

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0722853	<b>(X3) Date Survey Completed</b>  03/26/2025
<b>Name of Provider or Supplier</b>  Epiphany Dermatology, Pa	<b>Street Address, City, State</b>  1615 Hospital Parkway Suite 306, Bedford, TX	
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>D0000</b>	The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1412 Testing Personnel, moderate complexity
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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, patient final reports, and confirmed in interview, the laboratory failed to follow its own written policy for reporting patient KOH (potassium hydroxide) results for one of five patients in August 2023 (random review) and one of three patients in January 2025. Findings included: 1. Review of the laboratory's policy titled "Potassium Hydroxide Procedure Protocol" stated: "PROCEDURE ... Clinical Staff ... CLIA Required Paperwork ... Diagnosis (Positive or Negative)" 2. A random review of patient final reports from 2023 and 2025 revealed the following: 08/17/2023 Patient MRN: MM0001145827 Plan: KOH Prep "Examination of the slide showed: branching hyphae." 01/24/2025 Patient MRN: MM0003228674 Plan: KOH Prep "Examination of the slide showed: branching hyphae." The above results were not documented on the patient final reports as positive. The laboratory failed to follow their own written policy for reporting patient KOH results. 3. During an interview on 03/26/2025 at 11:59 a.m., the laboratory representatives after a review of the records confirmed the laboratory failed to follow their own written policy for reporting patient KOH results. Word Key: MRN- medical record number Prep- preparation</p>

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of CMS 209 form, laboratory policy, personnel records, and confirmed in interview, the Technical Consultant (who is also the laboratory director) failed to evaluate and document the performance of one of four Testing Persons (TP-3) who perform moderate complexity testing, at least semiannually during the first year the Testing Person tested patient specimens in 2023. Findings included: 1. Review of the CMS 209 form listed TP-3 as an individual who performed moderate complexity testing, which included microscopic procedures. 2. Review of the laboratory's policy "Laboratory: Quality Assessment, Competency Assessment" stated: "PROCEDURE ... 2. The following individuals are required to have competency assessments: Clinical consultant (if applicable) Technical consultant (if applicable) Technical Supervisor (if applicable) General Supervisor (if applicable) Testing personnel Dermatologists Dermatopathologists ... 4. Anyone who performs testing on patient specimens is required to have documented competency assessments on file including the following 6 categories: Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing Monitoring the recording and reporting of test results Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records Direct observations of performance of instrument maintenance and function checks Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples Assessment of problem-solving skills 5. The Laboratory Director or Technical Supervisor (if applicable) is responsible for performing all competency assessments ... Physicians ... 2. Competency shall be assessed semiannually the first year and annually after that." 3. Review of personnel records for TP-3 revealed the following: Hire date 10/10/2022 There was no record of semiannual competency evaluations for TP-3. The technical consultant did not ensure semi-annual competency assessments were evaluated and documented for TP-3. 4. During an interview on 03/26/2023 at 11:40 a.m., the laboratory representatives confirmed the above findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on review of CMS 209 form, laboratory policy, personnel records, and confirmed in interview, the Technical Consultant failed to evaluate and document the annual competency assessments for two of four Testing Persons (TP-3, TP-4) who perform moderate complexity testing in 2024 and 2025. Findings included: 1. Review of the CMS 209 form listed TP-3 and TP-4 as individuals who performed moderate complexity testing, which included microscopic procedures. 2. Review of the laboratory's policy "Laboratory: Quality Assessment, Competency Assessment"

stated: "PROCEDURE ... 2. The following individuals are required to have competency assessments: Clinical consultant (if applicable) Technical consultant (if applicable) Technical Supervisor (if applicable) General Supervisor (if applicable) Testing personnel Dermatologists Dermatopathologists ... 4. Anyone who performs testing on patient specimens is required to have documented competency assessments on file including the following 6 categories: Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing Monitoring the recording and reporting of test results Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records Direct observations of performance of instrument maintenance and function checks Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples Assessment of problem-solving skills 5. The Laboratory Director or Technical Supervisor (if applicable) is responsible for performing all competency assessments ... Physicians ... 2. Competency shall be assessed semiannually the first year and annually after that." 3. Review of personnel records for TP-3 and TP-4 revealed the following: TP-3: Hire date 10/10/2022 There was no record of annual competency evaluations for TP-3 in 2024. The technical consultant did not ensure an annual competency assessment was evaluated and documented for TP-3. TP-4 was also delegated as the Laboratory Director and Technical Consultant. His personnel records revealed annual competency assessments performed on 02/21/2024 and 02/28/2025 by TP-2. TP-2 was NOT delegated as a Technical Consultant. 4. During an interview on 03/26/2023 at 11:00 a.m., the laboratory representatives confirmed the above findings.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed to have documentation that one of three testing persons (TP-3) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Refer to D6065.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50

weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed to have documentation that one of three testing persons (TP-3) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Findings included: 1. Review of the CMS-209 form included TP-1 through TP-4 listed to perform moderate complexity testing. 2. Review of the laboratory's policy titled "Quality Assessment, Competency Assessment" stated: "QUALITY ASSURANCE ... 2. Personnel files are maintained for each employee to include a record of the employees' formal education (high school diploma or equivalent, college degree, medical degree), record of certification or licensure if applicable, documentation of continuing education, proficiency evaluations, and competency assessments." 3. A random review of personnel records revealed the laboratory did NOT have educational documentation to ensure TP-3 was qualified to perform moderate complexity testing. The laboratory was asked to provide documentation of TP-3's education on 03/26/2025 at 11:16 a.m. No documentation was provided. 4. During an interview on 03/26/2025 at 11:25 a.m., laboratory representatives confirmed the laboratory failed to have documentation that one of three testing persons (TP-3) met the qualifications required to perform moderate complexity testing prior to performing patient testing.