

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0940223	<b>(X3) Date Survey Completed</b>  11/04/2021
<b>Name of Provider or Supplier</b>  Michael Tahery Md, Inc	<b>Street Address, City, State</b>  503 N Central Ave Ste 200, Glendale, CA	
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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory's reagent materials in the Bacteriology laboratory and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to label reagents to indicate the opening date, preparation, and expiration dates, when such reagents are used. The findings included: 1. Based on the surveyor's observation during the laboratory tour on November 4, 2021 at approximately 11:30 a.m., the TP indicated that no opening, preparation, or expiration date labels were documented as well as initials of the person preparing the reagents for all the reagents used in the Microbiology laboratory (oxidase, catalase, indole, etc.). 2. The laboratory's TP affirmed in an interview conducted November 4, 2021 at approximately 12:00 p.m., that the reagents currently used to test patients' samples in the microbiology section were not labeled with opening, preparation, initials, and expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 1,210 microbiology samples annually.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check</p>

protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation, lack of maintenance protocol and documentation, and interview with the testing personnel (TP) it was determined that the laboratory failed to establish and document a maintenance protocol for the desiccant used in the container with antimicrobials testing discs used for susceptibility testing of bacterial organisms. The findings included: 1. The laboratory used various antimicrobial panels to test for susceptibility testing on bacteria isolated. 2. At the time of the laboratory tour on November 4, 2021 at approximately 11:30 a.m. the surveyor observed that the antimicrobials were stored in a plastic container with no desiccants to preserve the strength and potency of the antibiotic discs. 3. The TP affirmed that the laboratory failed to establish a maintenance protocol (placing of desiccants and changing them as needed in the container) for the antimicrobials' storage. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 1,090 bacteriology samples annually for which a antibiotic susceptibilities are performed on a number of bacterial isolates.

**D6179**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1495(b)(5)

Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation, review of policies and procedures, and interview with the technical supervisor/testing person; it was determined that the testing personnel failed to identify problems that could adversely affect test performance and reporting of test results. See D5415 and D5433.