| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0507433 | 05/02/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Lamb Healthcare Center | 1500 South Sunset, Littlefield, 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 |
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| **D0000** | The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of manufacturer's instructions, laboratory's procedures, Mean Normal Prothrombin Time (MNPT) study, and interview, the laboratory failed to verify the reference interval for Prothrombin Time (PT) tested on the ACL Elite for 11 of 11 months reviewed. Findings follow. A. Review of the ACL Hemostasis Systems Performance Verification Manual, Revision A August 28 2012, under Normal Reference Interval Chapter 8, stated, Establishing a Normal Reference Interval "Summary and Explanation The interpretation of clinical laboratory data is a comparative decision-making process. For this process to occur, reference intervals are needed for all test systems. Since all results will be compared to the reference interval, it is crucial that it be done correctly. For the purpose of this method, we will use the following definitions: Reference Range... refers to the entire range of values, i. e.., ALL the values collected in the study. Reference Interval.... refers to the 95% confidence limits of the Reference Range (ie. the mean +/- 2SD)... Record the data on the worksheet provided. Determine the mean, standard deviation (SD) and range once the data has been collected. The range is usually defined as the mean +/- 2 SD. For non-Gaussuan distributions, such as PT, a geometric mean is recommended... Expected Values The original laboratory's reported 95% reference limits may be considered valid for use in the secondary lab if no more than 2 of the 20 tested |

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| | subjects' values fall outside those original reported limits and pre-testing criteria are met. If 3 or more results fall outside the original range, 20 new subjects must be obtained and the testing repeated (you cannot just add an additional 3 samples)." B. Revew of the laboratory's policies and procedures found in the Coagulation & Serology Procedures Manual under the coagulation QC tab showed a copy of the above procedure in the procedure titled Reference Interval / Normal Reference Range mean normal PT. C. Review of the laboratory's established reference interval from 2012 showed the PT normal range to be 9.4 - 12.2 seconds. D. Review of the current Mean SD Calculation for Normal Range Study from 04/15/2021 - 04/29/2021 showed for the Reagent Lot N0504540, expiration 05/31/2022 had a geometric mean of 11.6 and 2SD of 1.5 with a range of 10.1 - 13.1 seconds. Five values were outside the established 9.4 - 12.2 seconds with sample numbers Female 1 at 12.8, Female 2 at 12.5, Female 3 at 12.6, Female 6 at 12.3, and Female 8 at 12.3. E. Interview with Technical Consultant #2 as listed on the CMS 209, on May 2, 2022 at 1500 hours via phone call confirmed the verification studies for the reference interval for Lot N0504540 had 5 values outside the established reference interval of 9.4-12.2 seconds. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the calibration verification, and interview, the laboratory failed to perform calibration verification every six months for D-Dimer performed on the Alere Triage for two of two events for the duration of 12 months reviewed. Findings follow. A. Review of the calibration verifications performed for D-Dimer from April 2021 - March 2022 showed none performed. Calibration verifications were requested but not provided. B. Interview with Technical Consultant #2 on April 14, 2022 at 1555 hours in the conference room confirmed they stopped performing calibration verifications for D-Dimer. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g) |

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| | (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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of quality control results and interview, the laboratory failed to monitor over time the accuracy and precision of the test system for D-Dimer performed on the Triage Meter using the Triage Control Total 5 for 1 of 1 years reviewed. Findings follow. A. Review of quality control results from April 2021 - March 2022 showed mean and standard deviation (SD) were not calculated for the D-Dimer quality control results. B. Interview with the Technical Consultant on April 14, 2022 at 1550 hours in the conference room confirmed statistical analysis was not performed on the D-Dimer quality control results. II. Based on review of quality control results and interview, the laboratory failed to monitor over time the accuracy and precision of blood gases performed on the Instrumentation Laboratory GEM Premier 3500 using Instrumentation Laboratory Contril 7 for 1 of 1 years reviewed. Findings follow. A. Review of quality control results from April 2021- March 2022 showed mean and standard deviation (SD) were not calculated for the blood gas quality control results. B. Interview with Testing Personnel #7 listed on the CMS 209 on April 13, 2022 at 1545 hours in the respiratory therapy room confirmed statistical analysis was not performed on the blood gas quality control results. |