

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0974783	(X3) Date Survey Completed 01/10/2019
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 1901 Medi Park # 2062, Amarillo, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>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) tested on the Sysmex CA 620 coagulation analyzer installed in September 2018. The findings included: Precision Verification Based on review of the laboratory's policies and procedures, Siemens CA 620 coagulation analyzer manufacturer's instructions, precision verification study, and confirmed in interview with facility personnel, the laboratory failed to follow manufacturer's instructions for verifying the between run precision for PT and APTT upon installation of the CA 620 analyzer September 2018. The findings included: 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 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.</p>

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 to 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, but did not assess between run precision. 4. Interview of the Laboratory Director conducted on January 10, 2019 at 10:47 AM 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 no documentation of review. 3. Interview of the Technical Consultant conducted on January 10, 2019 at 10:47 AM 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 reference interval studies found that the laboratory had defined a reference

interval of 9.1 - 12.0 seconds for Prothrombin Time, but had no documentation as to how this range was determined. 3. Interview of the Laboratory Director conducted on January 10, 2019 at 10:47 AM confirmed the laboratory did not know how these numbers were decided upon as the laboratory's reference intervals. 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 Laboratory Director conducted on January 10, 2019 at 10:47 AM confirmed that the laboratory had not verified the reportable ranges for PT and APTT using the Sysmex CA 620 coagulation analyzer.