

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2238939	(X3) Date Survey Completed 11/08/2023
Name of Provider or Supplier Medovate Dermatology	Street Address, City, State 1450 Busch Pwy - Ste 145, Buffalo Grove, IL	
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
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the lead technician (LT), the laboratory failed to retain original test reports for at least two years for five of five dates requested for moderate complexity mycology Potassium Hydroxide (KOH) testing in 2021, 2022 and 2023. Findings include: 1. Review of laboratory records and lack of documentation revealed that the laboratory failed to retain original test reports for at least two years after testing for KOH testing in 2021, 2022 and 2023. Five of five dates were requested: a. 11/02/2021 b. 04/29/2022 c. 07/26/2022 d. 02/22/2023 e. 10/24/2023 2. On 11/08/2023, at 11:42 a.m., an interview with the LT revealed, "Dr. X does around 1 or 2 (KOH) a month - KOH testing performed from 11/2021 - 11/2023". 3. On 11/08/2023, at 1:50 p.m., the LT confirmed the above findings.</p>
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p>

	<p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to monitor and evaluate the overall quality of two of two testing procedures; high complexity histopathology Mohs testing and moderate complexity mycology Potassium Hydroxide (KOH) testing at least twice a year in 2021, 2022 and 2023. (Refer to D5217).</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to evaluate the biannual method accuracy for two of two testing procedures; high complexity histopathology Mohs testing and moderate complexity mycology Potassium Hydroxide (KOH) testing at least twice a year in 2021, 2022 and 2023. Findings include: 1. Review of laboratory records and lack of documentation revealed that the laboratory failed to evaluate and document the biannual method accuracy for Mohs testing in 2021, 2022 and 2023. 2. Review of laboratory records and lack of documentation revealed that the laboratory failed to evaluate and document the biannual method accuracy for KOH testing in 2021, 2022 and 2023. 3. On 11/08/2023, at 8:57 a.m., the LD confirmed the above findings.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with the laboratory director (LD) and lead technician (LT), revealed the laboratory failed to monitor and evaluate the overall quality of the analytic systems for this condition. Findings Include: 1. Failed to ensure expired reagents were not used for Potassium Hydroxide (KOH) patient testing. (Refer to D5417). 2. Failed to perform and document scheduled service maintenance for microscopes utilized for Mohs and KOH testing (Refer to D5433).</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor's direct observation, and an interview with the lead technician (LT), the laboratory failed to ensure two of two reagents were not used for moderate complexity mycology Potassium Hydroxide (KOH) patient testing after exceeding their expiration dates in 2021, 2022 and 2023. Findings Include: 1. On 11/08/2023 at 8:16 a.m., the surveyor's direct observation revealed exceeded expiration dates for two of two KOH testing reagents. a. "KOHD 20% Potassium Hydroxide with DMSO (Lot K18CC6) - EXP: 2021-12-31" b. "Chlorazol Black E - UN1814, Potassium Hydroxide, Solution (Lot 9296) - EXP: 2021-10-23" 2. On 11/08/2023 at 8:16 a.m., the LT confirmed the above findings.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, direct observation, lack of documentation, and interview with the lead technician (LT), the laboratory failed to perform and document the service maintenance for two of two microscopes utilized for high complexity histopathology Mohs testing and moderate complexity mycology Potassium Hydroxide (KOH) testing in 2021, 2022 and 2023. Findings Include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to establish a maintenance protocol for two of two microscopes (Nikon 121240 and Olympus Model BX43F SN 1K50550) utilized for Mohs and KOH testing in 2021, 2022 and 2023. 2. Direct observation on 11/08/2023 at 8:16 a.m., revealed the laboratory failed to document the service maintenance dates performed after "6/20/15". No maintenance was performed in 2021 - 2023 for the microscope marked, "Nikon 121240". The service tag attached to the "Nikon 121240" reads as follows: "SALES LUKAS MICROSCOPE, Mundelein, IL "Serviced 6/20/15" "Technician XXXX" 3. Direct observation on 11/08/2023 at 8:16 a.m., revealed the laboratory failed to document the service maintenance dates performed after "10-14-18". No maintenance was performed in 2021 - 2023 for the microscope marked, "Olympus Model BX43F SN 1K50550". The two of two service tags attached to the "Olympus Model BX43F SN 1K50550" read as follows: 1. "IMEB Your Pathology Partner: Preventative Maintenance Inspection" "Serial # 1K50550" "Inspection Date 10-14-18" "Next Due Date 10-15-19" "Technician XX" 2. "Biomedical Engineering Dept. Electrical Safety Test" "Completed by XX - Date 10-14-18" "Inspection Due 10-13-19" 3. On 11/08/2023 at 8:16 a.m., an interview with the LT confirmed the above findings.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the lead technician (LT), the laboratory failed to make available a written procedure manual for two of two testing procedures, high complexity histopathology Mohs testing and moderate complexity mycology Potassium Hydroxide (KOH) testing in 2021, 2022 and 2023. Findings include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to provide laboratory personnel a written procedure manual for Mohs testing in 2021, 2022 and 2023. 2. Review of laboratory records and lack of documentation revealed the laboratory failed to provide laboratory personnel a written procedure manual for KOH testing in 2021, 2022 and 2023. 3. On 11/08/2023 at 09:14 a.m., the LT confirmed the above findings.