Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656661	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bristow Medical Center	700 W 7th Suite 6, Bristow, OK	

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	The recertification survey was performed on 04/12/2021 and 04/13/2021. The findings were reviewed with the laboratory director, laboratory manager, and testing person #1 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, obseration, and interview with the laboratory manager and testing person #1, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator; and failed to ensure blood products were stored under appropriate conditions in the blood bank refrigerator for 3 of 25 thermograph charts. Findings include: ALARM CHECKS (1) On 04/12/2021 at 09:25 am, testing person #1 stated to the surveyor the laboratory routinely maintained 2 units of O negative packed red blood cells and 2 units O positive packed red blood cells of in the Helmer blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (2) The surveyor reviewed the laboratory's written policy for performing alarm checks on the refrigerator. The policy required the alarm checks be performed on a quarterly basis; (3) The surveyor then reviewed the alarm check records for 2019, 2020, and 2021. It was identified that alarm checks were not performed as follows: (a) Between 04/20/2019 and 07/22/2020 (b) Between 07/22/2020 and 02/10/2021 (4) The surveyor reviewed the records with the laboratory manager and testing person #1. Testing person #1 stated on 04/12/2021 at 12:40 pm,

	the alarm checks had not been performed as indicated above. THERMOGRAPH CHARTS (1) On 04/12/2021 at 09:25 am, testing person #1 stated to the surveyor the laboratory routinely maintained 2 units of O negative packed red blood cells and 2 units O positive packed red blood cells of in the Helmer blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (2) On 04/12/2021 at 09:30 am, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (3) The surveyor reviewed 25 refrigerator charts dated from 04/02/2019 through 08/23/2019 and 12/02/2020 through 01/14/2021. The review indicated that 3 of 25 charts had not been changed by the 7th day of usage. The findings include: (a) Chart #7 - The chart was put into use on 05/14/19 and removed on 05/22/19 (8 days); (b) Chart #18 - The chart was put into use on 07/31/2019 and removed 08/08/2021(8 days); (c) Chart #20 - The chart was put into use on 08/15/2021 and removed 08/23/2021 (8 days). (4) The surveyor reviewed the charts with the laboratory manager and technical consultant #2. Testing person #1 stated on 04/12/2021 at 12:30 pm the charts had not been changed by the 7th day of usage as indicated above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and testing person #1, the laboratory failed to review and evaluate proficiency testing results for 2 of 11 events. Findings include: FAILURES (1) On 04/12/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records and identified the following failure: (a) Second 2019 Hematology Event (i) Blood Cell Identification - The laboratory failed the results for 1 of 5 samples (BCI-10); (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) The surveyor reviewed the records with the laboratory manager and testing person #1, and asked if corrective action had been taken and documented for the failure. The testing person #1 stated on 04/12/2021 at 12:25 pm corrective action had not been taken. BIASES (1) On 04/12/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2019 Chemistry Core Event (i) Glucose- 3 of 5 results exhibited a positive bias (aa) Sample CH-13- SDI of 2.7 (bb) Sample CH-14- SDI of 2.5 (cc) Sample CH-15- SDI of 2.9 (ii) Potassium - 4 of 5 results exhibited a positive bias (aa) Sample CH-12- SDI of 2.7 (bb) Sample CH-13- SDI of 3.0 (cc) Sample CH-14- SDI of 2.5 (dd) Sample CH-15- SDI of 2.6 (iii) Triglycerides - 4 of 5 results exhibited a positive bias (aa) Sample CH-12- SDI of 2.7 (bb) Sample CH-13- SDI of 3.0 (cc) Sample CH-14- SDI of 2.6 (dd) Sample CH-15- SDI of 2.6 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager and testing person #1. The laboratory manager stated on 04/12/2021 at 12:30 pm the biases had not been addressed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and testing person #1, the laboratory failed to verify the accuracy of Wet Prep analysis at least twice annually. Findings include: (1) On 04/21/2021 at 10:15 am, testing person #1 stated to the surveyor the laboratory performed Wet Prep analysis; (2) The surveyor reviewed 2019 and 2020 records, which showed the testing had not been verified for accuracy twice since in 2019 and 2020. Wet Prep analysis had not been verified for accuracy since 01/26/2019; (3) The surveyor reviewed the records with the laboratory manager and testing person #1. The testing person #1 stated on 04/12/2021 at 12:35 pm, Wet Prep analysis had not been verified for accuracy at least twice annually in 2019 and 2020.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the laboratory manager and testing person #1, the laboratory failed to follow written procedures for pipette function checks for 1 of 2 checks. Findings include: (1) On 04 /12/2021, the surveyor reviewed the manual titled, "General Procedure Manual" and the policy titled, "Pipette Calibration Policy LAB-250-10", stated, "Pipettes must be calibrated at least once per year to maintain accuracy and precision."; (2) The surveyor reviewed 2019 and 2020 pipette function checks and identified the following for 1 of 2 of checks: (a) Pipette checks had not been performed since 12/26/2019 (3) The surveyor reviewed the findings with the laboratory manager and testing person #1. Testing person #1 stated on 04/12/2021 at 04:00 pm, pipette checks had not been performed in 2020.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to follow the manufacturer's instructions for verifying flagged results for 14 of 19 patients; and failed to follow the manufacturer's

instructions for a coagulation lot change for 1 of 1 lot number; and failed to follow the manufacturer's instructions for the normal reference range for 1 of 2 years. Findings include: FLAGGED RESULTS (1) On 04/12/2021 at 10:15 am, testing person #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (b) Manual differential testing was performed in house. (2) On 04/13/2021, the surveyor reviewed the manufacturer's instructions for verifying flags obtained on the analyzer. For AG flags, the instructions stated, "Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc". In addition, the instructions stated, "Check Smear. etc"; (3) The surveyor randomly reviewed 19 patient records which contained AG flags from CBC testing performed from 04/01/2021 through 04/10/2021. For 14 of 19 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the AG flags. The findings for the 4 records were: (a) Patient testing was performed on 04/01/2021 at 12:46 am, with an AG flag obtained next to Platelet; (b) Patient testing was performed on 04/01/2021 at 04:58 pm, with an AG flag obtained next to Platelet; (c) Patient testing was performed on 04/02/2021 at 08:37 am, with an AG flag obtained next to Platelet; (d) Patient testing was performed on 04/02/2021 at 09:36 am, with an AG flag obtained next to Platelet; (e) Patient testing was performed on 04/03/2021 at 08:13 am, with an AG flag obtained next to Platelet; (f) Patient testing was performed on 04/03/2021 at 11:54 pm, with an AG flag obtained next to Platelet; (g) Patient testing was performed on 04/04/2021 at 07:48 pm, with an AG flag obtained next to Platelet; (h) Patient testing was performed on 04/06/2021 at 12: 24 am, with an AG flag obtained next to Platelet; (i) Patient testing was performed on 04/06/2021 at 04:28 am, with an AG flag obtained next to Platelet; (j) Patient testing was performed on 04/08/2021 at 09:14 am, with an AG flag obtained next to Platelet; (k) Patient testing was performed on 04/08/2021 at 12:03 pm, with an AG flag obtained next to Platelet; (l) Patient testing was performed on 04/08/2021 at 02:48 pm, with an AG flag obtained next to Platelet; (m) Patient testing was performed on 04/09 /2021 at 07:57 am, with an AG flag obtained next to Platelet; (n) Patient testing was performed on 04/10/2021 at 07:15 am, with an AG flag obtained next to Platelet. (4) The surveyor reviewed the records with testing person #1, who stated on 04/13/2021 at 10:20 am, the flags obtained for the above 14 patients had not been verified as required by the manufacturer. COAGULATION LOT CHANGE (1) On 04/12/2021 at 10:10 am, testing person #1 stated to the surveyor the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing (the INR was calculated using the PT reference interval mean); (2) On 04/13/2021, the surveyor reviewed the records for reagent lot change completed on 12/31/2019 for PT - HemosIL Recombiplastin reagent, lot #N0696619; (3) The surveyor reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents. For the normal reference interval is stated: (a) Section titled "Establishing a Normal Reference Interval" (i) "Reference Intervals should be established for each assay the lab performs."; (ii) "Reference Intervals should be established over several days, at different times of the day, including such variables as age of reagent, different vials of reagent, different operators."; (iii) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (iv) "Donors should span the adult age range. Pediatric ranges should be established separately."; (v) "Donors should be equally divided between male/female."; (vi) "If the INR system is utilized to report PT's, note the geometric mean value of the PT normal reference interval in seconds and use along with the lot-specific ISI value in

	the INR setup calculation page". (4) The surveyor reviewed the implementation records for HemosIL Recombiplastin reagent, lot #N0696619 and identified the following: (a) Although the laboratory had used 20 donors, there was no evidence of the health status for 6 of 20 donors. (5) The surveyor reviewed the findings with the laboratory manager and testing person #1. Testing person #1 stated on 04/13/2021 at 12:42 pm, the manufacturer's instructions had not been followed for the reagent lot change as specified above. COAGULATION NORMAL REFERENCE RANGE (1) On 04/12/2021 at 10:10 am, testing person #1 stated to the surveyor the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing (the INR was calculated using the PT reference interval mean); (2) On 04/13/2021, the surveyor reviewed the 2019, 2020, and 2021 coagulation records for the normal reference range and identified the following: (a) PT - HemosIL Recombiplastin reagent, lot #N0696619 had been in use from 12/31/2019 through 04 /06/2021; (b) The normal reference range had been verified when the lot was put into use. (3) The surveyor reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents. For the normal reference interval is stated; (a) "Reference Interval should be established whenever there is a change in: * Instrumentation and/or methodology. * Lot number of reagent. * Sample collection procedures. * At least once a year." (4) The surveyor asked testing person #1 if the normal reference interval had been verified at the one year interval. Testing person #1 stated on 04/13/2021 at 2:55 pm, the laboratory had not verified the normal reference after the one year interval as indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the laboratory manager and testing person #1 the laboratory failed to follow written quality control policies for 5 of 27 months. Findings include: (1) On 04/12/2021 at 10:00 am, testing person #1 stated the following to the surveyor: (a) Troponin I testing was performed in the laboratory using the Alere Triage Meter Pro analyzer; (b) D-Dimer testing was performed in the laboratory using the Alere Triage Meter Pro analyzer. (d) An IQCP (Individualized Quality Control Plan) had been developed for the above test systems. (2) The surveyor reviewed the IQCP that had been developed for the test systems. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor reviewed QC (quality control) records for 24 months (January 2019 through March 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) Troponin I (i) Between 01/19/2021 and 03/31/2021 (b) D-Dimer (i) Between 05/03/2019 and 07/02 /2019 (ii) Between 11/08/2019 and 01/07/2020 (iii) Between 02/24/2020 and 04/07 /2020 (iv) Between 01/09/2021 and 03/03/2021 (4) The findings were reviewed with

	the laboratory manager and testing person #1. Testing person #1 stated on 04/12/2021 at 02:45 pm, the laboratory had not performed quality control testing as required by the QCP.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and testing person #1, the laboratory failed to perform one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing for 11 of 23 days of patient testing. Findings include: (1) On 04/12/2021 at 10:00 am, the laboratory manager stated the following to the surveyor: (a) Blood Gas (pH, pCO2, pO2) testing was performed using the G3+ on the iSTAT (serial number 338763) analyzer. (2) The surveyor reviewed QC and patient testing records from January 2020 through July 2020. The review showed that two levels of QC testing had not been performed each eight hours of patient testing for 12 of 14 days of patient testing reviewed as follows: (a) 01/01 /2020- Patient #10088 had been tested at 10:50 am and level 1 and level 3 QC had not been performed; (b) 01/11/2020 - Patient #12903 had been tested at 01:24 pm and level 1 and level 3 QC had not been performed; (c) 01/17/2020 - A patient #11626 had been tested at 01:06 pm and level 1 and level 2 QC had not been performed; (d) 01 /18/2020 - A patient #10683 had been tested at 01:32 pm and level 1 and level 2 QC had not been performed; (e) 01/21/2020 - A patient #12991 had been tested at 08:56 am and level 1 and level 3 QC had not been performed; (f) 01/23/2020- A patient #10410 had been tested at 09:16 am am and level 1 and level 3 QC had not been performed; (g) 02/06/2020 - A patient #13073 had been tested at 06:44 pm and level 1 and level 3 QC had not been performed; (h) 02/21/2020 - A patient #13494 had been tested at 12:29 pm and level 1 and level 2 QC had not been performed; (i) 02/29/2020 - A patient #13594 had been tested at 09:35 am and level 1 and level 2 QC had not been performed; (j) 03/19/2020 - A patient #10088 had been tested at 11:43 am and level 1 and level 2 QC had not been performed; (k) 03/16/2020- A patient #13488 had been tested at 03:05 pm and QC had not been performed; (l) 07/08/2020 - A patient #10871 had been tested at 08:26 am and QC had not been performed. (3) The surveyor reviewed the records with the laboratory manager and testing person #1. Testing person #1 stated on 04/12/2021 at 03:35 pm two levels of QC materials had not been performed each 8 hours of patient testing as indicated above.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to perform two levels of quality control materials each eight hours of PT/INR testing for 1 of 15 patients. Findings include: (1) On 04/12/2021 at 10:05 am, testing person #1 stated the following to the surveyor: (a) PT/INR (Prothrombin Time /International Normalized Ratio) testing were performed on the ACL Elite analyzer; (b) Two levels of quality control (QC) materials were performed each eight hours of patient testing. (2) On 04/13/2021, the surveyor reviewed QC and patient testing records for testing performed from 12/01/2020 through 03/02/2021 and identified that two levels of QC testing had not been performed each eight hours of patient testing for 1 of 15 patients tested during the review period as follows: (a) QC testing had been performed on 01/12/2021 at 12:03 pm and patient testing had been performed on 01/13 /2021 at 12:07 am. (4) The surveyor reviewed the records with testing person #1, who stated on 04/13/2021 at 01:20 pm, two levels of QC materials had not been performed each eight hours of patient testing as shown above.
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 a review of records and interview with the laboratory manager and testing person #1, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) On 04/12/2021, the testing person #1 stated the following to the surveyor: (a) The laboratory performed Troponin I testing using the Alere Triage Meter Pro analyzer; (b) The laboratory performed D-Dimer testing using the Alere Triage Meter Pro analyzer; (c) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective 11/09/2018). The QA (Quality Assessment) portion of the IQCP required annual evaluations; (3) The surveyor then reviewed records for the testing performed on the Alere Triage Meter Pro analyzer. There was no evidence of a QA review for the IQCP as follows: (a) Troponin I testing - no evidence of a QA review since 11/09/2018 through the day of the survey 04/12/2021; (b) D-Dimer testing - no evidence of a QA review between 01/31/2019 and 01/28/2021. (4) The surveyor reviewed the records with the laboratory manager and testing person #1 and asked if annual QA reviews had been performed. Testing person #1 stated on 04/12/2021 at 12: 55 pm annual QA reviews had not been performed as indicated above.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt

	from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to have an adequate system in place to ensure that reliable test results were reported for 1 of 3 patient reports. Findings include: (1) On 04/12/2021 at 10:15 am, testing person #1 stated to the surveyor manual differential testing was performed, which required a 100 cell count; (2) On 04/13/2021 the surveyor randomly reviewed patient reports for testing performed in April 2021 and identified a patient tested on 04 /05/2021 at 10:03 pm, that contained a 96 cell count differential; (3) The report was shown to testing person #1 who stated on 04/13/2021 at 10:30 am, the cell count should have been 100.