

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227068	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Commonwealth Pediatrics	Street Address, City, State 7023 Old Jahnke Road, Richmond, 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 announced CLIA recertification survey was conducted at Commonwealth Pediatrics on August 19, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory was found to be out of compliance with the following standards and conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 CFR. 493.803 Condition: Successful Participation; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director.
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>

This CONDITION is not met as evidenced by:
Based on a pre-survey review of the laboratory's Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses for Hematocrit on two consecutive hematology testing events (an initial unsuccessful PT performance) as noted during the recertification inspection on August 19, 2025. Refer to D2130.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on a review of proficiency testing (PT) records, and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for the hematology analyte Red Blood Cell (RBC) on one (1) of five (5) hematology testing events reviewed (timeframe: December 2023 - August 19, 2025). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records (2024 Events 1-3, 2025 Events 1-2), a total of 5 events, revealed RBC scores less than 80% for the following hematology event: 2025 API Event 2: RBC scored 60% (challenge sample 09 reported as 2.69 with acceptable range 2.23-2.42, challenge sample 10 reported as 5.00 with acceptable range 5.04 -5.47); resulting in an unsatisfactory PT performance. 3. An interview with the Director of Quality Compliance on 8/19/25 at 4:00 PM confirmed the above findings.

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 pre-survey review of the laboratory's Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Hematocrit (HCT) for two (2) consecutive Complete Blood Count (CBC) hematology testing events resulting in an initial unsuccessful PT performance as reviewed on the date of the recertification, August 19, 2025. Findings include: 1. During pre-survey preparation and review of the CMS CASPER 0155 report on 8/15/25, the inspector noted the following: Hematology 2025-1st Event - laboratory received an unsatisfactory score of forty percent (40%) for analyte 0785 HCT (NON-WAIVED). 2. A review of the laboratory's American Proficiency Institute (API) PT records during the recertification inspection on 8/19/25, revealed HCT scores less than 80% for the following 2 consecutive hematology CBC events: 2025 API Event 1: HCT scored 40% (challenge sample 02 reported as 40.1 with acceptable range 36.3-30.4, challenge sample 04 reported as 54.3 with acceptable range 48.9-53.0, challenge sample 05 reported as 53.5 with acceptable range 44.9-48.7); 2025 API Event 2: HCT scored 60% (challenge sample 08 reported as 28.3

	<p>with acceptable range 25.5-27.0, challenge sample 09 reported as 19.7 with acceptable range 15.9-17.3); resulting in an unsuccessful PT performance. 3. An interview with the Director of Quality Compliance on 8/19/25 at 4:00 PM confirmed the above findings.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on pre-survey review of the laboratory's Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a pre-survey review of the laboratory's Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in a Health and Human Services (HHS) approved proficiency testing program. Refer to D2130 and D2131.</p>