Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2095182	05/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology, Pa	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
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 21 of 21 months reviewed. Findings follow. A. Review of the Medline hCG Pregnancy Test Strip (urine) package insert (V2 RB22WON) 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)." The procedure did not have a section for quality control. C. Review of the Urine Pregnancy Test Log from 07/12/21 - 05/01/23 showed no results for the red band control line or the clear background internal quality controls. Review of the log showed 66 patient tests were performed

	from 07/12/21 - 05/01/23. D. Interview with the medical assistant on May 2, 2023 at 1510 hours in the hall where the pregnancy tests were stored acknowledged she was not aware of the control line until explained, and confirmed it was not documented on the pregnancy log.
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 accuracy assessments, laboratory's policy and procedure, patient testing logs, and interview, the laboratory failed to perform twice a year accuracy assessments of its Frozen Section Biopsies for the dermatopathology interpretations for one of two years reviewed. Findings follow. A. Review of accuracy assessments from 2021 and 2022 for the dermatopathology interpretations of Frozen Sections Biopsies showed none available for review for 2021. B. Review of the laboratory's policy and procedure titled Proficiency Testing and Peer Review, effective January 2020, under Procedure stated, "...2. Proficiency shall be assessed at least semiannually. 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. Laboratories will be required to pay for External Quality Control. Internal Peer Review and Epiphany Dermatology Company Peer Review are provided at no cost to the Mohs laboratories. 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..." C. Review of the Frozen Biopsy Log showed from 01/22/21 - 11/29/21 there were four cases reported. D. Interview with the Clinical Operations Manager on May 2, 2023 at 1445 hours in the breakroom confirmed accuracy assessments for Frozens were not performed in 2021.
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: Based on review of the Mohs map and interview, the laboratory failed to include the correct date of birth on the Mohs map for one of ten cases reviewed from 05/25/21 - 02/20/23. A. Random review of 10 Mohs cases from 05/25/21 - 02/20/23 showed one Mohs map compared to the chart notes showed the date of birth was incorrect, as listed by case number and date of service: K21-97 from 12/13/21. B. Interview with

	the Clinical Operations Manager on May 2, 2023 at 1730 hours in the breakroom confirmed the date of birth on the Mohs map was incorrect.