

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2166594	<b>(X3) Date Survey Completed</b>  05/14/2021
<b>Name of Provider or Supplier</b>  Epiphany Dermatology, Pa	<b>Street Address, City, State</b>  1640 Fm 544, Bldg 3, Suite 100, Lewisville, 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>	Laboratory representatives were present at the entrance conference conducted 05/14 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 05/14 /2021. 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 State Health and Human Services Commission, Health Facility Compliance Arlington Group.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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 laboratory policy, proficiency testing (PT)records, and confirmed in interview, the laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations for 2020. Findings: 1. Review of the laboratory's policy titled "Mohs Surgery and Frozen Section Analysis, Proficiency Testing" revealed: "PROCEDURE: Physicians ... 3. Proficiency for Epiphany Dermatology Mohs Surgeons shall be assessed using one of the following methods. The Laboratory Director shall choose and implement whichever option works best for their particular laboratory .... External Quality Control Program Semiannually the Mohs technician shall randomly select a minimum of 2 cases per each Mohs surgeon. If the Mohs surgeon also performs biopsies for frozen section analysis, sample frozen cases should also be selected ... Internal Peer Review ... Semiannually the Mohs technician shall randomly select a minimum of 2 cases per each Mohs surgeon. If the Mohs surgeon also performs biopsies for frozen section analysis, sample frozen cases should also be selected." 2. Review of PT records for</p>

2020 revealed PT was performed once in 2020 (07/28/2020). The laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations in 2020. 3. During an interview on 05/14/2021 at 11:10 am, the Histotechnician confirmed the above findings.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, quality control logs, and confirmed in staff interview, the laboratory failed to ensure cryostat #1 temperature ranges were within the laboratory's specifications prior to performing patient testing for 19 of 22 days in 2020 (random review 10/2020-12/2020). Findings: 1. Review of the laboratory's "Quality Control Log" revealed the laboratory had an established acceptable temperature range for the cryostats as "-15 to -30 degrees Celsius". 2. Further review of the laboratory's "Quality Control Log" from 10/2020-12/2020 revealed the following days when the temperature was out of the acceptable range of -15C to -30 degrees Celsius for Cryostat #1: 10/19/2020; Temperature: -32C 10/21/2020; Temperature: -32C 10/22/2020; Temperature: -32C 10/28/2020; Temperature: -32C 10/29/2020; Temperature: -32C 11/02/2020; Temperature: -32C 11/09/2020; Temperature: -32C 11/11/2020; Temperature: -32C 11/12/2020; Temperature: -32C 11/16/2020; Temperature: -32C 11/18/2020; Temperature: -32C 11/23/2020; Temperature: -32C 11/25/2020; Temperature: -32C 11/30/2020; Temperature: -32C 12/02/2020; Temperature: -32C 12/03/2020; Temperature: -32C 12/07/2020; Temperature: -32C 12/09/2020; Temperature: -32C 12/10/2020; Temperature: -32C 3. During an interview on 05/14/2021 at 10:25 am, the Histotechnician confirmed the above findings.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policy, Quality Control Log, patient test reports and confirmed in interview, the laboratory failed to test and document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for 1 of 23 days in 2020 (random review 10/2020-12/2020). Findings: 1. Review of the laboratory's policy "Mohs Surgery and Frozen Section Analysis,

Proficiency Testing" revealed: "PROCEDURE ... Mohs Technicians ... Daily quality control of slides Hematoxylin and Eosin: On each day where frozen slides are produced for interpretation the surgeon will review the quality of the hematoxylin and eosin staining. The nuclei should stain blue. The cytoplasm should stain pink to light red. The daily H&E staining log is then completed with the comment of "acceptable" or "unacceptable". All corrective actions will be documented." Review of the laboratory's policy "Mohs Surgery and Frozen Section, Log Sheet and Accessioning" revealed: "QUALITY ASSURANCE: 1. Epiphany Dermatology uses a QC Log filled out by the surgeon/dermatologist on each day microscopic examination is performed. Columns are marked as acceptable-A or unacceptable-U. In the event any part of the QC is unacceptable corrective action is required and documented on the log." 2. Review of the laboratory's "Quality Control Log" did not include for each day of use, documentation of the intended reactivity for the toluidine blue stain on the following days patients were tested and reported in 2020 (random review 10/2020-12/2020): 12 /14/2020 Patient ID: CH20-1074, CH20-1075, CH20-1076, CH20-1077, CH20-1078, CH20-1079, CH20-1080, CH20-1081, CH20-1082, CH20-1083, CH20-1084, CH20-1085 3. During an interview on 05/14/2021 at 10:45 pm, the Histotechnician confirmed the above findings.