

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2162604	<b>(X3) Date Survey Completed</b>  12/30/2021
<b>Name of Provider or Supplier</b>  Epiphany Dermatology, Pa	<b>Street Address, City, State</b>  206 Denton Dr, Roanoke, 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>	<p>Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 review of the CMS (Centers for Medicaid &amp; Medicare Services) 116 form, laboratory policy, laboratory proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 2 of 2 testing events in 2020 and 2 of 2 testing events in 2021. Findings: 1. Review of the CMS-116 form submitted on the day of the survey by the laboratory revealed the laboratory performed KOH procedures. 2. Review of the laboratory policy titled "KOH Protocol" revealed the following: "PROCEDURE: Performing the KOH, Charting KOH reports,</p>

CLIA compliance Physicians and mid-level providers ... CLIA required paperwork: CLIA requires evaluations of all providers performing medium level complexity tests biannually. To fulfill this requirement each provider will receive an email from the Epiphany Dermatology Compliance Manager biannually containing 10 sets of images along with 4 associated questions following each image. The quiz is to be completed within the time range set by the Compliance Manager. All results will be maintained in an electronic file and available upon request. In some practices a second provider may be available for peer review of the slide at the time of diagnosis. If available, the name of the second provider as well as whether or not they concur with the diagnosis will be recorded. This record review may be used as a competency assessment in lieu of the electronic quiz. All results will be maintained and available upon request. Training sessions will be provided for all employees found to be non-competent." The laboratory policy failed to define the acceptable criteria for accuracy assessment of the testing material to ensure competency of testing personnel. 3. Review of the laboratory's proficiency testing records revealed the laboratory performed proficiency testing events for KOH procedures for two-time periods January through June (event 1) and July through December (event 2). Review of event 1 in 2020 revealed the following scores and percentages: Testing Person 2 (as listed on the CMS 209 form): 10/10; 100% Testing Person 3 (as listed on the CMS 209 form): 10/10; 100% Testing Person 1 (as listed on the CMS 209 form): 10/10; 100% Review of event 2 in 2020 revealed the following scores and percentages: Testing Person 2 (as listed on the CMS 209 form): 11/11; 100% Testing Person 3 (as listed on the CMS 209 form): 10/11; 91% Testing Person 1 (as listed on the CMS 209 form): 11/11; 100% Review of event 1 in 2021 revealed the following scores and percentages: Testing Person 2 (as listed on the CMS 209 form): 11/11; 100% Testing Person 3 (as listed on the CMS 209 form): 11/11; 100% Testing Person 1 (as listed on the CMS 209 form): 11/11; 100% Review of event 2 in 2021 revealed the following scores and percentages: Testing Person 2 (as listed on the CMS 209 form): 10/10; 100% Testing Person 3 (as listed on the CMS 209 form): 10/10; 100% Testing Person 1 (as listed on the CMS 209 form): 10/10; 100% The results for KOH procedures for the events in 2020 and 2021 were listed in a table and there was NO documentation of the results being evaluated by the Technical Consultant (who was also the laboratory director) for accuracy. The laboratory failed to verify the accuracy of KOH procedures at least twice annually in 2020 and 2021. 4. During an interview on 12/30/2021 at 2:35 pm, the Medical Assistant confirmed the above findings.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and confirmed in staff interview, it was revealed that laboratory policies were not approved, signed, or dated by the laboratory director before use. Findings: 1. Review of the laboratory's policy titled "High Complexity Laboratory Duties" stated the following: "Responsibilities: 3. The Laboratory Director is responsible for: The overall operation and administration of the laboratory. Assuring compliance with the applicable regulations. The initial approval of this standard operating procedure (SOP) and any subsequent revisions: The Laboratory Director must sign and approve all testing procedures when initially put into use. The Laboratory Director must sign and approve all testing procedures

whenever revisions are made. When there is a change in Laboratory Director, the new Director must review and sign all procedures within a reasonable period of time. Approval of procedures and changes to procedures must be personally performed by the Director named on the Laboratory's CLIA certificate. The Laboratory Director (or designee) must perform an annual review of this standard operating procedure (SOP)." 2. Review of the laboratory's policy manual revealed the laboratory director failed approve, sign and date ALL laboratory policies in the manual. The following is a random sampling of those policies: Review of the laboratory policy titled "High Complexity Laboratory Duties" stated the following: "Effective Date: February 2020, Revised Date: [blank] ... MODIFICATIONS AND UPDATES: CHANGES [blank] DATE [blank] DIRECTOR'S SIGNATURE [blank] Laboratory Director Signature [blank] Date [blank]" The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "KOH Protocol" stated the following: "Effective Date: September 01, 2018, Revised Date: 01/24/2019 ... MODIFICATIONS AND UPDATES: CHANGES [blank] DATE [blank] DIRECTOR'S SIGNATURE [blank] Laboratory Director Signature [blank] Date [blank]" The laboratory policy was not approved, signed and dated by the laboratory director. Review of the laboratory policy titled "Laboratory: Microscopic Interpretation, Quality Assessment; Proficiency Testing" stated the following: "Effective Date: February 2020, Revised Date: [blank] ... MODIFICATIONS AND UPDATES: CHANGES [blank] DATE [blank] DIRECTOR'S SIGNATURE [blank] Laboratory Director Signature [blank] Date [blank]" The laboratory policy was not approved, signed and dated by the laboratory director. 3. During an interview on 12/30 /2021 at 3:00 pm, the Medical Assistant confirmed the above findings.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
 Based on review of CMS (Centers for Medicare & Medicaid Services) 209 form, laboratory policies, personnel records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for 2 of 3 testing persons (TP-2, TP-3) engaged in the performance of moderate complexity testing. Findings: 1. Review of CMS 209 form listed TP-2 and TP-3 as testing persons of moderate complexity testing. 2. Review of the laboratory's policy titled "High Complexity Laboratory Duties" stated the following: "Responsibilities: 3. The Laboratory Director is responsible for: ... Signing Delegation Documents. Authorizing appropriately trained individuals to perform pre-analytic, analytic, and post analytic duties by signing the Job Authorization Grid." 3. Review of the personnel records for TP-2 and TP-3 revealed there were NO delegation of duties for testing persons engaged in moderate complexity testing by the laboratory director The laboratory director failed

to specify in writing the responsibilities and duties of testing persons engaged in moderate complexity testing. 4. During an interview on 12/30/2021 at 2:35 pm, the Medical Assistant was asked to provide documentation of the delegation of duties for testing personnel and none was provided. This confirmed the above findings.