

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2295549	(X3) Date Survey Completed 08/07/2025
Name of Provider or Supplier Tristate Men's Health V, Llc	Street Address, City, State 110 Polaris Pkwy, Suite 210, Westerville, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an electronic mail (email) interview with the Technical Consultant (TC), the laboratory failed to successfully participate in two out of two American Proficiency Institute (API) proficiency testing (PT) events for Prostate Specific Antigen (PSA) in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 516 out of 516 patient PSA tests performed between 01/01/2025 through 08/07/2025. Findings Include: 1. The laboratory failed to achieve satisfactory proficiency testing (PT) performance with a score of at least 80% (percent) for the analyte Prostate Specific Antigen (PSA) in the first and second PT events of 2025 in the subspecialty of Routine Chemistry. This is unsuccessful</p>

participation. (Refer to D2096) 2. The Technical Consultant, via electronic mail (email) on 08/07/2025 at 1:48 PM, confirmed the laboratory did not achieve satisfactory proficiency testing (PT) performance with a score of at least 80% (percent) for the analyte Prostate Specific Antigen (PSA) in the first and second PT events of 2025.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on record review and an electronic mail (email) interview with the Technical Consultant (TC), the laboratory failed to achieve satisfactory proficiency testing (PT) performance with a score of at least 80% (percent) for the analyte Prostate Specific Antigen (PSA) in the first and second PT events of 2025 in the subspecialty of Routine Chemistry. This is unsuccessful participation. This deficient practice had the potential to affect 516 out of 516 patient PSA tests performed between 01/01/2025 through 08/07/2025. Findings Include: 1. Review of the laboratory's 2025 American Proficiency Institute (API) for the first and second testing events revealed the following results: Testing PT Sample Sample Event Event Number Score Score First IA-01 unacceptable IA-02 unacceptable IA-03 acceptable 60% IA-04 acceptable IA-05 acceptable Second IA-06 unacceptable IA-07 acceptable IA-08 acceptable 60% IA-09 unacceptable IA-10 acceptable 2. The Technical Consultant, via electronic mail (email) on 08/07/2025 at 1:48 PM, confirmed the laboratory did not achieve satisfactory proficiency testing (PT) performance with a score of at least 80% (percent) for the analyte Prostate Specific Antigen (PSA) in the first and second PT events of 2025.