

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0673050	<b>(X3) Date Survey Completed</b>  01/16/2018
<b>Name of Provider or Supplier</b>  Kenneth A Grossman Md	<b>Street Address, City, State</b>  180 White Road Suite 103, Little Silver, NJ	
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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 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.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), observation of the maintenance sticker on the microscope, the lack of a maintenance log and interview with the Nurse Director (ND), the laboratory did not perform and document maintenance on the microscope, from March 2011 to the date of the survey. The ND confirmed on 1/16/18 at 1:15 pm the laboratory did not perform and document maintenance on the microscope. b) Based on surveyor review of the PM and interview with the ND, the laboratory did not establish a maintenance protocol for the microscope from 11/4/15 to the date of the survey. The ND confirmed on 1/16/18 at 1: 20 pm the laboratory did not have a maintenance protocol.</p>
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics</p>

of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Nurse Director (ND), the laboratory failed to check QC on each batch of Accu - Dermatophyte Test Medium (DTM) from 11/4/15 to the date of the survey. The finding includes: 1. The laboratory did not check each new lot number and shipment of media for: a. Physical characteristics b. Sterility c. Ability to support growth and select or inhibit specific organisms d. Produce a biochemical response. 2. The ND confirmed on 1/16/18 at 2:00 pm that the laboratory did not perform the above mentioned QC checks. This was cited on previous survey performed 11/4/15.

**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 surveyor review of the Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to indicate the "Test Report Date" on the FR from 11/4/15 to the date of survey. The LD confirmed on 1/16/18 at 2:20 pm that the "Test Report Date" was not on the FR.