

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0673421	<b>(X3) Date Survey Completed</b> 09/15/2023
<b>Name of Provider or Supplier</b> Dermatology Physicians Inc	<b>Street Address, City, State</b> 2106 Harrisburg Pike Suite 314, Lancaster, PA	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the laboratory tour and interview with Testing Personnel (TP) #1, the laboratory failed to discard expired reagent used for tissue marking in Histopathology from 04/30/2023 to date of survey. Findings include: 1) On the day of survey 09/15/2023 at 9:45 am while touring the laboratory, the surveyor discovered a bottle of StatLab Violet tissue Marking Dye (Lot # 118665) with expiration date 04/30/2023. 2) Interview with TP #1 on 09/15/2023 at 10:18 am confirmed the finding above.</p>
<b>D6054</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel (TP) #1, the Technical Consultant (TC) failed to evaluate and document the competency assessment of 1 of 4 TP who performed Potassium Hydroxide (KOH) and Scabies microscopic examinations in 2021. Findings include: 1) On the day of survey 09/15/2023 at 9:25 am, the laboratory could not provide documentation of the annual</p>

competency assessment for TP #2 (CMS-209 Personnel #3) who performed KOH and Scabies microscopic examinations in 2021. 2) TP #1 confirmed the above findings on 09.15/2023 at 10:18 am.

**D6125**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of Competency Assessment records and interview with Testing Personnel (TP) #1, the Technical Supervisor (TS) failed to evaluate the competency assessment through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 1 of 1 TP performing grossing and inking in Histopathology from 11/17/2021 to date of survey. Findings include: 1) On the day of survey 09/15/2023 at 9:30 am review of Competency Assessment records revealed the TS did not perform competency assessment through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples to evaluate grossing and inking for TP #1 (CMS-209 Personnel #2) from 11 /17/2021 to date of survey. 2) According to the CMS-116, the total annual volume for Histopathology is 11,862. 3) Interview with TP #1 on 09/15/2023 at 10:18 am confirmed the above findings.