Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D2289828	**(X3) Date Survey Completed** 06/18/2025
Name of Provider or Supplier Tristate Men's Health Iii Llc	**Street Address, City, State** 1430 Oak Court, Suite 303, Beavercreek, OH	
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**
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to report the correct Testosterone reference range values for two out of two patient test reports reviewed. This deficient practice had the potential to affect 1,434 out of 1,434 patients tested in the subspecialty of Endocrinology from 03/20 /2024 through 06/18/2025. Findings include: 1. Review of the laboratory's "Reference Ranges" policy and procedure approved by the Laboratory Director on 01/28/2025 found the following: Qualigen FastPack Male Reference Range IP System Testosterone 264-916 ng/dL 2. Review of two patient test reports found the following reference ranges listed: Chart Number Normal Reference Range 57342 20-49 yrs 214-1009 ng/dL >50 yrs 216-1004 ng/dL 56725 20-49 yrs 214-1009 ng/dL >50 yrs 216-1004 ng/dL 3. An interview with TP #1, confirmed the Testosterone reference ranges listed in the policy and procedure did not match the reference ranges listed on the patient reports. The interview occurred on 06/18/2025 at 12:10 PM. ng/dL = nanograms per deciliter
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

	This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, three out of three TP failed to follow the laboratory's general maintenance policy and procedures and document all calibrations and maintenance performed for the Gilson Microman pipettes. This deficient practice had the potential to affect 1,448 out of 1,448 patients tested in the subspecialties of Routine Chemistry and Endocrinology from 03/20/2024 through 06/18/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 06/09/2025, found three individuals listed and qualified to function as TP. 2. Review of the laboratory's policy and procedure manual titled, "General Maintenance" approved via signature and date by the Laboratory Director on 01/28/2025, found the following statement: "Pipet accuracy is required to be verified annually or more frequently if required by manufacturer. Specific companies can provide this service either by sending away the pipette or dispensed aliquots. Either method is acceptable and will usually have a 3 to 5-day turnaround time. Certificate of Accuracy should be retained in the laboratory records." 3. Direct observation of the laboratory found two Gilson Microman pipettes in use for specimen and reagent aliquotting. 4. The inspector requested the 2024 and 2025 annual pipette accuracy records and Certificates of Accuracy documents from TP #1. TP #1 confirmed the pipette accuracy verification had not been performed per the policy and procedures and was unable to provide the requested documents. The interview occurred on 06/18/2025 at 11:15 AM.