

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2117558	(X3) Date Survey Completed 06/17/2024
Name of Provider or Supplier Atlantic Men's Clinic Boca Raton, Llc	Street Address, City, State 2201 Nw Corporate Blvd Ste 100, Boca Raton, FL	
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	A recertification survey was conducted on June 17, 2024. Atlantic Men's Clinic Boca Raton LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of package inserts, temperature logs, Corrective Action Log and interview, the laboratory failed to identify and document corrective actions for temperatures out of range for the refrigerator for 16 days from 10/02/2023 to 06/14/2024. Findings: Observation on 06/17/2024 at 1:15 PM, noted containers for the FastPack cartridges and the controls for PSA (Prostate-Specific Antigen) and Testosterone listed the storage temperature of 2-8 degrees Celsius (C). Review of the product inserts for FastPack IP Total PSA Immunoassay and the FastPack IP Testo (testosterone) Immunoassay noted "Store at 2-8 degrees C. Review of the Daily Environmental Log noted, "Acceptable ranges for FastPack IP reagent packs and FastPack IP system analyzer are posted at the beginning of each column, if any of the readings are outside the range, record the corrective action (i.e. adjusted temperature control knob and checked testing supplies for deterioration) in the Corrective Action</p>

Log." The Daily Environmental Log noted the range for the refrigerator was between 2 and 8 C (35 - 46 degrees Fahrenheit (F)). On the following dates the temperatures were out of range: 10/02/2023 - 34 degrees F 10/03/2023 - 33 degrees F 04/02/2024 - 32 degrees F 04/04/2024 - 33 degrees F 04/05/2024 - 32 degrees F 04/12/2024 - 34 degrees F 04/15/2024 - 33 degrees F 04/17/2024 - 32 degrees F 04/18/2024 - 33 degrees F 05/09/2024 - 32 degrees F 05/10/2024 - 34 degrees F 05/14/2024 - 34 degrees F 05/20/2024 - 34 degrees F 05/31/2024 - 32 degrees F 06/03/2024 - 34 degrees F 06/14/2024 - 34 degrees F Review of the Corrective Action Log for 2023 and 2024 revealed there was no corrective action documented for the refrigerator temperatures that were out of range. On 06/17/2024 at 2:50 PM, the Laboratory Supervisor acknowledged the temperatures were out of range and no corrective action was documented.