Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1062238	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baylor Scott & White The Heart Hospital -	2813 South Mayhill Road, Denton, TX	

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	Entrance and exit conferences were held with laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility's blood and blood product transfusion policies and records, staff interview, and patient transfusion records, the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Findings included: 1. The facility policy titled "Blood Product Administration" (Revision Date 04/2019; Signed by the laboratory director 07/15/2019; Scope Organizational wide) stated the following:

"Horizon Medical Center will include training for administering blood transfusion during nursing orientation or through other continuing education programs. The training will include the following content: 1. With respect to blood transfusions: a. Blood components b. Blood administration procedures per hospital policy, State law, and nationally recognized standards of practice c. Patient monitoring requirements, including frequency and documentation of process for verification of the right blood product for the right patient; and transfusion reactions; identification, treatment, and reporting requirements. 2. Nursing staff will have documentation of completion of blood transfusion training during hospital orientation or through other continuing education programs." 2. Review of the facility document titled "Nursing Blood Administration Competency" listed the following performances evaluated for competency: "1. Recognizes the need for a Physician's order to type, crossmatch, and transfuse all blood products and a patient consent. 2. Recognizes a consent is good for the entire hospital stay. 3. Ensures an order is sent to the lab for the type, crossmatch, and transfusion. 4. Explains the procedure for drawing blood specimen from PICC line. 5. Explains the appropriate IV access needed to administer blood products. Need at least a 20 gauge IV device. 6. Reviews the necessary supplies and equipment needed for a blood transfusion: normal saline 250 mL bag, blood tubing, if leukocyte poor packed cells are to be given a filter is necessary, Thermometer, blood pressure cuff, stethoscope, blood transfusion record. 7. Reviews the notification process of the nursing supervisor to obtain blood product. Only one product at a time can be signed out of the blood bank room. 8. Reviews the bedside double check process per policy. (Two RN's or an RN and an LVN) 9. States the patient identification process using name and birth date. Explains the procedure to the patient and educates accordingly. 10. Reviews the necessary hand hygiene and appropriate PPE needed during the procedure. 11. States understanding that all blood products need to be started within 30 minutes from the time the blood product is signed out of the blood bank room or returns the product to the blood bank room. 12. Discusses the mandatory documentation as follows: the patient's vital signs: first set prior to start of the blood product, second set 15 [minutes] after start of blood product, and the next set one hour after the first set. In addition, any transfusion reaction, start and stop times, and any patient and blood product identification. 13. Describes all necessary documentation needed on the Blood transfusion record. 14. States and understands that blood products must be completely transfused within 4 hours from the time the blood is signed out of the blood bank room. 15. Files the transfusion documentation in the patient's medical record under transfusion. 16. Describes the necessary documentation as follows: Order to transfuse, Lab slips for type and crossmatch, written informed consent for blood product transfusion, patient teaching, and transfusion record with all pre and post vital signs, patient's tolerance of the transfusion, and completion of patient record for blood product transfusion. 17. Discussed the necessary procedure in the event of a blood transfusion reaction. This training/competency material did NOT indicate what vitals must be monitored and documented for signs of a transfusion reaction. The training/competency material did NOT include defined criteria for vital signs to promptly identify transfusion reactions. The training/competency material did NOT indicate what steps to take when a transfusion is identified. The training /competency material did NOT ensure prompt identification and reporting of a transfusion reaction. 3. The facility policy titled "Suspected Transfusion Reaction" (Revision Date 05/2019; Signed by the laboratory director 07/15/2019; Scope Organization wide) stated the following: "Nursing staff must be aware of the signs and symptoms that may indicate a transfusion reaction. The following signs and symptoms must immediately be reported to the physician: Signs and symptoms of anaphylaxis; Back, flank, or chest pain; Chills (with or without fever); Dyspnea; Fever (2 F from pretransfusion value); Flushing; Generalized Bleeding; Hemoglobinuria;

Hypertension; Pulmonary Edema; Cyanosis; Tachycardia; Hypotension; Itching; Jaundice; Nausea (with or without vomiting); Oliguria, anuria, hematuria; Pain at the Infusion site; Shock; Tachypnea; Urticaria; Wheezing; Rash. Signs and Symptoms of a possible Transfusion Reaction are listed at the bottom of the patient Blood Transfusion Record form." This policy did NOT list tachycardia as a sign or symptom of a transfusion reaction. The "Blood Transfusion Record" form that was included with the policy included all the signs and symptoms of a transfusion reaction listed in the policy PLUS tachycardia. This facility policy did NOT indicate what vitals must be monitored and documented for signs of a transfusion reaction. The "Blood Transfusion Record" did NOT include defined criteria for vital signs to promptly identify transfusion reactions. In 2018 and 2019, the facility had transfused 105 blood components and had never identified and reported a transfusion reaction. 4. A random review of Blood Transfusion Record forms from 05/2019 through 09/2019 revealed 21 of 21 forms that listed the following signs and symptoms of a transfusion reaction: Flank Pain; Chest/back pain; Chills; Dyspnea; Fever (2 degrees F of >); Flushing; Pulmonary Edema; Cyanosis; Tachycardia; Hypotension; N and V (Nausea and Vomiting); Oliguria; Tachypnea; Urticaria; Wheezing; Rash. This form in use was NOT the updated version of the "Blood Transfusion Record". The following signs and symptoms listed in the current "Suspected Transfusion Reaction" policy were NOT listed on the form in use: Signs and symptoms of anaphylaxis; Generalized Bleeding; Hemoglobinuria; Hypertension; Itching; Jaundice; anuria; hematuria; Pain at the Infusion site; Shock. 5. In interview with nursing personnel on 10/24/2019 at 1015 hours in the nursing unit breakroom, the first nurse was asked what are signs of a transfusion reaction. The nurse responded redness, tightness in chest, increase in blood pressure, and increase in temperature. The first nurse was asked where the facility lists the signs and symptoms of a transfusion reaction. She stated that she did not know. The nurse was asked how the facility defines hypotension and hypertension. She stated the patient's provider sets blood pressure parameters when the patient is admitted. The nurse was asked if these parameters were specific to blood component transfusions. She stated that the parameters were to indicate at what point the provider was to be notified by the facility at any time during the patient's admission. The nurse was asked what the facility transfusion reaction policy for temperature changes was. She stated she was not sure but probably anything above normal. The nurse was asked who she would contact for a transfusion reaction. She stated she would contact the provider, the charge nurse, and Carter Blood Care. The nurse was shown the following Blood Transfusion Records and asked if she considered the blood pressure and pulse rate increases significant: a. 05/28/2019; Patient 2004137; Unit Number W035219835798; Date/Time of transfusion 05/28 /2019 1215 hours Pre-Transfusion blood pressure 122/59 End of Transfusion blood pressure 159/67 The patient had blood pressure increase of 37 mm Hg. b. 05/28/2019; Patient 2004137; Unit Number W035219805921; Date/Time of transfusion 05/28 /2019 0915 hours Pre-Transfusion Pulse 71 1 Hour (from pre-transfusion) Pulse 97 The patient had an increase of 26 pulse rate She stated, "Yes, I think they are significant." The second nurse interviewed was asked what are signs of a transfusion reaction. She stated that increase in temperature, chills, pain, rash and blood in urine are signs of a transfusion reaction. The nurse was asked how the facility defines hypotension and hypertension. She stated she looks at the patient's base blood pressure and then the patient's provider sets blood pressure parameters when the patient is admitted. She was asked if these parameters were specific for transfusions. She stated the blood pressure parameters were for any time during the patient's admission. The second nurse was also shown the Blood Transfusion Records listed above. She was asked if she considered the changes in blood pressure and pulse rate significant. She stated she would recheck the vitals and then call the provider and

charge nurse. During an interview on 10/23/2019 at 1438 hours in the conference room, the laboratory manager was asked if the laboratory conducted a review of patient transfusion records. He stated that he completes a "Blood Product Utilization Review" form for each blood component transfused. He further stated that this form is completed using information from the "Blood Transfusion Record" form. The laboratory manager was asked to describe this review. He stated that he makes sure that all the required information on the "Blood Transfusion Record" is entered. He was asked if the vital sign entries were reviewed for signs of a transfusion reaction. He stated he did not really review the specific vital sign entries. He stated that the laboratory director also reviews this document. In 2018 and 2019, the facility had transfused 105 blood components and had never identified and reported a transfusion reaction. 6. A random review of "Blood Transfusion Record" forms (05/2019 - 09 /2019) revealed the following 6 of 21 transfusion reactions that were NOT identified, reported, or investigated by the facility: a. 05/16/2019; Patient 2004118; Unit Number W035219777391; Date/Time of transfusion 05/16/2019 2210 hours Pre-Transfusion blood pressure 134/55; Pulse 85 Blood pressure 15 minutes (from the start of the transfusion) 159/58; Pulse 103 The patient had blood pressure increase of 25 mm Hg and an increase of 18 pulse rate. "No Reaction" was indicated on the blood transfusion record. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Hypertension and tachycardia. Transfusion reaction was NOT identified or reported by transfusing nurse. b. 05/28/2019; Patient 2004137; Unit Number W035219805921; Date/Time of transfusion 05/28/2019 0915 hours Pre-Transfusion Pulse 71 1 Hour (from pre-transfusion) Pulse 97 The patient had an increase of 26 pulse rate. "No Reaction" was indicated on the blood transfusion record. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Tachycardia. Transfusion reaction was NOT identified or reported by transfusing nurse. c. 05/28/2019; Patient 2004137; Unit Number W035219835798; Date/Time of transfusion 05/28/2019 1215 hours Pre-Transfusion blood pressure 122/59 End of Transfusion blood pressure 159/67 The patient had blood pressure increase of 37 mm Hg. "No Reaction /Reaction" was NOT indicated on the blood transfusion record. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Hypertension. Transfusion reaction was NOT identified or reported by transfusing nurse. d. 07/09/2019; Patient 2004309; Unit Number W035219877683; Date/Time of transfusion 07/09/2019 0630 hours Pre-Transfusion blood pressure 147/62 End of Transfusion blood pressure 120/54 The patient had blood pressure decrease of 27 mm Hg. "No Reaction" was indicated on the blood transfusion record. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Hypotension. Transfusion reaction was NOT identified or reported by transfusing nurse. e. 09/27/2019; Patient 2004665; Unit Number W035219916421; Date/Time of transfusion 09/27/2019 0315 hours Pre-Transfusion blood pressure 140/67 End of Transfusion blood pressure 163/87 The patient had blood pressure increase of 23 mm Hg. "No Reaction" was indicated on the blood transfusion record. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Hypertension. Transfusion reaction was NOT identified or reported by transfusing nurse. f. 09/27/2019; Patient 2004665; Unit Number W035219916421; Date/Time of transfusion 09/27/2019 0810 hours Pre-Transfusion blood pressure 179/100 End of Transfusion blood pressure 139/74 "No Reaction" was indicated on the blood transfusion record. This is the patient previously listed (e). The patient's blood pressure from the start of the first unit of blood to the start of the second unit of blood increased 39 mm Hg. The patient's blood pressure dropped 23 mm Hg at the end of the transfusion of the second unit of blood. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Hypertension. Transfusion reaction was NOT identified or reported by transfusing

	nurse. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Word Key: Hg=Mercury IV=Intravenous LVN=Licensed Vocational Nurse mL=Milliliter PICC=Peripherally inserted central catheter PPE=Personal Protection Equipment RN=Registered Nurse
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, client services manual, and in interview with staff, the laboratory failed to ensure their client services manual was consistent with OPTI-CCA TS2 manufacturer's instructions for handling blood gas specimens. Findings included: 1. Review of the client services manual for arterial blood gas (ABG) specimens collection stated, "Criteria for rejecting out of facility ABG's.....Sample on ice." The laboratory received and analyzed ABG specimens from a State School located in Denton. 2. Review of the OPTI-CCA TS2 manufacturer's instructions (5.2.1) stated, "Sample preparation: Whole Blood Samples...Whole blood samples should be analyzed as soon as possible, ideally within 5 minutes after collecting the sample. For brief storage of up to one hour, the sample should be iced." The laboratory did not ensure their client services manual included ABG samples should be stored on ice until samples arrived and were analyzed. 3. During an interview on 10/23/2019 at 1100 hours, Testing Person 2 reviewed and confirmed the above findings.
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 direct observations, review of laboratory procedure, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing peripheral smears for 32 of 32 patients in 2019 (random review July through September). Findings: 1. Review of the laboratory's procedure for peripheral smear for CBC (complete blood counts) flags revealed: "PROCEDURE: ... TO MANUALLY STAIN THE SMEAR: 1. Dip slide into the stain and leave for 5 minutes. Touch the edge of slide against container to remove excess liquid. 2. Dip slide into buffer solution for one minute. Touch edge of slide against container to remove excess liquid. 3. Dip slide into rinse solution for one second each dip. Touch the edge of slide against container to remove excess liquid. 4. Leave slide to air dry." 2. Review of "Thermo SCIENTIFIC WRIGHT-GIEMSA STAIN KIT & REAGENTS" package insert revealed: "DIP PROCEDURE: 1. Dip slides in the Wright-Giemsa Stain Solution for your preferred staining time

	(approximately 60 seconds). Do not agitate. 2. Drain or blot edge of slide(s) or slide holder to remove excess stain. 3. Dip slide(s) in the Wright-Giemsa Buffer solution for approximately the same amount of time used in the staining step (approximately 60 seconds). a. Increasing or decreasing staining or buffering time will alter the color of the finished slide. 4. Drain or blot edge of slide(s) or slide holder to remove excess buffer. 5. Dip slide(s) into the Wright-Giemsa Rinse solution for 2-10 seconds using quick dips. 6. Wipe back of slides. 7. Dry slide(s) in vertical position, on an absorbent surface (e.g. paper towel). Do not blot smear ..." 3. During a tour of the laboratory on 10/24/2019 at 10:26 am, the surveyor observed a paper on the table where peripheral smears were prepared that stated: "1. Stain 5 minutes 2. Buffer 1 minute 3. Rinse (DI Water) 3 dips Try to set slides down and lift slides up in one motion, the less jostling in the jars the better After Rinsing, Blot sides of slide and lean against rack to dry" The procedure did not coincide with the manufacturer's instructions. The laboratory failed to follow manufacturer's instructions for staining peripheral smears. The laboratory began performing peripheral smears on 02/21/2019. 4. Review of patient test records revealed the following patients had peripheral smears performed in July through September (random review): 07/16/2019 Patient ID: 4199 07/17/2019 Patient ID: 4199 07/22/2019 Patient IDs: 4171, 1414, 4199, 4191, 4169 07/25/2019 Patient ID:4199 07/29/2019 Patient IDs: 1414, 3801 08/09/2019 Patient ID: 4239 08/12/2019 Patient IDs: 1414, 4203, 4239, 4211 08/19/2019 Patient IDs: 1414, 4211 08/26/2019 Patient ID: 4211 08/29/2019 Patient ID: 4249 08/30/2019 Patient ID: 4258 09/16 /2019 Patient ID: 4258 09/18/2019 Patient ID: 4258 09/20/2019 Patient ID:4258 09/23 /2019 Patient IDs: 4285, 1414, 4258 09/25/2019 Patient IDs: 4183, 4258 09/30/2019 Patient IDs: 4281, 1414, 4183, 4285 5. During an interview on 10/24/2019 at 10:26 am, testing person-1 stated that he performed the staining of peripheral smears according to the procedure found on the laboratory table. This confirmed the laboratory failed to follow manufacturer's instructions for the staining of peripheral smears.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration and poured dates. Findings: 1. During a tour of the laboratory on 10/24 /2019 at 10:26 am, the surveyor observed on a table where peripheral smears were performed in the laboratory: Four containers with orange lids: one was not labeled with any identifying information, the second container was labeled with "1 9/23", the third container was labeled with "2 9/23" and the fourth container was labeled "3 9 /23." The laboratory failed to label the secondary containers with the name of the reagent, lot numbers, concentration, and poured dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. During an interview on 10/24/2019 at 9:09 am, testing person-1 confirmed the above findings.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and staff interview, the laboratory failed to ensure reagents had not exceeded their expiration dates. Findings: 1. During a tour of the laboratory on 10/24/2019 at 10:26 am, the following reagents were observed to be stored in the reagent refrigerators that were in the storage closet: Refrigerator 1 1 box ACCESS CORTISOL CALIBRATORS, lot #831459, expiration date 04/30/2019 1 box ACCESS DHEA-S CALIBRATORS, lot #724865, expiration date 03/31/2019 1 box ACCESS TESTOSTERONE CALIBRATORS, lot#724685, expiration date 01/31/2019 1 box ACCESS TSH (3rd IS) CALIBRATORS, lot #831538, expiration date 03/31/2019 1 box ACCESS TOTAL T4, lot #831672, expiration date 06/30/2019 1 box ACCESS TOTAL T3 CALIBRATORS, lot #831461, expiration date 04/30/2019 1 box ACCESS SHBG CALIBRATORS, lot #889502, expiration date 02/21/2018 1 box ACCESS TSH (3rd IS) CALIBRATORS, lot #831731, expiration date 05/31/2019 1 box ACCESS Testosterone, lot #724425, expiration date 01/31/2019 1 box ACCESS HYBRITECH PSA, lot #831555, expiration date 05/31/2019 1 box ACCESS PROGESTERONE CALIBRATORS, lot #724644, expiration date 01/31/2019 1 box ACCESS PROGESTERONE, lot #724548, expiration date 04/30/2019 1 box ACCESS HYBRITECH PSA CALIBRATORS, lot #831312, expiration date 02/28/2019 2 boxes Access SUBSTRATE, lot #831696, expiration date 07/31/2019 1 box Access SUBSTRATE, lot #724611, expiration date 01/31/2019 1 box ACCESS SYSTEM CHECK SOLUTION, lot #123450, expiration date 05/31/2019 1 bottle ACCESS SYSTEM CHECK SOLUTION, lot #123450, expiration date 05/31/2019 1 box MATRIX PLUS CHEMISTRY REFERENCE KIT, lot #P371106, expiration date 08/30/2019 1 box TOTAL PROTEIN/ALBUMIN STANDARD KIT, lot #K370906, expiration date 07 /30/2019 1 box SERUM ISE STANDARD KIT, lot #K371706, expiration date 02/28 /2019 1 box CARBON DIOXIDE STANDARD KIT, lot #N371406, expiration date 01/30/2019 1 box Emit II Plus Cocaine Metabolite Assay, lot #1863, expiration date 04/30/2019 1 box Cannabinoid Assay, lot #730554191, expiration date 06/30/2019 1 box ACCESS SHGB CALIBRATORS, lot #889501, expiration date 06/27/2018 1 box Emit II Plus Amphetamines Assay, lot #1830, expiration date 11/30/2018 1 box Benzodiazepine Assay, lot #72947623, expiration date 01/31/2019 1 box DRI pH-Detect Test, lot #72947635, expiration date 11/2018 1 box DRI pH-Detect Test, lot #72959875, expiration date 03/2019 1 box BECKMAN COULTER IRON, lot #2555, expiration date 11/01/2017 1 box BECKMAN COULTER HbA1c, lot #1041A, expiration date 11/01/2017 1 box BECKMAN COULTER LACTATE DEHYDROGENASE, lot #2541, expiration date 02/01/2018 1 box BECKMAN COULTER AMYLASE, lot #2520, expiration date 01/01/2018 2 boxes BECKMAN COULTER CHOLESTEROL, lot#2535, expiration date 01/01/2018 2 boxes Emit 2000 Vancomycin Assay, lot #1846, expiration date 02/28/2019 1 box BECKMAN COULTER LDL-CHOLESTEROL, lot #2298, expiration date 09/01/2017 1 box BECKMAN COULTER TRIGLYCERIDE, lot #2537, expiration date 03/01/2018 1 box SYNCHRON and AU Systems Hemolyzing Reagent, lot #M804006, expiration date 06/30/2019 1 box AMMONIA/IRON STANDARD KIT, lot #L371906, expiration date 09/30/2019 1 box BILIRUBIN STANDARD KIT, lot #L370506,

	expiration date 05/30/2019 1 box URINE CHEMISTRY STANDARD KIT, lot #A372507, expiration date 07/30/2018 1 box BECKMAN COULTER FERRITIN, lot #2225, expiration date 08/01/2017 1 box MICROPROTEIN STANDARD KIT, lot #J373106, expiration date 07/30/2019 1 box Emit 2000 Vancomycin Calibrators, lot #K4, expiration date 11/17/2018 1 box BECKMAN COULTER UIBC, lot #2654, expiration date 08/01/2017 1 box MATRIX PLUS CHOLESTEROL REFERENCE KIT, lot #G370406, expiration date 01/30/2019 Refrigerator 2 1 box DRI Drugs of Abuse High Calibrator, lot #73106176, expiration date 09/30/2019 1 box DRI THC 50 ng/mL Urine Calibrator, lot #1398, expiration date 01/31/2019 1 box DRI Opiate Urine Calibrator 3, lot #72938907, expiration date 06/30/2019 1 box DRI pH-Detect pH 3.0 & 11.0 Calibrator Kit, lot #72977894, expiration date 11/2018 3 boxes MAS DOA TOTAL Liquid Assayed Drugs of Abuse Control, lot #DAT1905M, expiration date 05/31/2019 2. During an interview on 10/24/2019 at 9:09 am, testing person-1 confirmed the laboratory failed to ensure reagents had not exceeded their expiration dates.
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 review of OPTI-CCA TS2 verification studies, patient blood gas log, and in interview with staff, the laboratory failed to verify reference intervals (normal values) for venous blood gases. Findings included: 1. Review of the OPTI-CCA TS2 verfication studies did not include verifying reference intervals (normal values) for venous blood gases (pH, PCO2, PO2, potassium and SO2). The studies only included an ongoing reference interval study for arterial blood gas reference intervals. 2. Review of the patient blood gas log included one venous blood gas specimen analyzed and reported on 08/02/2019. The laboratory had not verified reference intervals (normal ranges) for venous blood gases. 3. During an interview on 10/23/2019 at 1415 hours, the technical consultant confirmed the laboratory had not completed a reference interval (normal range) study for venous blood gases.
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 direct observation, review of manufacturer's instructions, erythrocyte sedimentation rate (ESR) lot roll over data, and confirmed in interview, the laboratory failed to verify the criteria for acceptability for 2 of 2 sets of lot roll overs in 2019 (April and July) for ESR-Chex control material. Findings: 1. Review of ESR-Chex manufacturer's instructions revealed: "Expected Results ...Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits. However, the control means established by the laboratory should fall within the Expected Range specified for the control ...Per CLSI H26-A2 it is recommended that each level of control be run twice a day for 3-5 days to establish individual means for each measurand." 2. Review ESR lot roll over data for April and July 2019 revealed the following: April 2019 lot roll over, date in use 04/30/2019 Level 1: lot #90141380, expiration date 01/14/2020 Laboratory's established range: 5-12 Calculated mean from the analyzer: 6.8 Calculated SD from the analyzer: 0.7 (1SD) Calculated range from the analyzer: 5.4-8.2 The laboratory's established ranges used for everyday acceptability did not coincide with the calculated ranges from the analyzer. Level 2: lot #90141381, expiration date 01/14/2020 Laboratory's established range: 73-91 Calculated mean from the analyzer: 85.6 Calculated SD from the analyzer: 1.4 (1SD) Calculated range from the analyzer: 82.2-88.4 The laboratory's established ranges used for everyday acceptability did not coincide with the calculated ranges from the analyzer. Note: The laboratory did not have all the raw data for level 2 control used in establishing the statistical parameters. The laboratory adjusted level 2 control in June 2019 (specific date was not documented) and no data was provided for adjusting the statistical parameters. July lot roll over, date in use 07/29/2019 Level 1: lot #91261380, expiration date 05/06/2020 Laboratory's established range: 5-13 Calculated mean from precision verification study: 8.1 Calculated SD from precision verification study: 4 (2SD) Calculated range from precision verification study: 4.1-12.1 The laboratory's established ranges used for everyday acceptability did not coincide with the calculated ranges from precision verification study. Level 2: lot #91261381, expiration date 05/06/2020 Laboratory's established range: 88-100 Calculated mean from precision verification study: 95 Calculated SD from precision verification study: 5 (2SD) Calculated range from precision verification study: 90-100 The laboratory's established ranges used for everyday acceptability did not coincide with the calculated ranges from precision verification study. Note: The laboratory adjusted level 2 range on August 1, 2019 to 86-100. The laboratory failed to verify the criteria for acceptability for ESR-Chex control material lot roll overs. 3. During an interview on 10/23/2019 at 11:00 am, testing person-1 (TP-1) stated he did not know where all the raw data for the April lot roll over was located. During an interview on 10/23/2019 at 2:00 pm, TP-1 stated that for the July lot roll over for level 2 control he used a historical SD of 9 to adjust his range in August. He provided a spread sheet of data but could not determine how the SD was derived. For level 1 control he stated that he established his range by using the lowest data point of 5 and the highest data point of 13 for a range of 5-13. The laboratory failed to verify the criteria for acceptability for ESR-Chex control material lot roll overs.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, manufacturer's instructions, quality control (QC) records, patient test reports, and confirmed in interview, the laboratory failed to test and document for intended reactivity (QC) for Wright-Giemsa stain for CBC (complete blood count) peripheral smears in 2019. Findings: 1. Review of the laboratory's procedure for peripheral smear for CBC (complete blood counts) flags revealed: "SLIDE STAINING ... The staining reactions of blood are as follows: Type of blood cell/cell Component Erythrocytes Good Stain Pink to orange Acid stain Bright Red Alkaline Stain Blue or green ..." Note the laboratory only performed peripheral smears for red blood bell (RBC) morphology. 2. Review of "Thermo SCIENTIFIC WRIGHT-GIEMSA STAIN KIT & REAGENTS" package insert revealed: "EXPECTED RESULTS: RBC's Pink-tan with degrees of chromasia ... Note: ...The overall color of the red blood cells is a guide to stain quality and should be used in adjusting staining times for desired results. Specifically, RBC's should appear buff-pink; acid stain will render them bright red or reddish-orange, whereas alkaline stain will render them blue or green." 3. Review of QC records did not include for each day of use, documentation of the intended reactivity for the stain set for CBC peripheral smears performed in 2019. The laboratory began performing CBC peripheral smears on 02/21/2019. The following are a sampling of patients that had peripheral smears July through September (random review) with no documented QC being performed: 07/16/2019 Patient ID: 4199 07/17/2019 Patient ID: 4199 07/22 /2019 Patient IDs: 4171, 1414, 4199, 4191, 4169 07/25/2019 Patient ID:4199 07/29 /2019 Patient IDs: 1414, 3801 08/09/2019 Patient ID: 4239 08/12/2019 Patient IDs: 1414, 4203, 4239, 4211 08/19/2019 Patient IDs: 1414, 4211 08/26/2019 Patient ID: 4211 08/29/2019 Patient ID: 4249 08/30/2019 Patient ID: 4258 09/16/2019 Patient ID: 4258 09/18/2019 Patient ID: 4258 09/20/2019 Patient ID:4258 09/23/2019 Patient IDs: 4285, 1414, 4258 09/25/2019 Patient IDs: 4183, 4258 09/30/2019 Patient IDs: 4281, 1414, 4183, 4285 4. During an interview on 10/24/2019 at 9:09 am, testing person-1 stated that QC for CBC peripheral smears was not performed and documented, confirming the above findings.