Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2174856	12/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology, Pa	616 E Bailey Boswell Rd, Saginaw, TX	

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
D0000	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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicaid & Medicare Services) 116 form, laboratory policy, proficiency testing records, and confirmed by staff interview, the laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for 2 of 2 events in 2020 and 2 of 2 events in 2021. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histology (MOHs) procedures. 2. Review of the laboratory policy titled "Laboratory: Mohs Surgery Procedure" revealed the following: "QUALITY ASSURANCE ... 2. Biannual Peer Review will be performed in

accordance with the "Laboratory Policy: Mohs Surgery and Frozen Section, Proficiency Testing" policy. Slides will be reviewed and assessed for quality control to include overall slide quality, nuclear detail, cytoplasmic staining, and correct diagnosis. Corrective action is documented on the log sheet if required. 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." 3. Review of the laboratory's twice annual accuracy assessment for 2020 and 2021 revealed the following: 09/10/2020 Case #1 Review of Slide Diagnosis: Agree Review of Slide Quality: High Diagnostic Quality Slide adequate for diagnosis: Yes Mohs Map present in EHR: Yes Comments/Discrepancies: No residual SCC Case #2 Review of Slide Diagnosis: Agree Review of Slide Quality: High Diagnostic Quality Slide adequate for diagnosis: Yes Mohs Map present in EHR: Yes Comments /Discrepancies: Residual BCC, final margins clear Case #3 Review of Slide Diagnosis: Agree Review of Slide Quality: High Diagnostic Quality Slide adequate for diagnosis: Yes Mohs Map present in EHR: Yes Comments/Discrepancies: Residual BCC, final margins clear Case #4 Review of Slide Diagnosis: Agree Review of Slide Quality: High Diagnostic Quality Slide adequate for diagnosis: Yes Mohs Map present in EHR: Yes Comments/Discrepancies: No residual BCC Case #5 Comments/Discrepancies: Residual SCC is, final margins clear The proficiency testing form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 12 /30/2020 Mohs Accession Number: SW20-24 Original Slide Diagnosis: Squamous Cell Carcinoma In Situ Peer Slide Diagnosis: Squamous Cell Carcinoma In Situ Microscopic Examination: Sections show acanthosis, parakeratosis and areas of full thickness squamous atypia with disorganization of the epidermal architecture and loss of maturation. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-29 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW20-34 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW20-38 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: Sections show a keratinizing tumor composed of dermal nests and lobules of mildly atypical squamous cells with keratin pearls and identifiable intercellular bridges. Margins Clear: Yes Agree with Original Diagnosis: Yes The proficiency testing forms were signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 06/12/2021 Mohs Accession Number: SW21-05 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-10 Original Slide Diagnosis: Squamous Cell Carcinoma, Moderately Differentiated Peer Slide Diagnosis: Squamous Cell Carcinoma, Moderately Differentiated Microscopic Examination: Sections show a dermal tumor composed of

	nests and lobules of atypical squamous cells with nuclear and cytoplasmic pleomorphism, numerous mitotic figures and a few keratin pearls. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-12 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-14 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes The proficiency testing forms were signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 12/07/2021 Mohs Accession Number: SW21-31 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-35 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-42 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes Mohs Accession Number: SW21-14 Original Slide Diagnosis: No residual tumor identified. Peer Slide Diagnosis: Inflammation, No Residual Microscopic Examination: There is an [sic] horizontally-oriented array of collagen fibers parallel to the epidermis. Vertically-oriented blood vessels are also present. No malignancy is identified. An inflammatory cell infiltrate is also present. Margins Clear: Yes Agree with Original Diagnosis: Yes The proficiency testing forms were signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 4. During an interview on 12/08/2021 at 10:30 am, the Office Manager 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 direct observation, laboratory documents, and staff interview, the laboratory failed to ensure the proper storage conditions were maintained for potassium hydroxide (KOH) reagents and immersion oil for 12 of 12 months in 2020 and 12 of 12 months in 2021. Findings: 1. During a tour of the second laboratory area on 12/08 /2021 at 11:15 am, the following were observed stored on the counter next to the microscope: 1 bottle of Hardy Diagnostics KOH 20% solution, lot #484894, expiration date 02/11/2022, storage 15-30C 1 bottle of Cargille Immersion Oil Type A, cat# 16482, storage 4 to 40C 1 bottle of EDM3 Solutions Chlorazol Black E, Lot# 0303, expiration date 10/29/2022, store at room temperature 2. Review of the laboratory's annual test volume revealed the laboratory performed 65 KOH tests. 3. During an interview on 12/08/2021 at 11:30 am, the Office Manager was asked if the temperature was monitored and documented in the second laboratory area and she stated "no", confirming the above findings. The laboratory failed to ensure the proper storage conditions were maintained for KOH reagents and immersion oil.
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 209 form, laboratory records, personnel records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for 1 of 1 technical consultants (TC-1) and 5 of 6 testing persons (TP-2, TP-3, TP-4, TP-5, TP-6) engaged in technical oversight and performance of moderate complexity testing. Findings: 1. Review of CMS 209 form listed TC-1 as a consultant of moderate complexity procedures and TP-2, TP-3, TP-4, TP-5, TP-6 as testing persons of moderate complexity testing. 2. Review of laboratory records revealed the form "Appendix C - Technical Consultant Delegation Document" was signed by the laboratory director on 12/07/2021, however under the column for "Name of CLIA Technical Consultant" the box was blank. Review of the personnel records for TP-2, TP-3, TP-4, TP-5, TP-6 revealed there were 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 TC-1 and testing persons engaged in moderate complexity testing. 3. During an interview on 12/08 /2021 at 12:15 PM, the Office Manager confirmed the above findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each

	consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, laboratory records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for 1 of 1 clinical consultants (CC-1) providing clinical consultation in high complexity testing. Findings: 1. Review of CMS 209 form listed CC-1 as a consultant of high complexity procedures. 2. Review of laboratory records revealed the form "Appendix A - Clinical Consultant Delegation Document" was signed by the laboratory director on 12/07/2021, however under the column for "Name of CLIA Clinical Consultant" the box was blank. The laboratory director failed to specify in writing the responsibilities and duties of CC-1 engaged in high complexity testing. 3. During an interview on 12/08/2021 at 12:15 PM, the Office Manager confirmed the above findings.