

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1064236	(X3) Date Survey Completed 06/11/2026
Name of Provider or Supplier Primary And Urgent Care	Street Address, City, State 2306 Plank Road Suite 100, Fredericksburg, VA	
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 proficiency testing (PT) desk review was conducted for Primary & Urgent Care on June 11, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The surveyor attempted to interview the laboratory via email (06/04 /2026 and 06/11/2026) and telephone (06/09/2026, 06/10/2026 and 06/11/2026) but was unsuccessful due to no response from laboratory. The laboratory was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 CFR. 493.803 Condition: Successful Participation D6000 - 42 CFR. 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, and the laboratory's 2025 and 2026 American Proficiency Institute (API) Proficiency test (PT) results, the laboratory failed to successfully participate within the Hematology specialty for two consecutive PT testing events. The laboratory had unsatisfactory scores in the specialty of Hematology for the third event of calendar year 2025 and the first event of calendar year 2026. Refer to D2130 and D2131.
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 a Proficiency Testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, and the laboratory's American Proficiency Institute (API) evaluation reports for 2025 (Events one, two and three) and 2026 (Event one), the laboratory failed to achieve satisfactory performance (80%) for the analytes, White Blood Cell Count (WBC), WBC Differential (WBC diff) and Hematocrit (HCT), for two (2) consecutive testing events resulting in initial unsuccessful PT performance. The findings include: 1. Review of the CASPER 153 report revealed the following unsatisfactory scores: 2025 Event 3 WBC = 60%, WBC diff = 7% and HCT = 20%, 2026 Event 1 WBC = 0%, WBC diff = 0% and HCT = 0%, 2. A review of the laboratory's 2025 and 2026 API PT evaluation reports confirmed the above scores resulting in initial unsuccessful participation for the analytes WBC, WBC diff, and HCT. The review revealed the laboratory failed to participate in the 2026 Event 1 PT event resulting in a score of zero.
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 a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and, the laboratory's American Proficiency Institute (API) evaluation reports for 2025 (Events 1, 2, and 3) and 2026 (Event 1), the laboratory failed to achieve satisfactory performance (80%) for the specialty of Hematology for two consecutive PT events. The findings include: 1. Review of the CASPER-0155 report revealed the following unsatisfactory scores: 2025 Event 3: Hematology = 64%, 2026 Event 3: Hematology = 0%. 2. A review of the laboratory's 2025 and 2026 API PT scores for the specialty Hematology confirmed the above findings resulting in initial unsuccessful participation for the Hematology specialty.
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 PT desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, and the laboratory's American Proficiency Institute (API) 2025 and 2026 proficiency testing (PT) records, the laboratory director failed to ensure the overall quality of the laboratory services provided by failing to ensure successful participation in an Health & Human Services (HHS) approved PT program. 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 review of the CASPER 0155 report, and the laboratory's American Proficiency Institute 2025 and 2026 proficiency testing (PT) records, the laboratory director (LD) failed to ensure successful participation in their Health and Human Services (HHS) approved PT program. The laboratory had unsatisfactory scores in the specialty of Hematology for the third event of calendar year 2025 and first event of calendar year 2026. Refer to D2130 and 2131.