Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2203170	(X3) Date Survey Completed 08/30/2023
Name of Provider or Supplier Epiphany Dermatology, Pa	**Street Address, City, State** 7106 Sanger Ave, Waco, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policy and procedure, patient testing log, and interview, the laboratory failed to document the internal controls for the hCG (Human Chorionic Gonadotropin) Pregnancy Test Strip for 16 of 16 months reviewed. Findings follow. A. Review of the Medline hCG Pregnancy Test Strip (urine) package insert (MPH11325HC) under Quality Control stated, "Internal procedural controls are included in the test. A red band appearing at the C line is the positive procedural control if the proper testing procedure is followed. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test results." B. Review of the laboratory's policy and procedure titled hCG Urine Pregnancy Test, effective 2021, under Results, stated "Interpretation of results: Positive: Two distinct red lines should appear. One line should be in the control region (C) the other line should be in the test region (T). Negative: One red line should be in the control region (C). No apparent red or pink line appears in the test region (T). Invalid: Control line fails to appear (C)." Review of the laboratory's policy and procedure titled hCG Urine Pregnancy Test, revised 05/23/2023, under Quality Control and Quality Assurance, stated, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal

	control confirming sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the results. The Internal Quality Control will be documented each and every time a test is performed in office on the Urine Pregnancy Test Log." C. Review of the Urine Pregnancy Test Log from 04/19/2022 - 08/30/2023 showed no results for the red band control line or the clear background internal quality controls. Review of the log showed 340 patient tests were performed from 04/19/2022 - 08/30/2023. D. Interview with the medical assistant on August 30, 2023 at 1215 hours in the office when asked whether she looked for the control line on the test strip, acknowledged she has noticed it.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, laboratory's records and interview, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains used in the laboratory for the Hemotoxylin and Eosin (H&E) stain used in Mohs processing for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assessment: Environment, Instruments, Reagents, Materials and Supplies, revised 08/15/2023, stated, "All incoming lab supplies are marked with the date received, the date opened, and, when necessary, the expiration date. Once opened, each reagent will be labeled with the reagent name and strength, lot number, expiration date, new lot number if mixed within the laboratory, and expiration date of the new lot." And, review of the laboratory's policy and procedure titled Mohs Surgery, Moderate and High Complexity Technical Job Description, Training and Duties Protocol, revised 08/15 /2023, stated, "Chemical Reagent/Media Log Sheets: Chemical logs should be maintained indicating: Name Date of receipt Lot # Expiration date Date opened Hazard". B. The reagent log was requested on August 30, 2023 at 1115 in the office but not provided. C. Interview with the Compliance Specialist on August 30, 2023 at 1115 hours in the office verified that the laboratory did not maintain a reagent log.
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 the laboratory's policies and procedures, quality control (QC) records, patient testing logs, and interview, the laboratory failed to document the

	reactivity of the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for their quality control used in Mohs testing for 6 out of 38 days of testing reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Mohs Surgery and Frozen Section, Hematoxylin & Eosin Staining Protocol under Quality Assurance, effective 08/15/2023, stated, "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. If a slide is of inferior or non-diagnostic quality as determined by the surgeon /dermatologist (i.e. improperly embedded, poor stain quality, lack of tissue, folded tissue, air bubbles) the slide will be re-stained, or re-coverslipped as appropriate. If necessary, tissue may be re-embedded under the direction of the Laboratory Director and new slides may be cut to improve margin visualization. Deeper levels may be cut from tissue in the cryostat as needed..." B. Review of the Quality Control Log showed from 03/08/2022 - 08/21/2023 the QC for the H&E stain was not documented on 03/22 /2022, 04/05/2022, 04/19/2022, 05/03/2022, 05/17/2022, 04/03/2023. C. Review of the Mohs patient testing logs showed the following patients listed by case number were performed on the following testing dates: Testing Date Case numbers 1. 03/22 /2022 M22-056 - M22-064 2. 04/05/2022 M22-065 - M22-074 3. 04/19/2022 M22-075 - M22-084 4. 05/03/2022 M22-086 - M22-093 5. 05/17/2022 M22-094 - M22-106 6. 04/03/2023 M23-60 - M23-067 D. Interview with the Compliance Specialist on August 30, 2023 at 1110 hours in the office confirmed there was no documentation of the QC on those days of testing after a review of the records.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: I. Based on review of the patient testing log, patient test report, and interview, the laboratory failed to ensure the same result was documented on the testing log worksheet as reported in the chart for KOH (potassium hydroxide) test for fungal elements for two of two test reports reviewed. Findings follow. A. Review of the patient testing log from 07/26/2022 - 08/12/2022 against the patient test reports showed 2 of 2 with a different result. Review of the KOH log showed both patient results were negative, but the test reports (MRN: MM0001826264 & MM0000877408) were both reported as branching hyphae (positive). B. Interview with the Clinic Manager on August 30, 2023 at 1200 hours in the office confirmed the findings II. Based on review of the patient test reports, Mohs map, slides, and interview, the laboratory failed to identify and correct mislabeled slides and maps for two of 10 Mohs test reports reviewed. Findings follow. A. Review of nine randomly selected Mohs cases showed Mohs case M23-32 had a discrepancy with the stages reported in the test report (2 stages) and the stages represented on the slides and map (1 stage). Additional case was reviewed for the same patient with case M23-33 which also had a discrepancy with the number of stages reported in the test report (1 stage) and the stages represented on the slides and maps (2 stages). It was deduced that the slides and maps for the two cases had been swapped. B. Interview with the Compliance Specialist on August 30, 2023 at 1155 hours in the office concurred with the findings.