

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2099148	<b>(X3) Date Survey Completed</b> 02/27/2023
<b>Name of Provider or Supplier</b> American Medical Center Laboratory	<b>Street Address, City, State</b> 20820 Greenfield Road 2nd Floor, Oak Park, MI	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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 record review and interview with the Laboratory Director (LD), the laboratory failed to follow established written policies and procedures for its laboratory testing for 5 (July 2022 to February 2023) of 5 months of testing. Findings include: 1. A record review of the "Policies and Procedure" manual revealed for 5 (July 2022 to February 2023) of 5 months of testing the laboratory did not follow the "Laboratory General Maintenance" policy and procedures or the procedure was lacking current methods and technologies as follows: a. Documenting and recording of temperatures. b. General maintenance on the centrifuge. c. Thermometer calibration. d. Pipette calibration Validation not up to date. e. No procedure for specimen collection, handling, and processing of urine toxicology specimens. f. No policy or procedure for the temperature recording for the Corning LSE heating block. 2. An interview on 2/27/2023 at 11:53 am, the LD confirmed the "Policies and Procedure" manual was not followed and not current and up to date.</p>
<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>

This STANDARD is not met as evidenced by:  
. Based on observation, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to perform and document the thermometer calibration checks as required by the manufacturer before the expiration for 3 (traceable thermometers) of 3 thermometers in use in the laboratory. Findings include:  
1. During a tour of the laboratory on 2/27/2023 at 9:20 am, the surveyor observed 3 of 3 thermometers in use past their expiration date of 9/28/2020 as follows: a. Whirlpool refrigerator S/N 181625068. b. Whirlpool freezer S/N 181625066. c. Kenmore refrigerator S/N 181625052. 2. A record reviewed revealed a lack of documentation for the calibration of the 3 thermometers and/or replacement by the expiration of 9/28/2020. 3. A interview on 2/27/2023 at 9:22 am, the LD confirmed the 3 thermometers were not calibrated and/or replaced before their expiration.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
. Based on observation, lack of documentation, and interview with the Laboratory Director (LD) and the Testing Personnel (TP), the laboratory failed to perform and document the temperature recordings for the Corning LSE heating block on days of use for 8 (July 2022 to February 2023) of 8 months in use. Findings include: 1. During a tour of the laboratory on 2/27/2023 at 9:20 am, the surveyor observed a Corning LSE heating block on the tabletop with a thermometer in one of the testing wells. 2. A record review on 2/27/2023 at 11:53 am revealed a lack of documentation for the temperature of the heating block on the days of testing. 3. When queried on 2/27/2023 at 11:53 am, TP stated that the temperature is looked at but not recorded. 4. A interview on 2/27/2023 at 11:53 am, the LD and TP confirmed the heating block temperature was not recorded on the days on the testing.

**D5805**

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

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.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Laboratory Director (LD), the laboratory failed to provide the correct name and address of the laboratory performing

the highly complex toxicology testing on its test reports for 6 (A2, D4, H3, M9, R3, and V9) of 6 patient test reports reviewed. Findings include: 1. A review of the laboratory's patient test reports revealed the name and address of the laboratory performing the toxicology testing was not the same as what is written on the CMS-116 application or what's in the CMS database for the following test results: a. Run A patient 2 - MG604647. b. Run D patient 4 - BS371785. c. Run H patient 3 - JA877477. d. Run M patient 9 - ND28966. e. Run R patient 3 - GO795353. f. Run V patient 9 - LP3372. 2. An interview on 2/27/2023 at 1:15 pm, the LD confirmed the name and address on the patient's final reports was not the correct. \*\*\*Repeat Deficiency from the 9/19/2018 survey\*\*\*