

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0508127 | (X3) Date Survey Completed 01/16/2025 |
| Name of Provider or Supplier Mitchell County Hospital | Street Address, City, State 997 West I20, Colorado City, 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 |
|---------------------------|---|
| D0000 | The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard deficiencies were cited. |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, review of the laboratory's environmental records, review of patient records from September 2024 to December 2024, and confirmed in interview, the laboratory failed to follow its own policy on performing patient testing for RPR's within the allowable temperature range for 12 of 121 days. Findings include: 1. Review of the laboratory's policy titled "RPR Equipment Testing Procedure" approved by the laboratory director on 08/12/2015 stated: "ROOM TEMPERATURE READINGS: A. Check the room temperature before doing RPR's. It MUST read (23-28 C). B. Do not run RPR's if the room temperature is out of range ..." 2. Review of the laboratory's environmental records from September 2024 to December 2024 determined the recorded temperature ranges were outside the laboratory's policy for acceptable limits for the following days: September 2024: a. 09/02/2024: 22C b. 09/03/2024: 22C c. 09/13/2024: 22C d. 09/17/2024: 21C e. 09/20/2024: 21C October 2024: a. 10/07/2024: 22C b. 10/10/2024: 22C c. 10/17/2024: 22C November 2024: a. 11/05/2024: 21C b. 11/13/2024: 22C c. 11/25/2024: 22C December 2024: a. 12/31/2024: 21C 3. Review of patient final reports from September 2024 to December 2024 determined patient testing for RPR's was performed while recorded temperatures were outside the laboratory's acceptable limits: September 2024: a. Sample ID: 819093 b. Sample ID: 819215 c. Sample ID:</p> |

820598 d. Sample ID: 820611 e. Sample ID: 821147 f. Sample ID: 821570 October 2024: a. Sample ID: 823416 b. Sample ID: 823815 c. Sample ID: 824888 November 2024: a. Sample ID: 827446 b. Sample ID: 828510 c. Sample ID: 829942 December 2024: a. Sample ID: 834058 4. The general supervisor (as listed on the CMS-209 form) confirmed the findings during an interview conducted on 01/15/2025 at 1116 hours in the conference room. Key: RPR - Rapid Plasma Reagin C - degrees Celsius CMS - Centers for Medicare and Medicaid Services

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and confirmed in interview, the laboratory failed to include normal (reference) ranges for two of three coagulation policies reviewed. Findings include: 1. Review of the laboratory's policy titled "Prothrombin Time (PT) - Innovin procedure using plasma", approved by the laboratory director on 09/21/2012 determined: "Reference Interval Reference interval values determined for the current Innovin reagent lot number (+/- 2.0 SD) are [Blank] seconds." Further review of the laboratory's policy titled "Activated Partial Thromboplastin Time (aPTT) - Actin FSL", approved by the laboratory director on 09/21/2012 determined: "Reference Interval: Reference interval values determined for the current Actin FSL lot number (+/- 2.0 SD) are [Blank] to [Blank] seconds." 2. The general supervisor (as listed on the CMS-209 form) confirmed the findings during an interview on 01/15/2025 at 1425 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) 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.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for use (IFU), review of the manufacturer's certificates of analysis (COA), review of quality control (QC) records from January to December 2024, and confirmed in interview, the laboratory failed to follow manufacturer instructions for QC testing for 12 of 12 months in 2024. Findings include: 1. Review of the IFU titled "Cepheid GeneXpert Xpress SARS-CoV-2/Flu/RSV", version 302-5159, Rev. D May 2022 stated: "9 Materials Available but Not Provided External controls in the form of inactivated virus(es) are available from ZeptoMetrix (Buffalo, NY). External Positive Control: Catalog #NATFRC-6C (NATrol Flu/RSV/SARS-CoV-2) External Negative Control: Catalog #NATCV9-6C (Coxsackievirus A9)" 2. Review of the manufacturer's COA titled "seracare AccuPlex (Trademark) SARS-CoV-2, Flu A/B and RSV Reference Material Kit", version COA-0505-0174 Rev. 01 stated: "Research Use Only - Not for Use in Diagnostic Procedures" Further review of the manufacturer's package inserts determined there were two reference material kits used by the laboratory: a. Positive Reference Material Batch Number: 1064865 Negative Reference Material Batch Number: 10634486 b. Positive Reference Material Batch Number: 10693544 Negative Reference Material Batch Number: 10693543 3. Review of QC records from January 2024 to December 2024 determined the laboratory used reference material kits for research use only for the following dates: a. 01/31/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 b. 02/29/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 c. 03/31/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 d. 04/30/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 e. 05/31/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 f. 06/30/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 g. 07/31/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 h. 08/31/2024 Positive QC Lot: 10641865 Negative QC Lot: 10634486 i. 09/30/2024 Positive QC Lot: 10693544 Negative QC Lot: 10693543 j. 10/31/2024 Positive QC Lot: 10693544 Negative QC Lot: 10693543 k. 11/30/2024 Positive QC Lot: 10693544 Negative QC Lot: 10693543 l. 12/31/2024 Positive QC Lot: 10693544 Negative QC Lot: 10693543 4. The general supervisor (as listed on the CMS-209 form) confirmed the findings during an interview on 01/16/2025 at 1125 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services