

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2278296	(X3) Date Survey Completed 12/03/2024
Name of Provider or Supplier Tri-State Men's Health-West Chester, Ohio	Street Address, City, State 7795 Discovery Drive, West Chester, 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
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testosterone testing procedures performed in the subspecialty of Endocrinology. This deficient practice had the potential to affect 321 out of 321 patient testosterone tests from 05/29/2024 through 12/02/2024. Findings Include: 1. Review of the laboratory's policies and procedures titled "Reference Range", approved and dated by the Laboratory Director on 06/07/2024 found the following: "Testosterone 264-916 ng/dL" 2. Review of nine out of nine 2024 patient test records found the following testosterone reference ranges: "Normal Reference Range 20-49 yrs [214-1009 ng/dL]" "Normal Reference Range >50 yrs [216-1004 ng/dL]" 3. On 12/03/2024 at 11:30 AM, the TC stated the Laboratory Director had changed the testosterone reference ranges on 05/29/2024 but the "Reference Range" procedure manual had not been updated. The TC was unable to provide an updated testosterone procedure approved and dated by the Laboratory Director.</p>