Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2278296	10/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Tri-State Men's Health-West Chester, Ohio	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
D0000	An off-site revisit desk review inspection was completed on 10/21/2026 for all previous deficiencies cited during an on-site inspection on 09/29/2026. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC), the laboratory failed to achieve a proficiency testing (PT) score of at least 80% (percent) for the analyte testosterone in the second PT event in 2025. This deficient practice affected one out of three PT events in the subspecialty of Endocrinology in 2025. Findings Include: 1. Review of the laboratory's 2025 American Proficiency Institute (API) Endocrinology PT documentation, provided on 09/29/2026, revealed the following unacceptable analyte testing scores: Second PT Event Endocrinology 2025 Testosterone = 60% 2. During an interview on 09/29/2026 at 11:15 AM, the TC confirmed the unsatisfactory PT scores for the analyte listed above. 3. Record review revealed 369 Endocrinology tests in the subspecialty of Endocrinology from 12/04 /2024 through 09/29/2026.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC), the laboratory failed to follow its competency assessment policy and procedure. This deficient practice affected three out of three testing personnel (TP) from 12/04/2024 through 09/29/2026. Findings Include: 1. Review of the policy and procedure titled "Staff Orientation Training and Competency", approved via signature and date by the Laboratory Director (LD) on 06/07/2024 and 06/27/2026, and provided on 09/29 /2026, found the following statement: "As defined by CLIA, the following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing: 1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing." 2. Review of the laboratory's form CMS 209, signed and dated by the LD on 09/21/2026 and provided on 09/29/2026, found three staff members listed and qualified as TP. 3. Review of the laboratory's 2025 and 2026 competency assessment documents found the following assessment section completed via a check mark and initials by the TC: "I. Direct Observation of Test Performance" 4. During an interview on 09/29/2026 at 11:15 AM, the TC stated the 2025 and 2026 competency assessments for TP were completed remotely, direct observation did not occur, and the laboratory did not follow its policy and procedure. 5. Record review revealed 2,080 patient tests in the subspecialties of Routine Chemistry and Endocrinology from 12/04/2024 through 09/29/2026.