

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2095182	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Epiphany Dermatology, Pa	Street Address, City, State 2405 S Clear Creek Rd, Suite 104, Killeen, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, testing logs, and interview, the laboratory director failed to approve, sign, and date 18 of 18 laboratory policies and procedures prior to use. Findings follow. A. Random review of the laboratory's policies and procedures contained in the Policy and Procedure Manual and the Quality Assessment Manual showed the laboratory director had not approved, signed and dated any of the policies and procedures. 1. Review of the Policy and Procedure Manual included the following policies and procedures: a. Mohs Surgery Policy b. Mohs Surgery; Criteria for Rejection of Specimens c. Mohs Surgery and Frozen Section; Cryostat Maintenance d. Mohs Surgery and Frozen Section; Specimen and Record Retention e. Mohs Surgery and Frozen Section; Microscope Use Protocol f. Frozen Section Procedure g. KOH Protocol 2. Review of the Quality Assessment Manual included the following policies and procedures: a. Mohs Surgery and Frozen Section Analysis, Quality Assessment; Communications b. Mohs Surgery and Frozen Section Analysis, Quality Assessment; Competency Assessment c. Mohs Surgery and Frozen Section Analysis, Quality Assessment; Complaint Investigation d. Mohs Surgery and Frozen Section Analysis; Quality Assessment; Proficiency Testing e. Mohs Surgery and Frozen Section Analysis; Quality Assessment; Specimen Identity and Integrity f. Mohs Surgery and Frozen Section Analysis; Quality Assessment; Environment, Instruments, Reagents, Materials, and Supplies g. Mohs Surgery and Frozen Section Analysis, Quality Assessment; Histopathology Quality Control h. Mohs Surgery and Frozen Section Analysis; Quality Assessment; Procedure Manual i. Mohs Surgery and Frozen Section Analysis; Quality Assessment; Slide Quality Assessment j. Mohs Surgery and Frozen Section Analysis; Quality</p>

Assessment; Comparison of Test Results k. Mohs Surgery and Frozen Section Analysis; Quality Assessment; Test Reports B. Interview with the receptionist on November 10, 2021 at 1425 in the laboratory confirmed the findings. C. Review of the Mohs Surgery Log Sheet showed the laboratory began testing Mohs on 6/06/2020.

D5417

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

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.

This STANDARD is not met as evidenced by:

Based on observation, review of patient testing logs, and interview, the laboratory failed to ensure stains used for the Hematoxylin and Eosin stain used to prepare slides for Mohs were not used when they had exceeded their expiration date and tested 10 patient cases. Findings follow. A. On November 10, 2021 at 1500 in the laboratory the surveyor observed the following expired reagents in the flammable cabinet: 1. Leica Surgipath Harris Hematoxylin, Lot 042420, expired 10/24/2021, and 2. Leica Surgipath Hematoxylin Gill III, Lot 032420, expired 09/24/2021. B. Review of the Mohs Surgery Log Sheet showed 10 Mohs cases had been performed on 10/26/2021, accession number K21--78 to K21-87. C. Interview with the receptionist on November 10, 2021 in the laboratory confirmed the stains were expired, and no other Hematoxylin was available in the laboratory for slide preparation.