Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0893570	11/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology Of Montana, Llc	24 E Broadway St, Butte, MT	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of procedures, patient records and slides, and interview with medical assistant (MA) #1, (not listed on the CMS-209 Laboratory Personnel Report), the laboratory failed to follow written procedures to assess, and correct problems identified for five out of five patients' Micrographic Surgery-Operative Map and Pathology Reports and for 37 out of 37 patients entered into the Mohs Surgery Log Sheet as part of the preanalytic systems from January 1, 2021 to November 16, 2022. Findings: 1. A review of Mohs Surgery and Frozen Section Analysis, Quality Assessment, Test Records procedure revealed the laboratory failed follow their procedures as stated, "2. Results reports in the form of Mohs maps or Frozen Section forms will include the following information: Patient name; Unique identifier (date of birth and Mohs surgery or Frozen Section accession number), Tests name, Date of specimen collection; Test results and interpretation (diagnosis); Date and time reported; Units of measure and Suggested course of action." 3. A review of patient Micrographic Surgery-Operative Map and Pathology Report (Mohs map) revealed the laboratory failed to document the date of birth (DOB) for MT22-208, MT22-215, MT22-303 and MT22-245; and failed to provide the correct diagnosis description for MT22-244. 4. A review of the Mohs Surgery Log Sheet revealed the laboratory failed to provide information for either DOB, Site description and/or Diagnosis for MT21-55, MT22-001 - 017, MT22-018 - 029, MT22-42, MT22-208, MT22-215, MT22-245, MT22-294, MT22-303; and documented the information incorrectly for MT22-336 and MT22-244. 5. The Micrographic Surgery-Operative Map and Pathology Report's template lacks a place to record time reported and the laboratory failed to record the

	time surgery started and finished. 6. No documentation of corrective action for missed or incorrect documentation with Mohs map or log sheet, or assessment of the preanalytical system were available for review from January 1, 2021 to November 16, 2022. 7. An interview with the MA #1 on November 16, 2022, at 1:12 PM, confirmed these findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of two of two microscopes and review of maintenance documentation, procedure manual, and interview with the medical assistant (MA) #1, (not listed on the CMS-209 Laboratory Personnel Report), the laboratory failed to establish and follow procedures for performing function checks to verify the accuracy of their microscopes. Findings include: 1. Observed one microscope in the laboratory on November 16, 2022, at 9:15 AM, labeled with a "Western Microscope Sticker" revealed the microscope was past due for service as of 4/22 for preventative maintenance. 2. A review of "Microscope Use Protocol" revealed the laboratory failed to follow their protocol as stated, "preventative maintenance must be performed on each piece of equipment annually by a qualified technician." 3. The laboratory lacked service records from Western Microscope or another vendor to verify the accuracy of their microscopes from April 1, 2022 to November 16, 2022. 4. An interview with MA #1 on August 3, 2022, at 9:20 AM, confirmed these findings.