

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2093482	<b>(X3) Date Survey Completed</b> 10/23/2024
<b>Name of Provider or Supplier</b> Medical Dermatology Associates Of Chicago	<b>Street Address, City, State</b> 363 W Erie St, Suite 250, Chicago, IL	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to have a competency procedure in place to assess employee competency in the subspecialties of mycology and parasitology. Findings include: 1. Review of the laboratory's policy and procedure manual identified the laboratory failed to have a competency assessment procedure in place for microscopy testing of potassium hydroxide (KOH) in the subspecialty of mycology and scabies wet mount in the subspecialty of parasitology. 2. Interview with laboratory representative on 10/23 /2024, at 11:42 am, confirmed that the laboratory failed to have a competency procedure in place for microscopic KOH and scabies wet mount testing.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform bi-annual method accuracy evaluations for microscopic potassium hydroxide (KOH) wet</p>

	<p>mount testing in 2022 through the survey date of 10/23/2024. Findings include: 1. Review of laboratory records identified no documented bi-annual method accuracy evaluations for microscopic KOH wet mount testing in 2022 through the survey date of 10/23/2024. 2. Interview with the laboratory representative on 10/23/2024, at 11:14 am, confirmed that the laboratory failed to perform bi-annual method accuracy evaluations for microscopic KOH wet mount testing.</p>
<p><b>D5219</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to perform bi-annual method accuracy evaluations for microscopic scabies wet mount testing in 2022 through the survey date of 10/23/2024. Findings include: 1. Review of laboratory records identified no documented bi-annual method accuracy evaluations for microscopic scabies wet mount testing in 2022 through the survey date of 10/23/2024. 2. Interview with the laboratory representative on 10/23/2024, at 11:07 am, confirmed that the laboratory failed to perform bi-annual method accuracy evaluations for microscopic scabies wet mount testing.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> 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 review of laboratory policy and procedure manuals, lack of documentation, and interview with the laboratory representative; the laboratory failed to establish a procedure for microscopic scabies wet mount testing in the subspecialty of parasitology. Findings include: 1. Review of laboratory policy and procedure manuals revealed the laboratory failed to have a procedure in place for microscopic scabies wet mount testing in the subspecialty of parasitology. 2. Interview with the laboratory representative on 10/23/2024, at 11:42 am, confirmed the laboratory failed to have a procedure for microscopic scabies wet mount testing.</p>
<p><b>D5433</b></p>	<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</p>

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 policy and procedures manuals, laboratory records, lack of documentation, direct observation, and interview with the laboratory representative; the laboratory failed to perform and document annual maintenance for the laboratory's Linistain autostainer (Serial Number: LS5402A1806) and laboratory's Avantik fume hood (Serial Number: 11815513) used for the subspecialty of histopathology since 09/16/2022. Findings include: 1. Review of the laboratory's policy and procedure manual identified the procedure titled, "III. Maintenance Protocols", which indicated: a) Under "Fume Hood Air Filtronix", "2. Yearly maintenance of the fume good by WCMC EHS with record retention." b) Under "Shandon Linistain Autostainer", "5. Yearly maintenance of autostainer by Avantik /Belair Instrument Company with record retention." c) Under "Annual Maintenance", "Cryostat, Fume Hood, and Shandon Linistain Autostainer: Performed by Avantik/Bel Air Instrument Company ...." 2. Direct observation of the laboratory testing facility on 10/23/2024, at 09:50 am, revealed Tech One Biomedical service stickers on both the Linistain autostainer and Avantik fume hood indicating maintenance had not been performed since 09/16/2022. 3. Interview with the laboratory representative on 10/23 /2024, at 11:42 am, stated that service had been performed on the Linistain autostainer and Avantik fume hood in October 2024 and that she would email documentation of the service as soon as obtained. 4. As of 11/01/2024, at 1:15 pm, the surveyor had not received documentation of annual maintenance for the Linistain autostainer and Avantik fume hood in 2023 and 2024.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure manuals, laboratory records, the CMS-209 (laboratory personnel report), lack of documentation, and interview with the laboratory representative, the technical consultant failed to perform competency assessments on three of four moderate complexity testing personnel (TP) annually for microscopic potassium hydroxide (KOH) wet mount testing in the subspecialty of mycology and for microscopic scabies wet mount testing in the subspecialty of parasitology from 2022 through the date of survey, 10/23/2024. Findings include: 1. Review of the laboratory's policy and procedure manual identified the laboratory failed to have a competency assessment procedure in place for microscopy testing of KOH in the subspecialty of mycology and scabies wet mount in the subspecialty of parasitology. See D5209. 2. Review of employee competency assessments revealed three of four TP (TP #3, 4, and 5), as identified on the CMS-209 (laboratory personnel report), had no competency assessments performed for microscopy KOH wet mount testing or microscopic scabies wet mount from 2022 through the date of survey, 10/23 /2024. 3. Interview with the laboratory representative on 10/23/2024, at 10:30 am,

confirmed the technical consultant failed to perform competency assessments on three of four moderate complexity testing personnel (TP) annually from 2022 through the date of survey, 10/23/2024.