refer to the Laboratory Personnel Report), at 12:37 PM on 1/18/2024, the laboratory director failed to approve, sign, and date all laboratory policies and procedures. Findings are: 1. The laboratory used the Frened test system to perform testosterone testing. 2. The laboratory intended to use the Frened operator manual as the procedure manual. 3. At time of survey, the laboratory director had not approved, signed or dated, the Frened operator manual. 4. Interview with laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) confirmed the laboratory director failed to approve, sign, and date all laboratory policies and procedures.

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 proof of education for technical consultant, review of quality control (QC) records, and interview with the technical consultant the technical consultant failed to have proof of education (refer to D6035) and failed to establish and maintain a quality control program (refer to D6042).

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license

issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the technical consultant, at 11:34 on 1/18/2023, the technical consultant failed to have proof of education at time of survey. Findings are: 1. No proof of education for technical consultant was presented at time of survey. 2. Interview with the technical consultant at confirmed the laboratory did not have qualifications at time of survey.

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 quality control (QC) records and interview with the technical consultant, at 11:34 on 1/18/2023, the technical consultant failed to ensure the laboratory established and maintained an effective quality control program from 6/9

/2023 - 1/18/2024. Findings are: 1. The laboratory did not perform the electronic QC cartridge each day of patient testing (refer to D5445). 2. The laboratory did not perform external QC each day of patient testing (refer to D5447). 3. Interview with the technical consultant confirmed the technical consultant failed to ensure the laboratory established and maintained an effective quality control program.