

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1061366	(X3) Date Survey Completed 02/08/2022
Name of Provider or Supplier Epiphany Dermatology, Pa	Street Address, City, State 310 S Mesa Hills, Suite B, El Paso, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of manufacturer's instructions, reagent log, patient testing logs, and interview, the laboratory failed to ensure stains used in the Hematoxylin and Eosin stain used to process Mohs and Frozen dermatopathology specimens had not exceeded their expiration date by eight days and 14 cases. Findings follow. 1. During a tour of the facility on February 8, 2022 at 1450 hours, surveyor observed Gill 3 Hematoxylin, Lot 102630, Expired 01-31-2022 (expired eight days), located in the chemical cabinet in the Mohs laboratory. 2. Review of the Reagent and Culture media QA Log, used to record reagents used in the laboratory showed no column for the expiration date. 3. Review of the Mohs log showed 14 cases/slide sets, cases # 91-104, had been processed and tested. 4. Interview with the Laboratory Director on February 8, 2022, at 1450 hours in the laboratory confirmed the Hematoxylin used in the Hematoxylin and Eosin stain was expired and in use by the laboratory. Further interview with the Laboratory Director on February 8, 2022 at 1540 hours in the conference room confirmed they had a reagent log that could be utilized, but lacked a column for the expiration date. II. Based on review of manufacturer's instructions, reagent log, patient testing logs, and interview, the laboratory failed to ensure reagents used for the KOH (potassium hydroxide) procedure for the presence/absence of fungal elements in skin scrapings were not expired for one of four bottles. Findings follow. 1. During a tour of the facility on February 8, 2022 at 1500 hours, surveyor observed one bottle of expired Chlorazol Black E from patient room #25, Lot 0002, Expired 2022-01-02 (expired 38 days). 2. Review of the Reagent and Culture media QA Log, used to record reagents used in the laboratory showed no column for the expiration date. 3.</p>

Review of the patient log for microscope #2 from January 3, 2022 - February 8, 2022 showed 11 patients had been tested. 4. Interview with the Laboratory Director on February 8, 2022 at 1500 hours confirmed the Chlorazol Black E used for the KOH procedure was expired and available for use by the laboratory. Further interview with the Laboratory Director on February 8, 2022 at 1540 hours in the conference room confirmed they had a reagent log that could be utilized, but lacked a column for the expiration date.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
I. Based on review of test reports, and interview, the laboratory failed to report a KOH had been performed with its results into the patient's chart which also served as the patient test report for one of four KOH tests reviewed. Findings follow. 1. Random review of test reports showed MRN# 298615 performed on 01/27/2022 test results were not recorded in the patient's chart. Review of the three remaining test reports showed MRN# 454420 performed on 06/02/2021 test results were not recorded in the patient's chart until 01/30/2022 after an audit, 7 months 28 days later, and entered as an amendment. 2. Interview with the Laboratory Director on February 8, 2022 at 1615 hours in the breakroom acknowledged it had been a challenge for his practice to ensure all test results were recorded in the patient's chart. II. Based on review of the patient test reports, Mohs map, and slides, and interview, the laboratory failed to include part of the test report for one of nine Mohs test reports reviewed. Findings follow. 1. Review of nine randomly selected Mohs cases showed Mohs case MH21-93 was missing a Stage in the visit notes which also served as the patient test report. Review of the visit notes for the Mohs Surgery only documented 1 stage. 2. Review of the Mohs map showed there were 2 stages, Stage I showed a basal cell carcinoma, Stage II was clear. 3. Review of the case slides showed a total of four slides labeled for Stage I and II, and slides A and B for each stage. 4. Interview with the Laboratory Director on February 8, 2022 at 1630 hours in the break room confirmed the patient note was incorrect based on the Mohs map and slides, and added they would correct the surgery notes and re-bill for the missed stage. NOTE: Case in chart mislabeled as MH21-95. KEY: MRN = Medical Record Number

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the audit log for KOH, corrective action report, test reports, and interview, the laboratory failed to review the timeliness of their quality assurance activities to address problems in reporting the KOH test result into the patient chart which also served as the test report. (See D5805). Findings follow. 1. Review of the laboratory's quality assurance activities showed the audit log for KOH used to determine whether the KOH test results were reported in the patient's chart was performed within the last two weeks after the survey was scheduled for the dates from 03/22/2021 - 01/07/2022, 10 months and 5 days later from the oldest date. 2. Review of the Laboratory Quality Assessment Program for Corrective Action form showed the concern of the KOH test reports not getting recorded into the patient's chart was addressed on 01/28/2022 with providers. 3. Random review of four test reports showed MRN# 454420 performed on 06/02/2021 test results were not recorded in the patient's chart until 01/30/2022 after an audit, 7 months 28 days later, and entered as an amendment. MRN# 454420 from patient visit 06/02/2021 had a one month follow up visit. No indication that a KOH prep was performed would have been found in the chart at that time. 4. Interview with the Laboratory Director on February 8, 2022 at 1600 hours confirmed they had a process to determine and correct patient's charts when the test report was missing and agreed that 10-month intervals after the fact was insufficient and could see how that could pose patient care issues.