

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0215348	(X3) Date Survey Completed 08/30/2021
Name of Provider or Supplier Robinson & Max Dermatology, Pa	Street Address, City, State 101 W Ridgely Rd 4-B, Lutherville, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual, dermatophyte media package insert, and temperature log record review and interview with the laboratory director (LD), the laboratory did not ensure that the procedure for performing dermatophyte testing included the acceptable temperature range for incubating the dermatophyte testing media (DTM). Findings: 1. The laboratory performs dermatophyte testing using ACU-DTM dermatophyte testing media (DTM). The package insert for the DTM states, "Incubation at room temperature, 20 - 30 C (68 F - 86 F) is satisfactory for growth of most dematophytes. Lower temperatures may result in slower growth." 2. The laboratory's procedure</p>

"Dermatophyte Screen" states that the DTM should be incubated at "room temperature" which is not defined. 3. A review of the "DTM Room Temperature Monitoring" log showed that the acceptable temperature range is "65-85" which does not match the manufacturer requirements and is not listed in the procedure manual. 4. During an interview on 8/30/2021 at 11:30 AM, the LD confirmed that the written procedure manual did not include the acceptable temperature requirements for performing dermatophyte testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on procedure manual, dermatophyte media package insert, and temperature log record review and interview with the laboratory staff and laboratory director (LD), the laboratory failed to define, monitor, and document laboratory reagent refrigerator temperature to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory performs dermatophyte testing using ACU-DTM dermatophyte testing media (DTM). During an interview at 10:15 AM on the day of the survey the LD stated that the laboratory had switched to a new DTM on 4/19/2021 because of the lack of availability of the media they had previously been using for testing. The LD stated that this new DTM had to be stored in the refrigerator. 2. Procedure manual and DTM package insert review showed that the new DTM should be stored at 2 C - 8 C. Record review showed that the laboratory was not documenting the temperature of the refrigerator where the DTM was stored. This was confirmed by a laboratory staff member at 11:00 AM on the day of the survey. 3. During an interview on 8/30/2021 at 11:30 AM, the LD confirmed that the laboratory failed to document laboratory refrigerator temperatures to ensure proper reagent storage and reliable test system operation. II. Based on procedure manual, dermatophyte media package insert, and temperature and patient log record review and interview with the laboratory director (LD), the laboratory failed to define, monitor, and document laboratory room temperature to ensure reliable test system operation. Findings: 1. The laboratory performs dermatophyte testing using ACU-DTM dermatophyte testing media (DTM). 2. The procedure "Dermatophyte Screen" states that the DTM should be incubated at "room temperature" which is not defined. The package insert for the DTM states, "Incubation at room temperature, 20 - 30 C (68 F - 86 F) is satisfactory for growth of most dematophytes. Lower temperatures may result in slower growth." 3. A review of the "DTM Room Temperature Monitoring" log showed that the acceptable temperature range is "65-85" which does not match the manufacturer requirements; and 4. Laboratory room temperature was outside the package insert's acceptable range 49 of 96 times recorded from 1/1/2021 to 8/30/2021. 5. Patient log record review showed that DTM was inoculated with specimens from 2 patients (accession numbers "21-34" and "21-35") on 7/1/2021. These specimens were incubated at room temperature and the results interpreted on 7/13/2021. Laboratory room temperature was outside the package insert's acceptable range 7 of 9 times

recorded from 7/1/2021 to 7/13/2021. 6. During an interview on 8/30/2021 at 11:30 AM, the LD confirmed that the laboratory failed to define laboratory room temperature to ensure proper test system operation.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the Individualized Quality Assurance Plan (IQCP) and interview with the laboratory director (LD), the LD failed to ensure that the IQCP was maintained to identify failures in quality as they occur. Findings: 1. The laboratory performs dermatophyte testing using ACU-DTM dermatophyte testing media (DTM). The laboratory changed the DTM used for patient testing in April, 2021. This DTM has different storage and incubation requirements than the previous DTM for which the laboratory did not account. Cross-refer to D5413, part I and II for details. 2. Review of the laboratory's IQCP showed that it was last reviewed and signed by the LD in February 2021. 2. During an interview on 8/30/2021 at 11:30 AM, the LD confirmed that the laboratory's IQCP had not been updated or reviewed to include the change in DTM and its different storage and incubation temperature requirements.