

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0184808	(X3) Date Survey Completed 06/05/2024
Name of Provider or Supplier Penn Highlands Tyrone	Street Address, City, State 187 Hospital Drive, Tyrone, PA	
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 review of the CASPER 155 report and graded results from the proficiency testing (PT) organization, American Proficiency Institute (API), the laboratory failed to successfully participate in PT for Compatibility Testing in the specialty of Immunohematology. The laboratory had unsatisfactory scores for the 2nd event of 2023 and the 1st event of 2024. Refer to D2181 and 2173.</p>
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p>

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on review of the CASPER 155 report and graded results from the American Proficiency Institute (API) proficiency testing (PT) organization, the laboratory failed to attain an overall testing event score of atleast 100 percent for Compatibility Testing in the specialty of Immunohematology. The laboratory had unsatisfactory scores for the 2nd event of 2023 and the 1st event of 2024. Findings include: Analyte Year Event Score PT Agency Compatibility 2023 2 80% API Compatibility 2024 1 80% API

D2181

COMPATIBILITY TESTING
CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory 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 review of the CASPER 155 report and graded results from the American Proficiency Institute (API) proficiency testing (PT) organization, the laboratory failed to successfully participate in PT for Compatibility Testing in the specialty of Immunohematology for two out of three consecutive testing events. The laboratory had unsatisfactory scores for the 2nd event of 2023 and the 1st event of 2024. Findings include: Analyte Year Event Score PT Agency Compatibility 2023 2 80% API Compatibility 2024 1 80% API