| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 53D2009726 | 05/12/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Teton Dermatology, Llc Dba Epiphany Dermatology | 984 W Broadway, Ste 4, Jackson, WY | |

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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| **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 review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel and laboratory records, policy and procedure review, and staff interview, the laboratory failed to ensure annual competency assessments were completed for 5 of 5 testing personnel Doctor of Medicine (MD) #1, MD #2, MD #3, Physician Assistant (PA) #1, PA #2) for 2 of 2 years reviewed (2024, 2025). In addition, the laboratory failed to ensure annual competency assessments were completed for the responsibilities of the clinical consultant, the technical supervisor, and the general supervisor for 2 of 2 years (2024, 2025) reviewed. Review of the laboratory's records showed fungal and/or Scabies testing was performed on skin scrapings using KOH (potassium hydroxide) and Mohs histopathology slides were reviewed. The findings were: 1. Review of the CMS 209 Laboratory Personnel Report showed MD #1, MD #2, MD #3, PA #1, and PA #2 were listed as testing personnel. Doctor of Osteopathic Medicine (DO) #1 was listed as the clinical consultant and the technical supervisor for the specialty of histopathology. The laboratory director performed the responsibilities of the general supervisor. The following concerns were identified: a. Review of the personnel file for MD #1 showed competency assessment checklists for KOH and/or Scabies and the duties of the general supervisor were dated 9/10/24 and 9/1/25. The competency assessments did not have the signature of MD #1 and showed the competency assessments were signed and dated by the technical supervisor on 5/11/26. b. Review of the personnel file for DO #1 showed he performed the responsibilities of the technical supervisor for the histopathology specialty and the responsibilities of the |

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| | clinical consultant. Further review of the personnel file showed an annual competency assessment, dated 9/1/24, for the duties of the clinical consultant did not include the signature of DO #1, and was signed and dated by the laboratory director on 5/12/26. There was not a competency assessment for 2025. The competency assessments for the responsibilities of the technical supervisor were dated 9/10/24 and 9/1/25, did not have the signature of DO #1, and were signed and dated by the laboratory director on 5 /12/26. c. Review of the personnel file for MD #2 showed competency assessment checklists for KOH and/or Scabies were dated 9/10/24 and 9/1/25. The competency assessments did not have the signature of MD #2, and were signed and dated by the laboratory director on 5/12/26. d. Review of the personnel file for MD #3 showed competency assessment checklists for KOH and/or Scabies were dated 9/10/24 and 9/1 /25. The competency assessments did not have the signature of MD #3, and were signed and dated by the laboratory director on 5/12/26. e. Review of the personnel file for PA #1 showed competency assessment checklists for KOH and/or Scabies were dated 9/10/24 and 9/1/25. The competency assessments did not have the signature of PA #1, and were signed and dated by the laboratory director on 5/12/26. f. Review of the personnel file for PA #2 showed competency assessment checklists for KOH and /or Scabies were dated 9/10/24 and 9/1/25. The competency assessments did not have the signature of PA #2, and were signed and dated by the laboratory director on 5/12 /26. 2. Telephone interview with the corporate compliance officer on 5/12/26 at 11:26 AM revealed the competency assessments had not been completed, as required, and were signed retroactively. The laboratory director was not available for an interview. 3. Review of the policy "Laboratory: Quality Assessment, Competency Assessment", revised 8/15/23, showed "...PROCEDURE 1. Competency is the ability to perform a task successfully. In the laboratory, this means testing the right sample in the correct way to produce the best possible result for the highest quality patient care. Competency must be assessed at each step of patient care including preanalytic, analytic, and post analytic. In this laboratory some analytic and post analytic phases are performed. 2. The following individuals are required to have competency assessments: Clinical consultant; Technical Supervisor; General Supervisor; Testing personnel which included dermatologists and dermatopathologists...4. Anyone who performs testing on patient specimens is required to have documented competency assessments on file including the following 6 categories...5. The Laboratory Director or Technical Supervisor is responsible for performing all competency assessments... PHYSICIANS...2. Competency shall be assessed semiannually the first year and annually after that...QUALITY ASSURANCE 1. Review of employee competency assessments shall be part of the Epiphany Dermatology ongoing Quality Assessment program..." |
| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, review of personnel and laboratory records, policy and procedure review, and staff interview, the laboratory director failed to ensure annual competency assessments were completed for 5 of 5 testing personnel (MD #1, MD #2, MD #3, PA #1, PA #2) for 2 of 2 years reviewed (2024, 2025). In addition, the laboratory failed to ensure annual competency assessments were completed for the |

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| | responsibilities of the clinical consultant, the technical supervisor, and the general supervisor for 2 of 2 years (2024, 2025) reviewed. Review of the laboratory's records showed fungal and/or Scabies testing was performed on skin scrapings using KOH (potassium hydroxide) and Mohs histopathology slides were reviewed. Refer to D5209. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality assessment documentation, policy and procedure review, and staff interview, the laboratory director failed to ensure an ongoing quality assessment program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for 2 of 2 years reviewed (2024, 2025). The findings were: 1. Interview with the clinic manager on 5/12/26 at 11:26 AM revealed she uploaded the laboratory's quality assurance documentation to the corporate office periodically. Further, the clinic manager revealed she had uploaded documentation to the corporate office on 10/25/24, 6/17 /25, and 5/5/26. In addition, the clinic manager revealed the laboratory director reviewed the laboratory's monthly quality logs; however, there was no formal documentation available. The laboratory director was unavailable for an interview. 2. Review of the laboratory's documentation showed a "Corrective Action Documentation" form, under the category of Equipment/Environment, with 11 items which required corrective action. The form was dated 10/25/24 and was not signed by the laboratory director. There was no documentation to show the items identified on the corrective action form had been monitored to ensure the system changes had been successful. There was no documentation an evaluation of the additional 13 categories listed in the policy had been completed. 3. Review of the laboratory's documentation showed no evidence the "Laboratory: Quality Assessment Plan" policy had been implemented in 2024 or 2025. 4. Interview on 5/12/26 at 11:36 AM with the corporate compliance officer revealed the last onsite visit to the laboratory occurred in October of 2024 and there was not any documentation of a quality review in 2025. 5. Review of the "Laboratory: Quality Assessment Plan" policy, revised on 8/15/23, showed "... PROCEDURE: Quality systems for all general laboratory systems and for all phases of the total testing process including preanalytic, analytic and post analytic phases have been established. Epiphany Dermatology will ensure continuous improvement of our performance through ongoing monitoring of each system that will assure accurate and reliable test results are obtained and reported to our providers in a timely manner. Each of the following systems in the laboratory will be evaluated periodically as needed to ensure that it meets Epiphany Dermatology's quality goals. If a problem is identified, a Laboratory Director approved solution will be designed and implemented. To determine if the solution has worked, the system will be re-evaluated at a later date (e.g. 3 months later). Laboratories will keep written records of findings, reviews, and actions. The Plan will cover the following specific categories described in detail below. A Standard Operating Procedure has been created for each category. This Quality Assessment Plan will be reviewed annually and updated or revised as necessary..." The categories listed in the policy included: Communications; Personnel Competency; Corrective Actions, Electronic Systems; Patient Confidentiality; |

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| | Proficiency Training; Employee Safety; Procedure Manual; Environment, Instruments, Reagents, Materials, and Supplies; Specimen Collection, Submission, and Handling; Slide Quality Assessment; Test Records; Comparison of Test Results; and Test Report. "QUALITY ASSURANCE: 1. The Laboratory Director is ultimately responsible for all laboratory procedures...3. It is the ultimate responsibility of the Laboratory Director (or designee) to ensure proficiency of all staff, to review and sign off on all proficiency testing materials, and assign corrective action if needed. Corrective actions will be documented on the appropriate forms..." |