

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D2207992	<b>(X3) Date Survey Completed</b>  12/18/2024
<b>Name of Provider or Supplier</b>  Resolute Dermatology Llc	<b>Street Address, City, State</b>  6800 Hilltop Rd Ste 102, Shawnee, KS	
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>D5217</b>	<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 the review of the CMS116 test lists, lack of documentation of accuracy checks from 6/29/23 to date of survey, lack of proficiency testing enrollment, patient KOH test results, and interview with the office manager (OM), the laboratory failed to verify the accuracy of KOH testing for mycology twice a year from 6/29/23 to date of survey. Findings: 1. Review of the CMS116 test lists and accuracy check documentation revealed the laboratory did not perform accuracy checks twice a year for KOH testing from 6/29/23 (KOH testing start date) to date of survey. 2. The surveyor asked if the laboratory was enrolled in proficiency testing for KOH testing. The OM stated the laboratory was not enrolled in proficiency testing for KOH testing. 3. Review of patient testing records revealed six patients had test results for KOH testing for mycology from 6/29/23 to date of survey. 4. Interview with the OM on 12/18/24 at 2:10 p.m. confirmed, the laboratory failed to verify the accuracy of KOH testing for mycology twice a year from 6/29/23 to date of survey.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL 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>

This STANDARD is not met as evidenced by:  
Based on the review of the CMS116 test lists, lack of procedure for KOH testing, patient KOH test results and interview with the OM, the laboratory failed to have a procedure for KOH testing available to, and followed by, laboratory personnel.  
Findings: 1. Review of the CMS116 test lists showed KOH testing had been added since the last survey 3/23/23. 2. Review of the procedure manual revealed no procedure for KOH testing was included. 3. Review of patient testing records revealed six patients had test results for KOH testing for mycology from 6/29/23 to date of survey. 4. Interview with the OM on 12/18/24 at 2:05 p.m. confirmed, the laboratory failed to have a procedure for KOH testing available to, and followed by, laboratory personnel.

**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 upon the review of the CMS209 personnel form, lack of personnel competency assessment records and interview with the OM, the technical consultant (TC) failed to assess competency for two of two moderate complexity testing personnel (TP) for 2023 and to date of survey 2024. Findings: 1. Review of the CMS 209 revealed two moderate complexity TP. 2. The surveyor requested competency assessment records for the TP. No documentation of competency assessment for 2023 and to date of survey 2024 for the two of two moderate complexity TP was made available at the time of survey. 3. Interview with the OM on 12/18/24 at 2:05 p.m. confirmed, the TC failed to assess competency for two of two moderate complexity testing personnel (TP) for 2023 and to date of survey 2024.