

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2284964	(X3) Date Survey Completed 11/14/2025
Name of Provider or Supplier Tristate Men's Health	Street Address, City, State 950 Breckinridge Lane Ste 270, Louisville, KY	
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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a Proficiency Testing (PT) Desk Review of the Certification and Survey

	Provider Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2025 PT records (1st and 3rd events), the laboratory failed to successfully participate in a PT program for two out of three PT testing events for the subspecialty, Routine Chemistry for Prostate Specific Antigen, Total. (Refer to D2096 and 2097).
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 a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2025 PT records (1st and 3rd events), the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three PT testing events for the subspecialty, Routine Chemistry for Prostate Specific Antigen, Total. 1. Review of the CASPER-0155 report revealed the following: Routine Chemistry 2025- 1st Event The Laboratory received an unsatisfactory score of 20% for Prostate Specific Antigen, Total. Routine Chemistry 2025- 3rd Event The Laboratory received an unsatisfactory score of 40% for Prostate Specific Antigen, Total. 2. A PT desk review from API 2025 PT records confirmed the above findings.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) (g) Failure to achieve an overall testing event score of satisfactory performance for 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 a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Report and American Proficiency Institute (API) 2025 PT records (1st and 3rd events), the laboratory failed to achieve overall satisfactory performance (80% or greater) for two out of three PT testing events for the subspecialty of Routine Chemistry. 1. Review of the CASPER-0155 report revealed the following: Routine Chemistry 2025- 1st Event The Laboratory received an unsatisfactory score of 20%. Routine Chemistry 2025- 3rd Event The Laboratory received an unsatisfactory score of 40%. 2. A PT desk review from API 2025 PT records confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on a Proficiency Testing (PT) Desk Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2025 PT records (1st and 3rd events), the laboratory director failed to provide overall management and direction of the laboratory services to ensure successful PT participation for two out of three PT testing events for the subspecialty, Routine Chemistry for Prostate Specific Antigen, Total. (Refer to D6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a Proficiency Testing (PT) Desk Review of the Certification and Survey Providers Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2025 PT records (1st and 3rd events), the laboratory director failed to ensure that the PT samples were tested as required under Subpart H during two out of three PT testing events for subspecialty, Routine Chemistry for Prostate Specific Antigen, Total. (Refer to D2096 and D2097).