Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506479	05/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Seton Smithville- Lab/Rt	1201 Hill Road, Smithville, 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	Based on an announced validation inspection, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
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 nursing blood and blood products transfusion policies and procedures, transfusion records, and interview, the transfusion records were missing vital signs for seven (7) out of nine (9) units transfused. Findings follow. A. Review of the nursing policy and procedure titled Blood and Blood Products- Administering and Transfusion under Steps Transfusion stated, "When the qualified transfusionist is ready to administer the blood product: ...2. Obtain BP, Pulse, Temperature immediately prior to beginning transfusion and document in the EHR... 18. Obtain vital signs 15 minutes after beginning the transfusion and document in the patient's medical record..." And under Post-Transfusion stated, "3. Obtain post transfusion vital signs immediately following the transfusion and document on Blood Product Transfusion form and/or patient's medical record." The policy is missing what comprised the vital signs, missing obtaining Respiration Rate, and failed to define changes in respiration and pulse to indicate a transfusion reaction. B. Seven (7) out of nine (9) randomly selected units transfused reviewed were missing vital signs, Temperatures, or Respiration Rates: 1. Medical Record Number (MRN) 8023269 Unit # W221623250601-x packed red blood cells Started 04/11/2023 14:57 Stopped 04/11 /2023 18:10 Vitals taken at: 14:45 (pre), 15:12 (15 minute), 16:41 (45 minute), 18:10

	(end) Per policy, missing temperature at end 2. MRN 8018143 Unit # W221623653094-V packed red blood cells Started 05/25/2023 11:05 Stopped 05/25 /2023 13:50 Vitals taken at: 9:52 (pre), 11:20 (15 minute), 13:54 (end) Per policy, pre-vitals not taken prior to transfusion. No Respiratory Rates obtained. 3. MRN 8018143 Unit # W221623151896-J packed red blood cells, 2nd unit Started 05/25/2023 14:49 Stopped 05/25/2023 not provided Vitals taken at: 13:54 (pre), 15:05 (15 minute), 18: 00 (end?) Per policy, pre-vitals not taken prior to transfusion. No Respiratory Rates obtained. 4. MRN 8026256 Unit # W221623453486-G packed red blood cells Started 06/22/2023 19:41 Stopped 06/22/2023 22:40 Vitals taken at: 19:15 (pre), 19:56 (15 minute), 20:45 (1 hour), 21:42 (2 hour), 22:40 (end) Per policy, pre-vitals not taken prior to transfusion. Missing blood pressure at 1 hour. 5. MRN 8011386 Unit # W221623401024-9 packed red blood cells Started 09/27/2023 9:54 Stopped 09/27 /2023 11:30 Vitals taken at: 9:52 (pre), 10:09 (15 minute), 10:58 (1 hour), 11:37 (end) Missing blood pressure, pulse, temperature at 1 hour 6. MRN 8027149 Unit # W221623508447-9 packed red blood cells Started 10/26/2023 11:15 Stopped 10/26 /2023 13:55 Vitals taken at: 10:09 (pre), 11:30 (15 minute), 14:00 (end) Per policy, pre-vitals not taken prior to transfusion 7. MRN 8018240 Unit # W? packed red blood cells Started 11/03/2023 not provided Stopped 11/03/2023 not provided Vitals taken at: 13:34 (pre), 13:49 (15 minute), 16:32 (end) Per policy, missing temperature pre C. Interview with the Nurse Supervisor on May 3, 2024 at 1650 hours confirmed the findings.
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: I. Based on review of the laboratory's policy and procedure, Mean Normal Prothrombin Time (MNPT) study, interview, and annual test volumes, the laboratory failed to follow their own procedure and obtain acceptable donors by questionnaire for the MNPT study for one of one study reviewed in 2023 using the Instrumentation Laboratory ACL TOP CTS 300 for Prothrombin Time (PT). Findings follow. A. Review of the laboratory's policy and procedure titled ACL TOP 550/350 Changing Reagent or Lot Number of Reagent- Laboratory, revised 03/18/2022, under Procedural Steps stated, "6. For each new lot number of PT reagent, a new normal patient mean, the Geometric mean (Geo Mean) must be established. This is defined as the mean PT value in healthy subjects and is performed by an Instrumentation Laboratory associate. a. A minimum of 20 PT results from healthy subjects is required. b. Healthy subjects are considered those who have not taken any aspirin, nonsteroidal or anti-inflammatory medication, over-the-counter medication, herbal supplements, or vitamins that can impact platelet function for 7-10 days prior to collection..." B. Review of the Geometric Mean [MNPT Reference Interval], performed 07/06/2023 for Lot N0239577 of RecombiPlasTin 2G, did not indicate whether there was an equal number of males and females, that they were healthy and not taking medications, including aspirin, or their ages. C. Interview with the Laboratory Manager on May 1, 2024 at 1540 hours confirmed they don't use questionnaires or draw donors and acknowledged they save patient samples that tested within the normal range [on the previous lot of thromboplastin] and freeze the

specimens for the MNPT study. D. Review of annual testing volumes showed the lab performed 468 PT/INR tests in 2023. KEY: INR = International normalized ratio II. Based on review of the laboratory's policy and procedure, quality control (QC) records, interview, and annual test volumes, the laboratory failed to follow its own procedure for establishing the standard deviation for the Activated Partial Thromboplastin Time (APTT) on the Instrumentation Laboratory ACL TOP CTS 300 for six (6) of six (6) months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Changing Lot Number of Control/Establishing Control Ranges ACL TOP 550/350 - Laboratory, revised 08/01/2022, under Procedural Steps stated, "3. Refer to the reagent package insert for information for the expected %CV. 4. To ensure fewer QC failures during the initial use of the new %CV, the laboratory may choose to use the typical %CV from the package insert until a total of 50 data points have been generated. 5. The calculated %CV from these 50 samples will now be the working %CV. 6. Data points should be collected from different runs over multiple days using controls and reagents under the same conditions used for patient testing..." Expected Values 1. Determine the mean, SD, CV, and range once the data has been collected. 2. The range is usually defined as the mean +/- 2SD. 3. The total day-to-day coefficient of variation (CV) of the system should be less than 5% with the same lot of normal and abnormal controls." B. Review of the laboratory's quality control titled QC Statistic Report from 07/16/2023 - 12/31/2023 showed a new mean, SD, and CV from 07/16/2023 - 07/31/2023 with control lots N0138360 (Normal) and N0330391 (Abnormal) with 51 and 49 data points, respectively. 1. APTT 07/16/2023 - 07/31/2023 Normal Control mean = 29.8 SD = 0.5 CV = 1.8% N = 51 Abnormal Control mean = 56.9 SD = 0.8 CV = 1.3% N = 49 The laboratory failed to implement the new mean and CV. 2. Review of the target values from 07/16/2023 - 12/31/2023 for control lots N0138360 (Normal) and N0330391 (Abnormal) revealed: APTT 07/16 /2023 - 12/31/2023 Normal Control mean = 29.5 SD = 2.0 CV = 6.7% Abnormal Control mean = 56.0 SD = 4.2 CV = 7.5% 3. The laboratory 's performance showed the following monthly CVs: Normal Abnormal August 2023 1.8% 1.6% September 2023 2.0% 1.5% October 2023 1.9% 1.9% November 2023 1.6% 1.4% December 2023 2.2% 1.7% C. Interview with the Laboratory Manager on May 2, 2024 at 0930 hours confirmed they were using the ranges from the package insert. D. Review of annual testing volumes showed the lab performed 357 APTT tests in 2023. KEY: SD = standard deviation CV = coefficient of variation III. Based on review of the laboratory's textbook reference, manufacturer's instructions, laboratory policy and procedure, interview, and query showed the laboratory failed to routinely use a standardized volume of 12 mL of urine in their urinalysis procedure utilizing the KOVA System for 23 of 23 months reviewed. Findings follow. A. Review of the laboratory textbook by Nancy Brunzel titled Fundamentals of Urine and Body Fluid Analysis 1994, Chapter 8 Microscopic Examination of Urine Sediment under Specimen Volume stated, "The volume of urine recommended for a urinalysis is 12 mL; however, volumes ranging from 10 to 15 mL have been used. This volume from a well-mixed specimen contains a representative sampling of the formed elements. This amount of urine is not always available, especially from pediatric patients. In these instances, the volume of urine may be reduced to 6mL, and all numerical counts from the sediment exam result be doubled. In some facilities, when less than 3mL of urine is available for testing, the urine is microscopically examined, without the sediment's being concentrated. Whenever the actual volume used to prepare the sediment for the microscopic examination is less than that routinely required, a notation must accompany the specimen report. The decision to accept specimens with volumes less than 12 mL for a urinalysis, as well as the choice of protocol, is determined by each individual laboratory." B. Review of the KOVA Tubes package insert Kova Plastics System for Standardized Urinalysis, P/N 91062-21 EN 08/21,

	under KOVA System Test Procedure stated, "3. Centrifuge the KOVA Plastics Tubes (each containing 12mL of urine specimen or KOVA-Trol) at a relative centrifugal force (RCF) of 400 for five minutes..." C. Review of the laboratory's policy and procedure titled Urine Microscopic Examination-Laboratory, last revised 03/18/2022 (elapsed time 23 months: 03/18/2022 - 03/01/2024), under Specimen Collection, Processing, Storage, Preservation and Rejection Criteria stated, "4. Volume a. An optimal quality of urine to permit both the macro and microscopic evaluation is usually considered to be 12 mL but may vary with the collection container." And under Procedure stated, "3. Pour approximately 8 mL of the specimen into the conical centrifuge tube and cap tightly." The Procedure called for 8mL of urine instead of 12mL. D. Interview with testing personnel #4 (as listed on the CMS-209), on May 3, 2024 at 1745 hours confirmed the volume of urine spun for microscopic urinalysis was 8mL. E. Review of annual testing volumes showed the lab performed 1486 microscopic urinalysis tests in 2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, laboratory's policy and procedure, calibration verifications, and interview, the laboratory failed to perform calibration verification every six months for pH, partial pressure of Carbon Dioxide (pCO2), and partial pressure of Oxygen (pO2) performed on the Alere epoc for two of two years reviewed. Findings follow. A. Based on review of the epoc System Manual, 51000623 2013, at 3.7 Reader Electronic Internal QC Test stated, "Every time a Host and Reader connect, the Reader begins a two-level Electronic QC Test." And at 9.3.1 Calibration Verification stated, "Follow the Calibration Verification procedure to verify accuracy of Test Results over an extended measurement range of a Test. Performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While commercial Calibration Verification Sets contain five (5) Levels, verification of the measurement range can be accomplished using lowest, highest, and mid levels. Commercially available five (5) Level Calibration

	Verification Sets can be used for verification of calibration of epoc Test Cards within reportable ranges. Recommended products are described in Table 9.2 below." The electronic controls do not cover a high, low and mid-point, and did not qualify for the factory calibrated exception. B. Review of the laboratory's policy and procedure titled Quality Management- Blood Gas Lab, revised 02/12/2024, under Calibration Verification/Analytical Measurement Range stated, "Linearity will be evaluated every six months on the Siemens RP500 by using calibration verification material (NOTE-linearity/AMR will not be performed on the EPOC, it is considered a single use system and does not allow user calibration)." The procedure did not require calibration verification every six (6) months. C. Calibration verifications were requested on April 29, 2024 at 1340 hours but not provided. D. Interview with the Supervisor of the Blood Gas Team on April 29, 2024 at 1340 hours acknowledged they stopped performing calibration verifications in 2022 when Joint Commission told them it wasn't required." II. Based on review of the laboratory's policy and procedure, calibration verifications, and interview, the laboratory failed to adjust the analytic measurement range based on calibration verification results for Calcium performed on the Abbott Architect ci4000 for 12 out of 12 months reviewed in 2023. Findings follow. A. Review of the laboratory's policy and procedure titled Calcium - Laboratory, under Analytic Measurement Range stated, "The analytic measurement range of Calcium serum and urine is 2.0 to 24.0 mg/dL." B. Review of the calibration verifications performed 11/05/2022, 05/13/2023, and 10/07/2023 revealed all failed the high end of the calibration verification for vial 5 that represented 23.777, 24.020, and 24.230 mg/dL respectively. The last linear value was vial 4 at 18.512, 18.617, and 18.772 mg/dL respectively. C. Interview with the Laboratory Manager on May 3, 2024 at 1630 hours acknowledged they were aware of the failures at the high end, but were not able to change their reporting system because their Cerner system is network wide across multiple locations. III. Based on review of the laboratory's policy and procedure, calibration verifications, and interview, the laboratory failed to adjust the analytic measurement range based on calibration verification results for Albumin performed on the Abbott Architect ci4000 for six (6) out of six (6) months reviewed for 2023. Findings follow. A. Review of the laboratory's policy and procedure titled Albumin - Laboratory, under Analytic Measurement Range stated, "The analytic measurement range for Albumin BCP is 0.4 to 11.0 g/dL." B. Review of the calibration verifications performed 05/13/2023 and 10/07/2023 revealed both failed the high end of the calibration verification for vial 5 that represented 10.940 and 11.137 g/dL respectively. The last linear value was vial 4 at 8.378 and 8.533 g/dL respectively. C. Interview with the Laboratory Manager on May 3, 2024 at 1630 hours acknowledged they were aware of the failures at the high end, but were not able to change their reporting system because their Cerner system is network wide across multiple locations.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

	review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, regulations, and interview, the laboratory director failed to specify in writing the duties and responsibilities of 13 of 13 blood gas testing personnel engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Finding follow. A. Review of the form Job Description for Respiratory Therapy under "Responsibilities" did not include the duties and responsibilities of blood gas testing for testing personnel #6-18 (as listed on the CMS-209). B. Review of the regulations for testing personnel responsibilities at 493.1425 (b) stated, "Each individual performing moderate complexity testing must- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; (b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples; (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; (4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance; (5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and (6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications." C. Interview with the Supervisor of the Blood Gas Team on April 30, 2024 at 1440 hours confirmed they did not have a delegation of duties for testing personnel for their blood gas testing.