| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 08D0205587 | 09/26/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Panzer Dermatology & Associates | 537 Stanton-Christiana Road, Newark, DE | |

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 |
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| **D0000** | A Recertification Survey was conducted on September 26, 2025 at approximately 9:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows: |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and facility document and policy review, the laboratory failed to follow their policy for performing personnel competency assessments in 2024. This was noted for 23 (Testing Personnel [TP] #9 through TP #17 and TP #19 through TP #32) of 24 personnel reviewed. Findings included: A "Quality Assurance Policy" section of the facility's "Laboratory Manual," last reviewed on 09/09/2025, revealed, "The Laboratory Director and Supervisor will use personal observation to perform ongoing evaluation of all laboratory personnel to ensure competence in job performance. Annual Competency Assessments will be completed by [the] Laboratory Supervisor and/or Laboratory Director. All will be reviewed by the Laboratory Director." "Annual Competency Assessment: Laboratory Personnel" documents revealed staff performed duties as histotechnicians, histotechnician manager, and histotechnician supervisor. A facility "KOH Log" for 2024 revealed staff performed KOH (potassium hydroxide preparation) testing. A facility "Scabies Log" for 2024 revealed staff performed scabies testing. Staff competency forms revealed no documented evidence that competency assessments were completed in 2024 for TP #9 through TP #17 who conducted histopathology testing or for TP #19 through TP #32 who conducted KOH/scabies testing. On 09/26/2025 at 10:15 AM, Laboratory |

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| | Manager (LM) #8 revealed that annual competency assessments were not completed in 2024 for TP #9 through TP #17. During a follow-up interview on 09/26/2025 at 10: 25 AM, LM #8 revealed the staff were not assessed for competency in performing KOH tests for fungal elements or wet mounts for scabies. On 09/26/2025 at 12:45 PM, the Laboratory Director (LD) revealed the requirement for conducting annual competency assessments for the TP who provided histopathology testing was not met. During a follow-up interview on 09/26/2025 at 12:55 PM, the LD revealed that annual competency evaluations were not completed for the TP who completed KOH testing for fungal elements or wet mounts for scabies. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and facility document and policy review, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) testing for fungal elements and wet mount examinations for scabies twice annually. This was noted for 2 (2024 and 2025) of 2 testing years reviewed. Findings included: The facility's "KOH (Potassium Hydroxide) Slide" and "Scabies Prep" sections of the "Laboratory Manual," last reviewed 09/09/2025, revealed there was no procedure directing staff to verify the accuracy of the tests. The facility's "KOH Log" and "Scabies Log" documents revealed the laboratory performed KOH testing for fungal elements and wet mount examinations for scabies in 2024 and 2025; however, there was no documented evidence that the facility verified the accuracy of the tests twice annually. On 09/26 /2025 at 10:25 AM, Laboratory Manager (LM) #8 revealed the laboratory did not have a procedure in place to assess the accuracy of testing twice annually for KOH testing for fungal elements or microscopic examinations for scabies. On 09/26/2025 at 12:55 PM, the Laboratory Director (LD) revealed the accuracy of KOH testing for fungal elements and wet mount examinations for scabies was not being verified twice annually for all staff. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, interview, and facility policy review, the facility failed to document quality control (QC) results for immunohistochemical and special stains for each patient slide or group of slides. This was noted for 2 (2024 and 2025) of 2 years of testing reviewed. Findings included: An "Immunohistochemical [IHC] Staining" section of the "Laboratory Manual," last reviewed on 09/09/2025, revealed, "Each case must have a positive control slide per antibody requested; each patient must have one negative control slide." The policy revealed there were no instructions for |

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| | documenting the review of QC slides. A "Special Requests" section of the "Laboratory Manual," last reviewed on 09/09/2025, revealed, "A positive control slide must accompany each special stain ordered." The policy revealed there were no instructions for documenting the review of QC slide. On 09/26/2025 at 11:50 AM, Testing Personnel (TP) #10 was observed removing a batch of immunohistochemistry slides that had finished staining on a Leica processor. TP #10 pointed out the positive and negative control slides. On 09/26/2025 at 11:55 AM, TP #10 stated that he looked at the slides to make sure the QC was acceptable before the slides were given to the Laboratory Director (LD) to read. TP #10 stated the QC results were not documented. On 09/26/2025 at 12:45 PM, the LD stated that he reviewed the QC slides but did not document the review. The LD stated that he would not read any patient slides or issue results unless the QC slides were acceptable. |