| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D0667597 | 06/07/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Brazos County Health District | 201 North Texas Avenue, Bryan, 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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| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Review of the manufacturer's instructions for use, patient test records and interview of facility personnel found the laboratory failed to test a negative and positive control each day when testing patient specimens for Human Immunodeficiency Virus (HIV) antibodies. The findings included: 1. Review of the manufacturer's instructions for use for the INSTI HIV-1/HIV-2 Antibody Test kit found: On page one: " COMPLEXITY : WAIVED for Fingerstick Whole Blood Any modification by the laboratory to the INSTI test or the FDA approved INSTI test instructions will result in the test no longer meeting the requirements for waived category. COMPLEXITY: MODERATE for Venous Whole Blood and Plasma samples" On page two under the heading External Quality Control: " INSTI HIV-1/HIV-2 Positive and Negative Controls Antibody Test Kit Controls are available separately for use only with the INSTI HIV-1 /HIV-2 Antibody Test kit. These controls are used to verify test performance and interpretation of the results. The Positive controls and the Negative control are to be run on separate Membrane Units. The HIV-1 and the HIV-2 Positive controls have been manufactured to produce a faint blue color in the test spot. The negative control will produce a blue color in the Control spot, but no color in the Test spot for a Non-reactive test result. Use of non-validated control material may not produce the required results and therefore would be inadequate for quality assurance programs for the INSTI HIV-1/HIV-2 Antibody Test. INSTI HIV-1/HIV-2 Positive and Negative Controls should be run under the following circumstances: for new INSTI operator |

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| | verification prior to performing testing on patient specimens when switching to a new lot number of INSTI test kits whenever a new shipment of INSTI kits is received When temperature during storage of the kits falls outside of 2 -30 degrees Celsius (C) when temperature of the test area falls outside of 15 - 30 degrees C At regular intervals as determined by the user facility." 2. Review of patient test records found the laboratory tested 581 patient specimens using the INSTI HIV-1/HIV-2 Antibody Test kit between October 1, 2021 and June 7, 2022 without testing quality control materials each day of testing. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted June 7, 2022 at 10:39 AM confirmed that the laboratory used the INSTI HIV-1 HIV-2 Antibody Test Kit in a moderate complexity capacity and did not test quality control materials each day of patient testing for HIV 1/2 between October 2021 and the date of the inspection. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Review of patient reports and interview of facility personnel found the laboratory failed to ensure the final test report included the date of testing for eight of eight patient reports reviewed. The findings: 1. Review of eight patient reports between March 30, 2022 and May 12, 2022 found no date of report on the final test report. 2. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted June 7, 2022 at 12:02 PM confirmed that the date of report does not appear on the final patient report. |