

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0225370	(X3) Date Survey Completed 11/24/2020
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 on-site survey was conducted at Bristow Pediatrics, LLC on November 24, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory was conducted on October 21, 2020 with an off-site record review of documentation and a follow-up phone conference on November 17, 2020. Specific deficiencies cited are as follows:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, Laboratory Personnel Report form (CLIA) (CMS-209 Form), and an interview, the laboratory failed to rotate PT among the four (4) testing personnel (TP) for five (5) of 5 events reviewed. Dates of record review included all 3 events in 2019 and the first 2 events in 2020. Findings include: 1. The review of the American Proficiency Institute (API) PT records revealed that testing personnel (TP) A performed all 3 events in 2019 and the 1st and 2nd events in 2020. (See attached personnel code list.) 2. Review of the CMS 209 Laboratory Personnel form revealed 4 TP performing patient testing from January 1, 2019 and up to the date of survey on November 24, 2020. 3. An interview with the primary TP on November 24, 2020 at approximately 10:00 AM confirmed the findings.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

REPEAT DEFICIENCY Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, policy review, and interview with the primary TP, the technical consultant (TC) failed to perform and document the semi-annual competency assessment for two (2) of 2 new TP. Dates of record review included November 1, 2018 up to November 24, 2020. Findings include: 1. Review of the CMS-209 form revealed that the lab director performs the duties of technical consultant, that TP B was trained and performed patient testing beginning November 17, 2018 and TP C was trained and performed patient testing beginning November 16, 2018. (See attached TP code sheet.) 2. Review of TP records revealed a lack of documentation by the TC of performance and review of the semi-annual competency assessment. The record review revealed a competency assessment performed November 11, 2019 for TP B and November 12, 2019 for TP C. No documentation of a semi-annual competency assessment was available for review upon request. 3. Review of the laboratory policy for "Competency Evaluation for Personnel" (signed by the lab director but no date documented) revealed the following statement: "III. Interval: A. Newly hired personnel or a current staff member who is learning a procedure for the first time must demonstrate competency in accordance with the following schedule: 1. Initial training and competency must be documented prior to the reporting of any patient results. 2. Six months following initial competency assessment. 3. Twelve months following the initial competency assessment. 4. Annually thereafter." 4. An interview with the primary TP on November 24, 2020 at approximately 10:00 AM confirmed that the findings.