Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225370	08/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bristow Pediatrics, Llc	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 on August 7, 2018 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:
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 the review of the American Proficiency Institute (API) microbiology proficiency (PT) testing scores for the third event in 2017 and the second event in 2018, the review of the CASPER 0153D Unsuccessful PT report and an interview with the primary testing personnel at approximately 4:30 PM, the laboratory failed to

	achieved satisfactory performance of at least 80% for two out of three consecutive events for the urine and throat cultures resulting in unsuccessful PT performance (Cross Reference D2028).
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, the CASPER 155 report and interview, the laboratory failed to participate in the second PT event of 2018 and received scores of "0" for urine and throat cultures. Findings include: 1. Review of the American Proficiency Institute (API) PT records and the CASPER 155 report revealed that API reported the 2018 2nd event as: 0% "failure to participate" for both urine and throat cultures. 2. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the laboratory failed to participate in the 2nd event in 2018 for urine and throat cultures and received a score of 0%. **This is a repeat deficiency.
D2028	BACTERIOLOGY CFR(s): 493.823(e) 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 the review of proficiency (PT) testing scores, the CASPER 0153D report, and an interview, the laboratory failed to achieved satisfactory performance of at least 80% for two out of three consecutive events for urine and throat cultures, in which the laboratory received scores of 0% for both PT events, resulting in unsuccessful performance (Cross Reference D2021). Findings include: 1. Review of the American Proficiency Institute (API) PT records and the CASPER 155 report revealed that the laboratory received PT scores of 0% for the 3rd event in 2017 and the 2nd event in 2018 for both urine and throat cultures, resulting in unsuccessful performance. 2. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the laboratory received scores of of 0% for both events, resulting in unsuccessful performance.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of temperature records and interviews, the laboratory failed to retain the laboratory temperature records from September 1, 2016 through July 31, 2017 at the date of survey on August 7, 2018. Findings include: 1. The laboratory monitors the temperatures for the laboratory refrigerator, room temperature and incubator utilized for patient testing. Review of the temperature records for the laboratory revealed that there was no documentation available from September 1, 2016 through July 31, 2017. 2. In an interview with the primary testing personnel at approximately 3:00 PM, she/he stated that the temperatures were taken for the lab testing area but that they could not find the records. 3. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the requested laboratory refrigerator, room temperature and incubator temperature records could not be produced for review at the date of survey on August 7, 2018.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of manufacturer's operating guide, package inserts (PI), calibration records, quality control (QC) records, billing records, daily patient test logs, and interviews, the laboratory failed to: 1. perform the calibration procedures as defined by the manufacturer in 2018 (Cross Reference D5437); 2. perform external QC materials each day of patient testing for 29 days from August 1, 2016 and up to March 7, 2018 (Cross Reference D5447); 3. perform QC procedures for the 9 lot numbers of BD BBL-Taxo A discs received from August 1, 2016 and up to August 7, 2018 (Cross Reference D5471); 4. document the ability of each batch of media received in the laboratory for its ability to support growth, inhibit specific organism growth or the production of a specific biochemical response from August 1, 2016 up to August 7, 2018 (Cross Reference D5477); 5. have an established QA plan to identify and address analytic issues in the specialties of hematology, chemistry and bacteriology (Cross Reference D5791).
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of manufacturer's operating guide, calibration records, and an interview, the laboratory failed to perform the Medonic M-series Hematology analyzer calibration procedures as defined by the manufacturer at the date of survey on August 7, 2018. Findings include: 1. Review of the manufacturer's operating guide for the Medonic M-series Hematology analyzer revealed the following statement: "Calibration: calibration must be performed upon setup of the instrument and then at a minimum of every 6 months." 2. Review of the calibration records for the hematology instrument revealed documentation of instrument calibration last performed on 12/6 /17. No documentation was available for review for a calibration performed in 2018, the 6 month calibration, as prescribed by the manufacturer at the date of survey. 3. An interview with the primary testing personnel at approximately 4:30 PM confirmed that there was no documentation available for review at the date of survey of the laboratory performing the 6 month Medonic calibration procedures as defined by the manufacturer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the manufacturer requirements, laboratory quality control (QC), daily patient test logs and an interview, the laboratory failed to perform two (2) levels of external QC materials for the Piccolo Hepatic Function Panel each day of patient testing for twenty-nine (29) days from August 1, 2016 and up to March 7, 2018. Findings include: 1. Review of the manufacturer's requirements for the non-waived Piccolo Hepatic Function Panel revealed the following statement: "NEW QUALITY CONTROL PROCESS INFORMATION Effective January 1, 2016, laboratories will have two acceptable QC options for non-waived testing with the Piccolo Xpress Chemistry System: Option 1. Follow the CLIA regulatory requirements for quality control as written. Option 2. Implement IQCP as described by CMS." 2. Review of the QC records and daily patient test logs revealed that the laboratory did not have an Individualized Quality Control Plan (IQCP) for the Piccolo Hepatic Function Panel and that the laboratory failed to assay two levels of QC material on the following dates: August 1, 2016- one patient resulted (Accession 7354), October 4, 2016- one patient resulted (Accession 7627), October 7, 2016- one patient resulted (Accession 4272), October 21, 2016- one patient resulted (Accession 7883), October 26, 2016- one patient resulted (Accession 7891), November 21, 2016- one patient resulted (Accession 8056), November 22, 2016- one patient resulted (Accession 8056), November 23, 2016- one patient resulted (Accession 8058),

	December 5, 2016- one patient resulted (Accession 7989), December 12, 2016- one patient resulted (Accession 7989), December 22, 2016- one patient resulted (Accession 8236), January 3, 2017- one patient resulted (Accession 7989), January 5, 2017- one patient resulted (Accession 8328), January 17, 2017- one patient resulted (Accession 8390), February 2, 2017- one patient resulted (Accession 8488), February 13, 2017- one patient resulted (Accession 8587), February 17, 2017- one patient resulted (Accession 8590), February 20, 2017- one patient resulted (Accession 8636), March 1, 2017- one patient resulted (Accession 8720), March 3, 2017- one patient resulted (Accession 7122), March 18, 2017- one patient resulted (Accession 8814), March 28, 2017- one patient resulted (Accession 2293), September 1, 2017- one patient resulted (Accession 9928), September 13, 2017- one patient resulted (Accession 9985), September 13, 2017- one patient resulted (Accession 9993), October 21, 2017- one patient resulted (Accession 10210), November 9, 2017- one patient resulted (Accession 10351), November 11, 2017- one patient resulted (Accession 10351), March 7, 2018- one patient resulted (Accession 10651), a total of 29 days and 26 patients. 3. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the laboratory did not perform external QC materials each day of patient testing for 29 days listed above from August 1, 2016 and up to March 7, 2018.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the package insert (PI), laboratory Quality Control (QC) and billing records, and interview, the laboratory failed to perform QC procedures for the nine (9) lot numbers BD BBL-Taxo A Discs received from August 1, 2016 and up to August 7, 2018. Findings include: 1. The laboratory utilizes the HealthLink Strep Select Agar culture plates and Becton Dickinson (BD) BBL-Taxo A Discs to screen patients for Streptococcus pyogenes, Group A Strep infections. Review of the BD PI for the BBL Taxo A disc system revealed the following statements: "At the time of use, check performance with pure culture of stable control organisms producing known, desired reactions. The use of Streptococcus pyogenes ATCC 12384 is recommended to demonstrate zone formation. Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures." 2. Review of the QC and billing records for the Taxo A Discs revealed no documentation of QC performed for the 9 lot numbers received from August 1, 2016 and up to August 7, 2018. 3. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the laboratory failed to perform QC procedures for the 9 lot numbers of BD BBL-Taxo A discs received from August 1, 2016 and up to August 7, 2018.
D5477	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of billing records, visual checks and interviews, the laboratory failed to document the ability of each batch of media received in the laboratory from August 1, 2016 up to the date of survey on August 7, 2018 for its ability to support growth, inhibit specific organism growth or the production of a specific biochemical response for sixty-one (61) lot numbers of media. Findings include: 1. The laboratory performs in-house bacteriology testing utilizing the following media: HealthLink- TSA Blood Agar with 5% sheep blood and MacConkey biplate (for urine culture) and Healthlink Strep Selective agar (Strep A screening). Review of the billing records and visual checks revealed that the laboratory received nineteen (19) lot numbers of HealthLink-TSA Blood Agar with 5% sheep blood and MacConkey biplate and forty-two (42) lot numbers of Healthlink Strep Selective Agar, a total of sixty-one (61) lot numbers, from August 1, 2016 up to the date of survey on August 7, 2018. 2. Review of visual check records revealed no documentation of the ability of each lot number of media to support or inhibit specific organism growth or the production of a specific biochemical response. The inspector requested to review the quality control documentation for the media. The documentation was not available for review. 3. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the laboratory failed to document the ability of each batch of media received in the laboratory to support growth, inhibit specific organism growth or the production of a specific biochemical response from August 1, 2016 up to the date of survey on August 7, 2018. **This is a repeat deficiency.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the quality assurance (QA) plan, manufacturer's operating guide, package inserts (PI), calibration records, quality control (QC) records, billing records, daily patient test logs, and interviews, the laboratory's established QA plan failed to identify and address analytic issues in the specialties of hematology, chemistry and bacteriology (Cross Reference D5437, D5447, D5471 and D5477). Findings include: 1. Review of the manufacturer's operating guide, package inserts (PI), calibration records, quality control (QC) records, billing records, and daily patient test logs revealed the following analytic issues: - No documentation of the lab performing calibration procedures as defined by the manufacturer in 2018. - No

	documentation of the lab performing external QC each day of patient testing for 29 days for Piccolo Hepatic Function Panel from August 1, 2016 and up to March 7, 2018. - No documentation of the lab performing QC procedures for the 9 lot numbers of BD BBL-Taxo A discs received from August 1, 2016 and up to August 7, 2018. - No documentation of the ability of each batch of media received in the laboratory for its ability to support growth, inhibit specific organism growth or the production of a specific biochemical response from August 1, 2016 up to the date of survey on August 7, 2018. 2. Review of the QA plan signed by the laboratory director (no date provided) revealed no statement of a mechanism used by the laboratory to monitor and address issues in the specialties of hematology, chemistry and bacteriology. There was no documentation of review of available QC records and calibrations by the laboratory director. 3. An interview with the primary testing personnel at approximately 4:30 PM confirmed that the current QA plan failed to identify and address analytic issues in the specialties of hematology, chemistry and bacteriology.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the quality assurance (QA) plan, quality control (QC) and calibration records and interviews with the primary testing personnel, the laboratory director failed to ensure that the established QA plan identified and addressed analytic issues in the specialties of hematology, chemistry and bacteriology (Cross Reference D5791).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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: Based on the review of CMS 209 Laboratory Personnel Report Form (CLIA), testing personnel (TP) records, laboratory policy, and interview, the technical consultant failed to follow the established policy to perform and document semi-annual competency assessments for three (3) of three (3) TP in 2017 and 2018. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there are four (4) testing personnel. (See attached personnel code list.) 2. Review of the TP records revealed no documentation of the evaluation and review of the semi-annual competency assessments by the technical consultant for the following 3 TP: TP A- hired and trained October 20, 2016, TP B- hired and trained August 21, 2017, TP C- hired and trained August 29, 2017. 3. Review of the laboratory policy for "Competency Evaluation for Personnel" (signed

	by the lab director but no dated 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 testing personnel at approximately 4:30 PM confirmed that the technical consultant failed to perform the evaluation and review of the semi-annual competency assessments in 2017 and 2018 for the new TP as described within the established policy.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of CMS-209 Laboratory Personnel Report Form (CLIA), testing personnel (TP) records, laboratory policy and interviews, the technical consultant failed to follow the established policy to perform and document annual competency assessments for two (2) of two (2) TP in 2017 and 2018. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there are four (4) TP. (See attached personnel code list.) 2. Review of the personnel records for TP A and D revealed no documentation of an annual competency assessment performed by the technical consultant in 2017 and 2018. The inspector requested the competency assessments for TP A and D. The documentation was not available for review. 3. Review of the laboratory policy for "Competency Evaluation for Personnel" (signed by the lab director but no dated 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 testing personnel at approximately 4:30 PM confirmed that the technical consultant failed to perform the annual competency assessment for TP A and D in 2017 and 2018 as described within the established policy.