Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225370	09/29/2022
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 September 30, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes two Conditions under 42 CFR part 493 CLIA Regulation: D5400-42 CFR. 493.1250 Analytic Systems D6000-42 CFR. 493.1403 Laboratory Director
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 a review of the laboratory's policies and procedures, tour, hematology analyzer performance verification records, calibration records, media logs, patient logs, temperature logs, quality assurance corrective action logs, lack of documentation, and interviews, the laboratory failed to: 1. document an evaluation /verification of precision and reportable range for the Medonic M-Series Complete Blood Cell Count (CBC) testing after the hematology analyzer re-installation at a new physical location on May 21, 2022 (Cross Reference D5421); 2. follow their established Medonic M-Series calibration procedure when re-installing the instrument at a new physical location from May 21, 2022 until September 6, 2022 (Cross Reference D5437); 3. document the ability of each batch of media received in the

	laboratory to support growth and inhibit specific organism growth for twenty-one (21) lot numbers of media (Cross Reference D5477); and 4. follow their established policy and document corrective action on the dates the laboratory's throat and urine culture incubator temperature was outside of acceptable limits (Cross Reference D5785).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, tour, review of hematology analyzer performance verification records, lack of documentation, and interviews, the laboratory failed to document an evaluation/verification of precision and reportable range for the Medonic M-Series Complete Blood Count (CBC) testing after the hematology analyzer's re-installation to a new physical address on May 21, 2022. Findings include: 1. During the tour of the laboratory on September 30, 2022 at approximately 9:00 AM, the surveyor noted one (1) Medonic M-Series (Serial Number 19608) in use for CBC patient testing. The Clinical Manager nurse stated: "We moved to this location on May 21, 2022 and began testing on May 23, 2022." 2. Review of the Medonic M-Series hematology analyzer's performance verification documentation revealed a lack of documentation of the laboratory director approved evaluation/verification of CBC precision or reportable range for the timeframe of the installation at the new laboratory location on May 21, 2022 up to the date of the inspection, September 30, 2022. The surveyor requested the performance verification records. The laboratory provided no documentation for review. In an interview with the clinical manager on September 30, 2022 at approximately 9:15 AM, the clinical manager stated, "On May 23, 2022, we ran all 3 levels of QC prior to running patients. All levels were within range." 3. In an exit interview with the clinical manager on September 30, 2022 at approximately 12:00 PM, the above findings were confirmed.
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 a review of the laboratory's policies and procedures, tour, Medonic M-Series calibration documentation, lack of documentation and interviews, the laboratory failed to follow their established Medonic M-Series calibration procedure when re-installing the instrument at a new physical location from May 21, 2022 until September 6, 2022. Findings include: 1. During the tour of the laboratory on September 30, 2022 at approximately 9:00 AM, the surveyor noted one (1) Medonic M-Series (Serial Number 19608) in use for Complete Blood Count (CBC) patient testing. The Clinical Manager nurse stated: "We moved to this location on May 21, 2022 and began testing on May 23, 2022." 2. Review of the laboratory's policy and procedure manuals revealed a "CDS M-Series Hematology Analyzer Procedure Manual", which stated "Calibration must be performed more frequently that every 6 months if: Major maintenance is performed that could affect calibrations; Troubleshooting indicates a need for recalibration; The instrument is moved to another location; Technical Support advises recalibration to resolve an issue." 3. Review of the Medonic's calibration documents revealed a calibration performed on 3/17/2022 and 9/6/2022. The surveyor requested to review documentation of the calibration performed after the re-installation of the Medonic at the present location. The laboratory provided no documentation to review. 4. In an exit interview with the clinical manager on September 30, 2022 at approximately 12:00 PM, the above findings were confirmed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and interviews, the laboratory failed to retain manufacturer's assay package inserts for seventeen (17) of 17 hematology QC lot numbers utilized for evaluating the precision /accuracy of the Complete Blood Count (CBC) analyzer in the twenty-two months reviewed (December 2020 to September 30, 2022). Findings include: 1. Review of the laboratory's Medonic M-Series hematology analyzer QC records revealed the following 16 CDS Boule Con-Diff tri-level QC lot numbers placed in use to evaluate precision/accuracy for CBC patient testing from December 2020 January 2021 through the date of the survey on September 30, 2022: lot numbers 220082, 220085, 220090, 220113, 221023, 221050, 221060, 221063, 221080, 221103, 221110, 222010, 222020, 222023, 222030, 222040 and 222070. A total of 17 lot numbers. 2. The surveyor requested to review the assay information sheets for the 17 QC lot numbers listed above. The laboratory provided no documentation for review. On

	September 30, 2022 at approximately 10:15 AM the clinical manager stated "We have the calibration inserts but we didn't keep the QC inserts." 3. In an exit interview with the clinical manager on September 30, 2022 at approximately 12:00 PM, the above findings were confirmed.
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 the laboratory's media "Certificate of Analysis", visual check documentation, culture logs and interviews, the laboratory failed to document the ability of each batch of media received in the laboratory from December 1, 2020 up to the date of survey on September 30, 2022 for its ability to support growth and inhibit specific organism growth for twenty-one (21) lot numbers of media. Findings include: 1. The laboratory performs in-house bacteriology testing utilizing the following media: Hardy Diagnostics- TSA Blood Agar with 5% sheep blood and MacConkey biplate (for urine culture) and Hardy Diagnostics Strep Selective agar (Strep A screening). 2. Review of the laboratory's media "Certificates of Analysis" and visual checks revealed the laboratory received ten (10) lot numbers of Hardy Diagnostics-TSA Blood Agar with 5% sheep blood and MacConkey biplate and eleven (11) lot numbers of Hardy Diagnostics-Strep Selective Agar, a total of 21 lot numbers, from December 1, 2020 up to the date of the survey on September 30, 2022. 3. Review of visual check records revealed a lack of documentation of the ability of each lot number of media to support or inhibit specific organism growth. The surveyor requested to review the quality control documentation for the media. The laboratory provided no documentation for review. 4. In an exit interview with the clinical manager on September 30, 2022 at approximately 12:00 PM, the above findings were confirmed.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, daily temperature logs, lack of documentation, and interviews, the laboratory failed to follow their established policy and document corrective action on the dates the laboratory's throat and urine culture incubator temperature were outside of acceptable limits for three-hundred sixty-two (362) days of four-hundred sixty-eight (468) days during the review timeframe of December 1, 2020 until September 30, 2022. Findings include: 1.

	Review of the laboratory's policy and procedure manual revealed a policy, "Quality Assessment Plan", which stated "F. Temperature Monitoring (including a chart to monitor room temperature for labs.) 1. All temperature sensitive equipment such as freezers, refrigerators, and incubators must be monitored at least twice daily.(opening and closing the lab, and when specimens are tested.)...c. The incubator needs to be between 33 degrees C and 37 degrees. 2. Temperatures logs will be kept in the corresponding logbook in the lab. 3. Temperature deviations will be brought to the Lab Director's attention immediately." 2. Review of the "Temperature Control Log" from December 1, 2020 until September 30, 2022 revealed a lack of corrective action documentation and Lab Director notification when the incubator temperature was warmer than acceptable (greater than 37 degrees Celsius) for the following number of days and cultures incubated/reported: 12/2020-19 of 24 days-7 cultures; 01/2021-19 of 20 days-6 cultures; 02/2021-15 of 20 days-4 cultures; 03/2021-21 of 23 days-3 cultures; 04/2021-21 of 22 days-4 cultures; 05/2021-20 of 20 days-7 cultures; 06/2021-22 of 22 days-5 cultures; 07/2021-22 of 22 days-4 cultures; 08/2021-21 of 21 days-2 cultures; 09/2021-17 of 21 days-1 culture; 10/2021-21 of 21 days-0 cultures; 11/2021-20 of 20 days-3 cultures; 12/2021-23 of 23 days-7 cultures; 01/2022-20 of 20 days-3 cultures; 02/2022-20 of 20 days-2 cultures; 03/2022-22 of 22 days-5 cultures; 04/2022-21 of 21 days-2 cultures; 05/2022-18 of 20 days-2 cultures. 362 of 468 days with 67 cultures incubated/reported. The surveyor requested to review corrective actions taken for the dates listed above when the temperatures were outside the laboratory's established criteria. The laboratory provided no documentation of corrective actions taken for review. 3. In an exit interview with the clinical manager on September 30, 2022 at approximately 12:00 PM, the above findings were confirmed.
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 laboratory's "Quality Assurance Manual", policies and procedures, quality control (QC) records, calibration verification records, patient records, and interviews, the laboratory's quality assessment plan failed identify and address issues within the specialties of hematology and microbiology from December 2020 to September 2022 (Cross Reference D3031, D5421, D5439, D5477, D5785). Findings include: 1. Review of the laboratory's Quality Assessment (QA) documentation, policies and procedures, instrument validation/verification records, quality control (QC) records, calibration verification records, patient records revealed the following analytic issues: -lack of the evaluation/verification of precision and reportable range for the Medonic hematology analyzer when the instrument was moved to a new physical location (see D5421); -lack of calibration of the Medonic hematology analyzer when the instrument was moved to a new physical location (see D5437); -lack of retention of the hematology QC package inserts from December 2020 to September 2022 (see D5469); -lack of documentation of each batch of media's ability to inhibit and support growth (see D5477); -lack of documentation of the corrective actions taken when incubator temperatures were out of range (see D5785). 2. Review of the "Quality Assurance Manual", revealed the following statements "Policy for Laboratory Monitoring" which states "The calendar of lab

	events including maintenance and reporting will be posted in the lab. The API calendar with shipping and due dates will be kept in the Proficiency Notebook and displayed for the lab staff. Weekly lab staff meetings will review lab policies, due dates and lab issues. Notes will be kept in the director's notebook. Monthly the lab staff will gather all of the logs, and QC information for the Laboratory Director's review. Variations will be discussed." In an interview with the clinical manager on September 30, 2022 at approximately 10:45, the clinical manager stated, "I gather all the documents, complete the Month-End CLIA Reporting form and give everything to the lab director to review." 3. Review of the laboratory's QA documentation from December 2020 until August 2022 revealed a completed "Month-End CLIA Reporting" form for twenty-one (21) of 21 months reviewed. 21 of 21 "Month-End CLIA Reporting" forms lacked documentation of the identification of and corrective actions taken for the above listed issues within the specialties of hematology and microbiology. 4. In an exit interview with the clinical manager on September 30, 2022 at approximately 12:00 PM, the above findings were confirmed.
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 review of the laboratory's policies and procedures, tour, hematology analyzer performance verification records, calibration records, quality control records, media logs, patient logs, temperature logs, quality assurance corrective action logs, lack of documentation, and interviews, the laboratory director failed to: 1. ensure Quality Control (QC) policies and procedures were established and maintained for microbiology cultures from December 2020 until September 2022. Cross Reference D6020. 2. identify and address quality assurance (QA) failures for 22 months (timeframe December 2020 to date of inspection September 30, 2022). Cross Reference: D6021.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, media quality control (QC) logs, patient records, lack of documentation, and an interviews, the Laboratory Director failed to ensure Quality Control (QC) policies and procedures were established and maintained for microbiology cultures from December 2020 until September 2022 (see D5477).

D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Quality Assurance Manual", policies and procedures, quality control (QC) records, calibration verification records, patient records, temperature records, lack of documentation and interviews, the laboratory director failed to identify and address the following quality assurance (QA) failures: 1. lack of evaluation/verification of precision an reportable range for the Medonic M-Series Complete Blood Count (CBC) testing after the analyzer was re-installed at a new physical location. Cross Reference D5421. 2. lack of calibration of the Medonic M-Series analyzer after the analyzer was re-installed at a new physical location. Cross Reference D5437. 3. lack of retention of manufacturer's assay package inserts for seventeen (17) of 17 hematology QC lot numbers utilized for evaluating the precision /accuracy of the CBC analyzer in the 22 months reviewed (timeframe December 2020 to date of inspection September 30, 2022). Cross Reference: D5469. 4. lack of documentation of each lot number of media's ability to support or inhibit growth. Cross Reference D5477. 5. lack of documentation of the corrective actions taken when the temperature of the laboratory's incubator was out of acceptable limits. Cross Reference D5785.