Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660749	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Anson General Hospital Laboratory	101 Avenue J, Anson, 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
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 the laboratory's policies and procedures, manufacturer's instructions, verification studies performed by the laboratory and interview of facility personnel, the laboratory failed to follow manufacturer's instructions for verifying the precision, reference range, reportable ranges and accuracy of the Prothrombin Time (PT) and Activated Thromboplastin Time (APTT) tested on the Sysmex CA 620 coagulation analyzer installed in May 2018. THIS IS A REPEAT DEFICIENCY from the 08/08/2017 survey. The findings included: Precision Verification 1. The laboratory had not written a separate policy / procedure for the use of the Sysmex CA 620 coagulation analyzer , using the manufacturer's Operator Guide as its own procedure (signed by laboratory director 05/09/2018) 2. Review of the manufacturer's instruction guideline titled "Precision Verification" (1/2013), states the following: on page III-1 "Between-run precision measure the degree of imprecision over time and requires testing over a minimum of five days." on page III-2 "The laboratory should determine Between Run Precision over a minimum of 5 days using 4 replicates of each level of control More runs and days will increase confidence in the results. Record results on the appropriate Precision Worksheet." Further review of instructions found on page III-2, "5. The laboratory should determine Between Run Precision over a minimum of 5 days using 4 replicates of each level of control. More runs and days

will increase confidence in the results. Calculation of Precision 1. Calculate the Mean, SD, and %CV for controls. 2. Calculate the acceptable limits of error. Regulated analytes are PT, APTT & Fibrinogen. according the the manufacturer, the acceptable limit for within run precision is: PT + 2% APTT + 2%" 3. Based on a review of the verification studies for the Sysmex CA 620, the laboratory performed within run precision studies May 2-3, 2018 , but did not assess between run precision. Review of the within run precision found that the laboratory's % CV for Citrol 3 (5.3%)exceeded the manufacturer's acceptable limits of 2%. 4. Interview of the Technical Consultant conducted on January 15, 2019 at 1:21 PM confirmed the laboratory did not evaluate the data for the within run precision, and did not assess the between run precision over a minimum of 5 days as required by the manufacturer. Method Verification 1. Review of the manufacturer's instructions for Method verification found the following instructions to the laboratory on page IV-1: "Performance of a method verification study defines the relationship between a system currently in use and a new system. Accuracy is closeness to the true value. The PT and APTT are screening tests with no recognized reference method to determine accuracy. Best results for method verification studies require a minimum of 40 patient samples (20 normal and 20 abnormal). Range should be from below to substantially above the expected reference range. Studies should be performed over several days. Samples should be tested on the current system, followed immediately, but by no more than 1/2 to 1 hour later by testing on the new system. Clotting factor activity can deteriorate over time affecting APTT values and to a lesser extent, the PT. Run Tests as appropriate following the recommended operating procedure (see application sheets). Record results on worksheets. Perform regression analysis." 2. Review of the laboratory's own method verification found that it had not been evaluated for acceptability 3. Interview of the Technical Consultant conducted on January 15, 2019 at 1:21 PM confirmed the laboratory did not evaluate the data for the method verification for acceptability. Reference Interval 1. Based on a review of the manufacturer's instructions titled "Reference Interval" (1/2013), the document states the following: "A reference interval must be established for Fibrinogen, Prothrombin Times, APTT's, D-Dimer's and Thrombin Times by each institution. Some tests, such as factor assays, do not require that each individual lab perform a reference interval study, as clinical investigations have established reference values that are widely accepted by the medical community. Requirements: Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) Donors should not take any medications, including aspirin. A minimum of 20 donors with a reasonable even distribution of males and females should be included. Donors should span the adult age range. (NOTE: a separate range should be established for pediatric populations). The FDA defines pediatric as up to 21 years of age. Testing should be performed over a period of several days and by different people, if possible to allow for day to day variation. A minimum of 4-6 specimens should be drawn each testing day, following the established laboratory protocol for collection, storage, and processing of patient plasma samples. The test result from the donors should be analyzed statistically and verification of the mean (plus/minus) 2 SD or 95 percent confidence limit should be calculated. Software that performs this calculation can be used to verify the Laboratory or the IFU (instructions for use) reference interval. Note: Because the reference interval is defined with a plus/minus 2SD, values falling outside this range may or may not be normal and should be further evaluated. Statistically, a certain percentage of these patients will be normal. However, by defining the normal ranges in this manner, patients' who are abnormal will be less likely to go undetected. (See CLSI document C28-A.)." 2. Review of the laboratory's own method verification found the laboratory had not been evaluated for acceptability. 3. Interview of the Technical Consultant conducted on January 15, 2019

	at 1:21 PM confirmed the laboratory did not evaluate the data for the method verification for acceptability. Reportable Range 1. Review of the manufacturer's instructions titled Reportable Range found on page VI-1 found the following instruction to the laboratory: "Reportable range determination is addressed both in CLIA requirements and CLSI Guidelines. While CLIA requires the laboratory to verify the Reportable Range, the method used is not explicit, and leaves this up to the individual laboratories." 2. Review of the records provided for the verification of the Sysmex CA 620 found no documentation of reportable range verification. 3. Interview of the Technical Consultant conducted on January 15, 2019 at 1:21 PM confirmed that the laboratory had not verified the reportable ranges for PT and APTT using the Sysmex CA 620 coagulation analyzer.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, manufacturer's product inserts, quality control records, patient test records and staff interview, the laboratory failed to establish and maintain the quality control plan for the Triage Cardiac Panel. Findings included: 1. Review of the laboratory's Individualized Quality Control Plan (I QC P) for the Triage Cardiac Panel found under the heading external quality control testing - "external QC will be with each new lot, shipment and every 30 days." 2. Review of the manufacturer's product insert found on page 7 - "users should follow government guidelines (for example, federal, state or local) and or accreditation requirements for quality control." 3. Review of quality control records for 2018 found that the laboratory tested two levels of quality control material using the Triage Cardiac Panel on the following dates: January 10, 2018 lot C3348A expiration June 3, 2018. January 28, 2018 lot C3351A expiration July 21, 2018. February 6, 2018 lot C3351A expiration July 21, 2018. March 19, 2018 lot C3354A expiration August 26, 2018. April 30, 2018 lot C3354A expiration August 26, 2018. May 23, 2018 lot C3383A expiration January 14, 2019. June 5, 2018 lot C3383A expiration January 14, 2019. July 11, 2018 lot C3383A expiration January 14, 2019 July 26, 2018 lot C3401A expiration March 9, 2019 September 5, 2010 lot C3401 expiration March 9, 2019 the laboratory had no means of evaluating the performance of quality control materials tested over time. 4. Review of patient test records found that the laboratory tested 5 patients using the Triage Cardiac Panel on the following dates without testing at least two levels of quality control material at least once every 30 days: August 28, 2018 patient 22208 was tested without evidence of quality control testing. August 30, 2018 patients 22264 and 22270 were tested without evidence of quality control testing. September 1, 2018 patient 22298 was tested without evidence of quality control testing. September 2, 2018 specimen 22310 was tested without evidence of

	quality control testing 5. Interview of the technical consultant conducted on January 16, 2019 at 10:08 AM confirmed that the laboratory failed to test at least two levels of external quality control material at least once every 30 days as defined in their IQ CP when using the Triage Cardiac Panel.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Review of policies and procedures, verification records, and patient test records found that the technical consultant failed to verify that the Sysmex CA 620 coagulation analyzer used for testing ProTime and activated thromboplastin time met the manufacturer's specifications for accuracy, precision and reportable range and verified the reference range. (See D5421)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the quality control program had been established and maintained for the of Alere Triage Cardiac Panel using the Alere triage meter. (See D5441)