

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2108648	(X3) Date Survey Completed 11/08/2023
Name of Provider or Supplier Super Male Mens Clinic	Street Address, City, State 5345 Sw College Rd Ste 402, Ocala, 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	At the time of the announced, on-site recertification survey, Super Male Mens Clinic, was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 API (American Proficiency Institute) proficiency testing records and staff interview, the laboratory failed to retain proficiency testing records for 2 testing events in 2022. The findings include: Review of API proficiency testing records for the 1st Event in 2022 and 3rd Event in 2022 showed there was no raw data printouts kept from the Tosoh analyzer used for PSA (prostate-specific antigen), testosterone, and estradiol patient testing. During an interview on 11/8/23 at 11:00 AM, Testing Person A confirmed that the proficiency testing records were missing.</p>
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>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the facility failed to document corrective action when the refrigerator temperature was out of range for 7 out of 43 days (September 2023, October 2023); and failed to document corrective action when the freezer temperature was out of range for 23 out of 64 days reviewed (April 2022, September 2023, October 2023). The findings include: 1. Record review of the refrigerator temperature log dated September 2023 showed the acceptable temperature is 2-8 degrees C. The acceptable temperature for the freezer showed -70C to -20C. (a). The temperature documented for the refrigerator on 9/20/23 showed 1C. The temperature on 9/25/23 and 9/27/23 showed -1C. (b). The temperature for the freezer on 9/1/23, 9/8/23, 9/13/23, and 9/18/23 showed -17C. The temperature on 9/5/23, 9/11/23, 9/19/23 showed -18C. The temperature on 9/6/23 and 9/29/23 showed -19C. The temperature on 9/16/23 showed -16C. 2. Record review of the refrigerator temperature log dated October 2023 showed the acceptable temperature is 2-8 degrees C. The acceptable temperature for the freezer showed -70C to -20C. (a). The temperature for the refrigerator on 10/3/23, 10/8/23, 10/19/23 showed 0C. The temperature on 10/4/23 showed -5C. (b). The temperature for the freezer on 10/3/23 showed -19C. 3. Record review of the refrigerator temperature log dated April 2022 showed the acceptable temperature is 2-8 degrees C. The acceptable temperature for the freezer showed -70C to -20C. (a). The temperature for the freezer on 4/1/22, 4/18/22, and 4/19/22 showed -10C. The temperature on 4/4/22, 4/14/22, and 4/29/22 showed -18C. The temperature on 4/5/22 and 4/28/22 showed -15C. The temperature on 4/17/22 and 4/26/22 showed -17C. The temperature on 4/22/22 showed -14C. The temperature on 4/25/22 showed -12C. The documents did not show any corrective action when the temperatures were out of range. The interview with Testing Person A on 11/8/23 at 12:30pm confirmed the corrective action documentation was missing.