

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2146748	<b>(X3) Date Survey Completed</b> 05/21/2024
<b>Name of Provider or Supplier</b> Medical City Argyle, A Campus Of Medical	<b>Street Address, City, State</b> 7218 Crawford Rd, Argyle, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, chemistry analytic documentation, and confirmed in interview, the laboratory failed to ensure retention of chemistry analytic records for two of two years from 2022-2024 (May 2022-May 2024). Findings Included: 1. During a tour of the facility on 05/20/2024 at 10:10 AM, the surveyor observed 1 Vitros Chemistry Analyzer (Serial Number:46001052) previously used for patient analysis. The surveyor observed the following tests previously performed on the chemistry analyzer: Acetaminophen Albumin ALP (alkaline phosphatase) ALT (Alanine transaminase) Amylase AST (aspartate aminotransferase) Bilirubin, Total BUN (Blood Urea Nitrogen) Calcium Chloride CO2 (Carbon Dioxide) CK (Creatine Kinase) Creatinine Digoxin Na (Sodium) Cl (Chloride) K (Potassium) Ethanol Glucose Hgb A1C (Hemoglobin) Lactic Acid Lipase Magnesium Phosphorous Protein, Total Sailcylate Vancomycin 2. Review of laboratory policy, "Records Management" (Effective Date: 03/01/2022) revealed the following: "Policy 1. It is this Company's policy to apply effective and cost-efficient techniques (1) to manage and maintain complete, accurate, and high-quality records, and (2) to avoid cost and burden if storage and retention by routinely disposing of documentation that does not serve an ongoing business purpose and is not otherwise required to be maintained by law or regulation. Records are to be retained in accordance with applicable laws and regulations and this policy. ...Section IV.</p>

Records Destruction ...Records can only be discarded when the specified retention period has expired ..." Further review of the above policy revealed the following retention of analytic records timeframes: "TX-MED-50-54 Records related to the minor maintenance, daily function checks, routine and package surveys, and instrument calibration performed in accordance with manufacturer's instructions on facility testing equipment. Retention Time: 3 years" 3. Review of chemistry analytic documentation revealed the laboratory failed to ensure retention of the following records for two of two years in 2022-2024 (May 2022-May 2024): a. Instrument printouts b. Manufacturer's package inserts/instructions c. Quality control documentation d. Calibration data e. Maintenance activities The surveyor requested the above documentation on 05/20/2024 at 02:20 PM, and none was provided. 4. In an interview on 05/21/2024 at 01:15 PM, Technical Consultant 2 (TC-2) confirmed the laboratory failed to ensure retention of chemistry analytic records for two of two years from 2022-2024 (May 2022-May 2024).

**D3039**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(5)

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, quality assurance (QA) documentation, and confirmed in interview, the laboratory failed to ensure retention of QA reports for four of four specialties discontinued in November 2023. Findings Included: 1. Review of laboratory procedure manual revealed the laboratory previously performed the following specialties (Discontinued in November 2023): a. Chemistry (Vitros Analyzer Serial Number: 46001052) b. Blood Bank (Typing and Antibody Screens) c. Bacteriology (Gram Stains) d. Hematology (Sysmex Analyzer Serial Number: 201516) 2. Review of laboratory QA documentation revealed no QA reports for the above specialties prior to November 2023. The surveyor requested QA reports for chemistry, blood bank and bacteriology prior to discontinuing the testing in November 2023, and none were provided. 3. In an interview on 05/21/2024 at 01:15 PM, Technical Consultant 2 (TC-2) confirmed the laboratory failed to ensure retention of QA reports for four of four specialties discontinued in November 2023.

**D5401**

**PROCEDURE MANUAL**

CFR(s): 493.1251(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.

This STANDARD is not met as evidenced by:  
Based on direct observation, review of laboratory policy, chemistry analytic documentation, and confirmed in interview, the laboratory failed to follow their own records retention policy for two of two years in 2022-2024 (May 2022-May 2024). Findings Included: 1. During a tour of the facility on 05/20/2024 at 10:10 AM, the surveyor observed 1 Vitros Chemistry Analyzer (Serial Number: 46001052) previously used for patient analysis. The surveyor observed the following tests

previously performed on the chemistry analyzer: Acetaminophen Albumin ALP (alkaline phosphatase) ALT (Alanine transaminase) Amylase AST (aspartate aminotransferase) Bilirubin, Total BUN (Blood Urea Nitrogen) Calcium Chloride CO2 (Carbon Dioxide) CK (Creatine Kinase) Creatinine Digoxin Na (Sodium) Cl (Chloride) K (Potassium) Ethanol Glucose Hgb A1C (Hemoglobin) Lactic Acid Lipase Magnesium Phosphorous Protein, Total Sailcylate Vancomycin

2. Review of laboratory policy, "Records Management" (Effective Date: 03/01/2022) revealed the following: "Policy 1. It is this Company's policy to apply effective and cost-efficient techniques (1) to manage and maintain complete, accurate, and high-quality records, and (2) to avoid cost and burden if storage and retention by routinely disposing of documentation that does not serve an ongoing business purpose and is not otherwise required to be maintained by law or regulation. Records are to be retained in accordance with applicable laws and regulations and this policy. ...Section IV. Records Destruction ...Records can only be discarded when the specified retention period has expired ..." Further review of the above policy revealed the following retention of analytic records timeframes: "TX-MED-50-54 Records related to the minor maintenance, daily function checks, routine and package surveys, and instrument calibration performed in accordance with manufacturer's instructions on facility testing equipment. Retention Time: 3 years"

3. Review of chemistry analytic documentation revealed the laboratory failed to ensure retention of the following records for two of two years in 2022-2024 (May 2022-May 2024): a. Instrument printouts b. Manufacturer's package inserts/instructions c. Quality control documentation d. Calibration data e. Maintenance activities The surveyor requested the above documentation on 05/20/2024 at 10:20 AM, and none was provided.

4. In an interview on 05/21/2024 at 01:15 PM, Technical Consultant 2 (TC-2) confirmed the laboratory failed to follow their own records retention policy for two of two years in 2022-2024 (May 2022-May 2024).

**D5803**

**TEST REPORT**  
CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, patient final reports, and confirmed in interview, the laboratory failed to have a system in place to readily obtain patient results for four of four specialties reviewed in 2024. Findings Included: 1. Review of laboratory procedure manual revealed the laboratory previously performed the following specialties (Discontinued in November 2023): a. Chemistry (Vitros Analyzer Serial Number: 46001052) b. Blood Bank (Typing and Antibody Screens) c. Bacteriology (Gram Stains) d. Hematology (Sysmex Analyzer Serial Number: 201516) 2. The surveyor requested patient reports for the above specialties prior to November 2023. The facility provided blood bank patient results the following business day (18 hours). The facility stated retrieval of the chemistry, gram stain, and hematology patient results would also be a lengthy process, and they would be unable to retrieve the results by the end of the survey. This confirmed the laboratory failed to have a system in place to readily obtain patient results for four of four specialties reviewed in 2024. 3. In an interview on 05/21/2024 at 01:20 PM, Technical Consultant 2 (TC-2) confirmed the above.