

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0054055	<b>(X3) Date Survey Completed</b> 07/21/2021
<b>Name of Provider or Supplier</b> Memorial Medical Center	<b>Street Address, City, State</b> 815 Virginia N Street, Port Lavaca, 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 surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A. Based on review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to ensure plasma samples for lactic acid were separated from the cells within 15 minutes of collection. The findings included: 1. Review of the manufacturer's instructions for Lactic Acid under, "Specimen Collection and Preparation" (Instructions For Use BAOSR6X93 10, January 2019), it stated, "...Keep the sample on ice and separate plasma from cells within 15 minutes of collection ..." 2. Review of 20 patient final reports from May 2021 found the following 4 samples were tested when the laboratory failed to provide documentation of separating plasma from cells within 15 minutes of collection: Order #72864 Date: 05-21-2021 Collection Time: 2015 Receive Time: 2040 (elapsed time past 15 minutes was 10 minutes) Order #73445 Date: 05-23-2021 Collection Time: 2024 Receive Time: 2049 (elapsed time past 15 minutes was 10 minutes) Order #73474 Date: 05-24-2021 Collection Time: 0005 Receive Time: 0032 (elapsed time past 15 minutes was 12 minutes) Order #75601 Date: 05-27-2021 Collection Time: 0033 Receive Time: 0059 (elapsed time past 15 minutes was 11 minutes) 3. The laboratory was asked to provide documentation of ensuring the plasma samples were separated from the cells within</p>

15 minutes of collection. No documentation was provided. 4. Interview with the technical consultant on July 20, 2021 at 14:00 hours in the laboratory confirmed the findings. She revealed that times may not have been entered correctly. This confirmed the findings. B. Based on review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to ensure that results provide only a preliminary analytical test result. The findings included: 1. Based on review of the manufacturer's instructions for Emit II Plus Cannabinoid Assay (August 2010, 9N052.2D\_B) stated under the Intended Use section, " ...The Emit II Plus Cannabinoid Assay provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available ..." 2. Based on review of the manufacturer's instructions for Emit II Plus Opiate Assay (September 2010, 9B052.6D\_D) stated under the Intended Use section, " ...The Emit II Plus Opiate Assay provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available ..." 3. A random review of patient results from July 2021 revealed the following patient urine drug screens were resulted as positive or negative, and not as a preliminary positive: Order # 301 Date: 07-07-2021 Cannabinoid Result: Positive Order #6785 Date: 07-19-2021 Cannabinoid: Positive 4. The patient report did not indicate that the results would be sent out for confirmation. Nor, did the patient report state the results were preliminary positive. 5. Interview with the technical consultant on July 20, 2021 at 13:15 hours in the laboratory confirmed the findings.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
 Based on a review of the laboratory's verification studies, a review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of verifying its normal range for the analytes run on the GEM 4000 chemistry analyzer. The findings included: 1. A review of the laboratory's verification records for the GEM 4000 chemistry analyzer revealed the laboratory performed studies in January 2020 for the following analytes: pH PO2 PCO2 HCO3 Hemoglobin CO2 2. A review of the laboratory's patient test records revealed the laboratory identified three patient normal ranges for Arterial Blood Gases: Adult Arterial Blood Gas: Analyte Normal Range Unit pH 7.35 - 7.45 none PO2 83 - 108 mmHg PCO2 35 - 48 mmHg HCO3 21 - 28 mmol/L Hemoglobin 12 - 15 g/dL CO2 22 - 32 mmol/L Adult Venous Blood Gas: Analyte Normal Range Unit pH 7.32 - 7.43 L PO2 35 - 42 mmHg PCO2 41 - 51 mmHg HCO3 22 - 29 mmol/L Hemoglobin 14 - 18 g/dL CO2 22 - 32 mmol/L Cord Blood Gas Venous: Analyte Normal Range Unit pH 7.25 - 7.45 none PO2 17 - 41 mmHg PCO2 27 - 49 mmHg 3. The laboratory was asked to

provide documentation of verifying the normal ranges to ensure they were reflective of their population. No documentation was provided. 4. n interview with the laboratory manager on July 20, 2021 at 15:30 hours in the laboratory revealed the laboratory did not verify the patient normal ranges. The ranges from the previous analyzer were carried over but not verified. Key: PO2 - partial pressure oxygen PCO2 - partial pressure carbon dioxide HCO3 - bicarbonate CO2 - carbon dioxide mmHg - millimeters Mercury g/dL - grams per deciliter mmol/L - millimoles per liter L - liters

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of quality control logs, review of patient final reports, and confirmed in interview with facility personnel, the laboratory failed to provide documentation of performing a positive and negative control each day of patient testing for acid fast bacilli (AFB) smears. The findings included: 1. Review of acid fast stain quality control logs for February 2020 found a positive and negative quality control was documented on February 27, 2020 and February 28, 2020. 2. Review of patient final reports for acid fast found the following 1 of 3 patient results was performed when the laboratory failed to have documentation of performing a positive and negative quality control: Order #42050 Date: 02-29-2020 Direct Acid Fast Stain Result: No AFB seen 3. An interview with the technical consultant on July 21, 2021 at 13:30 hours confirmed the findings.