

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2305593	(X3) Date Survey Completed 06/16/2026
Name of Provider or Supplier Penn Highlands State College	Street Address, City, State 239 Colonnade Blvd, State College, 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
D0000	A desk review for proficiency testing results was conducted by the Pennsylvania State Agency for Penn Highlands State College on 06/16/2026. The laboratory was found out of compliance with the following conditions: 493.803 Condition: Successful participation. 493.1441 Condition: Laboratories performing high 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 review of the CASPER 0155 report and graded results from the proficiency testing (PT) organization, College of American Pathologists (CAP), the laboratory failed to successfully participate in PT for Total Bilirubin, Phenytoin, Hematocrit,

	Computability Testing and the specialty of Hematology. The laboratory had unsatisfactory scores for the 3rd event of 2024, the 1st, 2nd, and 3rd events of 2025, and the 1st Event of 2026.. Refer to D2096, D2118, D2130, D2131, and D2181.
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 review of the CASPER 0155D Report and graded results from the proficiency testing organization, College of American Pathologists (CAP), the laboratory failed to achieve an overall testing score of satisfactory performance for the routine chemistry analyte: Bilirubin, Total (TBil) . The laboratory had unsatisfactory scores for the 1st and 2nd events of 2025. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2025 Event 1 Tbil: 40% - 2025 Event 2 Tbil: 60% 2. Further review of the laboratory's 2025 CAP PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the routine chemistry analyte: Tbil.
D2118	TOXICOLOGY CFR(s): 493.845(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 review of the CASPER 0155D Report and graded results from the proficiency testing organization, College of American Pathologists (CAP), the laboratory failed to achieve an overall testing score of satisfactory performance for the toxicology analyte: Phenytoin (Phy) . The laboratory had unsatisfactory scores for the 3rd event of 2025 and 1st event of 2026. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2025 Event 3 Phy: 0% - 2026 Event 1 Phy: 0% 2. Further review of the laboratory's 2025 and 2026 CAP PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the toxicology analyte: Phy.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 0155D Report and graded results from the proficiency testing organization, College of American Pathologists (CAP), the laboratory failed to achieve an overall testing score of satisfactory performance for the

	hematology analyte: Hematocrit (Hct). The laboratory had unsatisfactory scores for the 3rd event of 2024 and 1st event of 2025. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2024 Event 3 Hct: 0% - 2025 Event 1 Hct: 0% 2. Further review of the laboratory's 2024 and 2025 CAP PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the hematology analyte: Hct.
D2131	HEMATOLOGY CFR(s): 493.851(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 review of the CASPER 0155D Report and graded results from the proficiency testing organization, College of American Pathologists (CAP), the laboratory failed to achieve an overall testing score of satisfactory performance for the specialty: Hematology (Heme) . The laboratory had unsatisfactory scores for the 3rd event of 2024 and 1st event of 2025. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2024 Event 1 Heme: 0% - 2025 Event 1 Heme: 75% 2. Further review of the laboratory's 2024 and 2025 CAP PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the specialty: Heme.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) (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 0155D Report and graded results from the proficiency testing organization, College of American Pathologists (CAP), the laboratory failed to achieve an overall testing score of satisfactory performance for the immunohematology analyte: Compatability Testing (XM) . The laboratory had unsatisfactory scores for the 1st and 3rd event of 2025. Findings include: 1. Review of the CASPER 0155D report revealed the following unsatisfactory scores: - 2025 Event 1 XM: 80% - 2025 Event 3 XM: 80% 2. Further review of the laboratory's 2025 CAP PT agency's graded results confirmed the above findings resulting in unsatisfactory performance for the immunohematology analyte: XM.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the CASPER 0155 report and graded results from the proficiency testing (PT) organization, College of American Pathologists (CAP), the laboratory director failed to provide overall management and direction in accordance with 493.1445. Findings include: The laboratory failed to successfully participate in proficiency testing for the following: - Compatibility testing (Immunohematology): CAP Event 1 and CAP Event 3 in 2025. - Hematocrit (Hematology): CAP Event 3 in 2024 and CAP Event 1 in 2025 - Hematology (Specialty): CAP Event 3 in 2024 and CAP Event 1 in 2025. - Phenytoin (Toxicology): CAP Event 3 in 2025 and CAP Event 1 in 2026. - Bilirubin, Total (Routine Chemistry): CAP Event 1 and CAP Event 2 in 2025. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 desk review of the laboratory's proficiency testing results from the College of American Pathologists (CAP) and the CASPER 0155D report, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2096, D2118, D2130, D2131, D2181.