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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D2179378 | (X3) Date Survey Completed 05/29/2024 |
| Name of Provider or Supplier Limitless Male Medical Clinic | Street Address, City, State 1300 37th Street Suite 1, West Des Moines, 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 |
|---------------------------|--|
| D3037 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at 10:22 am on 5/29/2024, the laboratory failed to retain all proficiency testing records for four out of seven proficiency testing events from 1/1/2022 - 5/29/2024. The findings include: 1. For 2022 testing event 1, the laboratory did not retain the proficiency testing results from the Frend analyzer or the attestation statement. 2. For 2022 testing event 2, the laboratory did not retain the proficiency testing results from the Frend analyzer. 3. For 2023 testing event 2, the laboratory did not retain the proficiency testing results from the Frend analyzer or the attestation statement. 4. For 2024 testing event 1, the laboratory did not retain the proficiency testing results from the Frend analyzer.</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> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at 10:22 am on 5/29/2024, the laboratory failed to verify the accuracy at least twice annually for the analyte, testosterone for one out of two time periods from 1/1/2023 - 12/31/2023. The findings include: 1. The laboratory enrolled in proficiency testing for the analyte, testosterone</p> |

in 2023. 2. For 2023 testing event 1, the laboratory did not participate in the event. 3. For 2023 testing event 3, the laboratory did not participate in the event. 4. The laboratory only participated in 2023 testing event 2, and did not verify accuracy by another method.

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 the FrenD quality control (QC) logs and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at 10:43 am on 5/29/24, the laboratory failed to take and document correct action when testosterone QC failed to meet the laboratory's established criteria for eight out of 95 days of testing from 9/1/23 - 5/29/24. The findings include: 1. The laboratory used the following QC ranges for lot number 6360A23002 of testosterone testing: Level 1: 221.0 - 565.9 ng/dL Level 2: 819.1 - >1500 ng/dL 2. The laboratory accepted the following out of range testosterone QC (lot number 6360A23002) without documenting correct action: *1/2/2024 Level 2: 772.9 ng/dL *1/8/2024 Level 1: 186.9 ng/dL *1/15/2024 Level 1: 161.1 ng/dL and Level 2: 790.9 ng/dL *1/22/2024 Level 1: 135.1 ng/dL *1/29/2024 Level 1: 147.1 ng/dL *2/05/2024 Level 1: 220.7 ng/dL and Level 2: 774 ng/dL *2/29/2024 Level 1: 214.2 ng/dL *3/28/2024 Level 1: 150.9 ng/dL 3. The laboratory performed patient testosterone testing on the following dates without 2 levels of QC within the acceptable range: *1/15/2024 - 1 patient *1/18/2024 - 1 patient *1/19/2024 - 1 patient *1/30/2024 - 1 patient *2/8/2024 - 1 patient *2/29/2024 - 1 patient 4. At the time of the survey, the laboratory did not have corrective action documented for the out of range QC.

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 audits and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:45 am on 5/29/2024, the laboratory director failed to ensure the laboratory maintained a quality assessment

program from 1/1/2023 - 5/29/2024. The findings include: 1. At the time of the survey, the laboratory had not performed any quality assessment audits from 1/1/2023 - 5/29/2024.