

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0225370	(X3) Date Survey Completed 07/16/2026
Name of Provider or Supplier Bristow Pediatrics, Llc	Street Address, City, State 9709 Buchanan Loop, Manassas, 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 Bristow Pediatrics, LLC on July 16, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to record an evaluation for analytes scored as unacceptable on one of three events under both hematology and microbiology specialties' modules in calendar year 2025. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) Hematology and Microbiology PT records (2024 Event 3, 2025 Events 1-3, 2026 Event 1), a total of five events per speciality, revealed no evidence of an evaluation for the following unacceptable analyte scores: 2025 API Hematology Event 2: Mean Corpuscular Hemoglobin challenge sample #HSY09 scored unacceptable - laboratory reported result as 71.5 pg / expected result was 24.1 - 26.4 pg, Monocyte Percentage (%) challenge sample #HSY10 reported as 13.1 % / expected results was 7.0 - 12.2 %; 2025 API Microbiology Event 3: Urine Culture challenge sample #UR14 scored unacceptable - laboratory reported result as No Growth / expected result was Pseudomonas aeruginosa. The inspector requested to review records that the laboratory evaluated the three unacceptable results outlined above. Documentation was not available for review. 2. An exit interview with the lead laboratory testing personnel on 07/16/26 at 3:00 PM confirmed the above findings.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

A. Based on a review of proficiency testing (PT) records, procedures, lack of documentation, and interview, the laboratory director (LD) failed to ensure that chemistry non-graded analyte PT results were evaluated for accuracy on two of five events per protocol during the review timeframe of August 2024 to July 16, 2026. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2024 Event 3, 2025 Events 1-3, 2026 Event 1), a total of five events, revealed that the laboratory utilized API to assess accuracy for their Abbott Abaxis point of care chemistry analyzer and that API released non-graded chemistry analyte responses for: Total Bilirubin (T Bili) due to variance on the following 2 events: API 2025 Event 2 - T Bili challenge CH-07; API 2025 Event 3 - T Bili challenges CH-12; Alkaline Phosphatase (ALKP) on the following 2 events: API 2025 Event 2 - ALKP challenge CH-06; API 2026 Event 1 - ALKP challenge CH-02; --a total of 4 non-graded Core Chemistry challenge samples were reported by API; 2. Review of the laboratory's PT review documentation revealed no evaluation/verification of accuracy recorded for the non-graded challenge sample results outlined above. The inspector requested to review an evaluation for the non-graded challenges. The documentation was not available. 3. Review of the available procedures revealed that the laboratory utilized the API proficiency testing company's protocols for their PT procedure. The inspector noted API instructions stated, "Laboratories are responsible and must document self evaluation using statistics presented in the Participant Data Summary Report for samples that have not been graded." 4. An exit interview with the lead laboratory testing personnel on 07/16/26 at 3:00 PM confirmed the above findings. B. Based on a review of PT records, lack of documentation, and interview, the LD failed to ensure that the laboratory documented an evaluation for unsatisfactory analyte scores received on one of three events under both hematology and microbiology specialties' modules in calendar year 2025. * CROSS REFERENCE D5221