| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0506530 | 03/04/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Hemphill County Hospital Laboratory | 1020 South Fourth Street, Canadian, 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 laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on March 4, 2024. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>(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 laboratory calibration records, laboratory policy, and confirmed in interview, the laboratory failed to ensure calibration verification occurred at least every 6 months of D-Dimer testing on the Sysmex CA600 coagulation analyzer for one of two years of records reviewed in 2023 and 2024. The findings included: 1. Review of laboratory D-Dimer calibration records included the last calibration date, for D-Dimer, on 6/8/2024. Surveyor asked for the calibration records for December |

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| | 2024, and none was provided. 2. Review of the laboratory policy titled "Siemens Innovance d-Dimer", section VIII "Calibration" did not include instructions for calibration verification at least once every six months. 3. In an interview on 3/4/2025 at 13:40 hours, in the office, the general supervisor (GS) confirmed that D-Dimer calibration had not been performed every 6 months in 2024. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory quality control (QC) records, laboratory reagent instructions for use (IFU), laboratory policy, patient test report, and confirmed in interview the laboratory failed to ensure negative QC reactivity for three of eight blood bank reagents use for patient red cell ABO typing, and patient undetected antibody testing, for records reviewed from June 2024 to December 2024. The findings included: 1. Review of laboratory blood bank quality control records from June 2024 to December 2024 included the following reagents without a negative QC reactivity: Reagent, test use: Anti-A, used in ABO determination of patient red cells. Anti-B, used in ABO determination of patient red cells. Screen Cell I, used in the detection of unexpected antibodies in patient serum. Screen Cell II, used in the detection of unexpected antibodies in patient serum. Surveyor asked for documentation that negative reactivity was ensured for all blood bank reagents and none could be provided. 2. Review reagent IFU included the following information: 2. a. Blood Grouping Reagent: Anti - A, section "Quality Control" "Quality control of reagents is essential and should be performed on each day of use in accordance with local, state and federal regulations. For ABO blood grouping reagents, appropriate antigen positive and negative red blood cells should be used." 2.b. Blood Grouping Reagent: Anti-B, section "Quality Control" "Quality control of reagents is essential and should be performed on each day of use in accordance with local, state and federal regulations. For ABO blood grouping reagents, appropriate antigen positive and negative red blood cells should be used." 2.c. "Reagent Red Blood Cells For the Detection of Unexpected Antibodies", section "Quality Control": "Quality control of reagents is essential and should be performed on each day of use in accordance with local, state and federal regulations." 3. Review of laboratory policy did not include instructions for to ensure negative reactivity was achieved for blood bank reagents used in patient ABO types and unexpected antibody screens. 4. Review of patient test records from June 2024 to December 2024 included the following 10 patients with ABO red cell typing and unexpected antibody testing bank testing performed: Date: Patient MRN 06/12/2024: 2151315 08/22/2024: 2166853, 2158045 10/11/2024: 2159245 10/20/2024: 2158720 11/08/2024: 2152426 11/29/2024: 2154726 12/16 /2024: 2150643 12/18/2024: 2153218, 2150643 5. In an interview on 3/4/2025 at 15: 00 hours, in the office, the general supervisor confirmed that blood bank QC did not include a negative reactivity for Anti-A, Anti-B, Antibody Screen Cell 1, and Antibody Screen Cell 2. |