

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2115892	<b>(X3) Date Survey Completed</b>  11/26/2019
<b>Name of Provider or Supplier</b>  Super Male Of Villages Llc	<b>Street Address, City, State</b>  17809 Se 109th Ave, Summerfield, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	At the time of the announced, onsite recertification survey, Super Male of Villages was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493. .
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to perform the required calibration of the TOSOH AIA-360 analyzer prior to performing patient testing of estradiol samples for 3 of 8 days reviewed in December 2018. Findings include: The record review on 11/26/19 of quality control records for the analyte estradiol showed that calibration had expired on 12/18/18. Calibration was not performed until 1/3/19. Patient testing records indicated one patient had estradiol testing during that time frame. The interview with Testing Personnel #1 on 11/26/19 at 12:00pm confirmed that calibration had not been performed although the manufacturer states recalibration of a lot number is required after 90 days and patients should not be tested until calibration is completed.</p>

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory staff, the laboratory reported patient results with controls that were not acceptable for 2 out of 4 days of patient testing in August 2019. Findings include: 1. A record review of quality control (QC) records for Testosterone testing showed on 8/6/19 the low control was reported as 301.4 which exceeded the 2+ standard deviation of 155.0. The medium control on the same date was reported as 648.9 which exceeded the 2+ standard deviation of 638.0. The review of patient testing records showed one patient was tested that day. 2. On 8/13/19 the Testosterone low control was reported as 376.4 and the medium control was reported as 780.8. The review of patient testing records showed 2 patients were tested that day. The interview with Testing Personnel #1 on 11/26/19 at 11:38am confirmed the QC was out of range and further investigation should have been performed prior to reporting patient results.