Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2125271	09/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology, Pa	2504 Ridge Rd Suite 102, Rockwall, 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	An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the Leica CM 1520 Cryostat operator's manual (V1.5 RevG-10/2016), review of laboratory policy, a random review of laboratory environmental records (01/03/2020-12/01/2020), review of the laboratory's

corrective action records, and confirmed in staff interview, the laboratory failed to ensure room temperature readings were within the laboratory's defined specifications for the Leica CM 1520 Cryostat for 14 of 44 days in 2020 and relative humidity readings were within the laboratory's defined specifications for 2 of 44 days in 2020. Findings included: 1. During a tour of the laboratory area on 09/24/2021 at 02:00 pm, two Leica CM 1520 cryostats (Serial Numbers 0268 and 0384) were observed in use. 2. Review of the Leica CM 1520 cryostat operator's manual (V1.5 RevG-10/2016) stated the following in the section titled "Installation Site Requirements": "The place of installation must meet the following requirements: Room temperature consistently 18C - 35C [64.4F- 95 F] ...Relative humidity, maximum 60% (non-condensing)." 3. The laboratory policy titled, "Laboratory: Mohs Surgery and Frozen Section, Quality Assessment; Environment, Instruments, Reagents, Materials, and Supplies" (Reviewed and Approved by the laboratory director 01/18/2020), stated the following: "Equipment: Each day of operation (testing), the temperature will be read and recorded for all temperature sensitive equipment. If any readings are not within acceptable limits as set by the manufacturer, appropriate remedial action will be taken and documented .... Quality Assurance: ...3. Log sheets recording dates, temperatures, and humidity will be periodically monitored for all temperature sensitive equipment. Corrective action will be taken as necessary." 4. Review of laboratory environmental records (01/02/2020-09/21/2021), titled "Quality Control Log" revealed the laboratory defined an acceptable temperature range of 68 - 77F and a relative humidity not to exceed 60%. This log also stated, "All abnormal values/remedial actions must be logged on the PROBLEM LOG with the corrective action taken." Further review of the laboratory's environmental records revealed the following days when the temperature readings or relative humidity readings were NOT within defined specifications: Date: 01/03/2020; Temperature reading 79F Date: 01/10/2020; Temperature reading 79F Date: 01/14/2020; Temperature reading 81F Date: 01/17 /2020; Temperature reading 81F Date: 01/21/2020; Temperature reading 82F Date: 02 /18/2020; Temperature reading 81F Date: 03/03/2020; Temperature reading 81F Date: 03/06/2020; Temperature reading 79F Date: 03/17/2020; Temperature reading 79F Date: 03/24/2020; Temperature reading 79F Date: 03/27/2020; Temperature reading 79F Date: 04/03/2020; Temperature reading 79F Date: 04/24/2020; Temperature reading 79F Date: 04/28/2020; Temperature reading 79F Date: 10/23/2020; Relative humidity reading 63% Date: 11/10/2020; Relative humidity reading 71% 5. Review of the laboratory form titled, "Problem Log" revealed documented problems from 05/19 /2018 through 04/28/2021. No corrective actions were documented for the out of range temperature or relative humidity levels listed above. The laboratory failed to ensure room temperature readings and relative humidity readings were within the laboratory's defined specifications for the Leica CM 1520 and to ensure corrective actions were documented per laboratory policy. 6. In an interview on 09/24/2021 at 02: 05 pm in the laboratory area, after review of the environmental records and instrument specifications, the laboratory representative confirmed the above findings. II. Based on direct observation, review of the Leica CM 1520 Cryostat operator's manual (V1.5 RevG-10/2016), review of laboratory policies, review of laboratory environmental records (01/2021 through 08/2021), and confirmed in staff interview, the laboratory failed to ensure room temperature readings, relative humidity, and internal Cyrostat temperature readings were within specifications for the Leica CM 1520 Cryostat for eight of eight months in 2021. Findings included: 1. During a tour of the laboratory area on 09/24/2021 at 02:00 pm, two Leica CM 1520 cryostats (Serial Numbers 0268 and 0384) were observed in use. 2. Review of the Leica CM 1520 cryostat operator's manual (V1.5 RevG-10/2016) stated the following in the section titled "Installation Site Requirements": "The place of installation must meet the following requirements: Room temperature consistently 18C - 35C [64.4F- 95 F] ...Relative humidity,

	maximum 60% (non-condensing)." 3. The laboratory policy titled, "Laboratory: Mohs Surgery and Frozen Section, Quality Assessment; Environment, Instruments, Reagents, Materials, and Supplies" (Reviewed and Approved by the laboratory director 01/18/2020), stated the following: "Cryostat: ...Temperature must be recorded each day of testing. The cryo chamber should range between -20C to -30C ...If environmental temperature or humidity operational ranges are provided by the manufacturer they are as follows: Temperature 18C to 35C / 64.4F- 95 F; Humidity: no greater than 60%." 4. Review of laboratory environmental records (01/2021-08 /2021), titled "Temperature and Humidity Cryostat Room" revealed the laboratory failed to ensure the acceptable temperature range of 18C to 35C / 64.4F- 95 F and the acceptable relative humidity range of no greater than 60% was defined on the document. Review of laboratory environmental records (01/2021-08/2021), titled "Cryostat Temperature Log Sheet" revealed the laboratory failed to ensure the acceptable Cryostat chamber temperature range of -20C to -30C was defined on the document. 5. In an interview on 09/24/2021 at 02:05 pm in the laboratory area, after review of the environmental records, the laboratory representative confirmed the above findings.
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 direct observation and in interview with staff, the laboratory failed to ensure in-use tissue marking dyes had not exceeded their expiration date. Findings included: 1. During a tour of the laboratory area on 09/24/2021 at 02:35 pm, the following reagents were observed opened and stored near the grossing station: StatLab Orange Tissue Marking Dye, Lot #079008; expiration date 03/01/2021 StatLab Green Tissue Marking Dye, Lot #077919; expiration date 03/01/2021 StatLab Red Tissue Marking Dye, Lot #085677; expiration date 08/31/2021 StatLab YellowTissue Marking Dye, Lot #077605; expiration date 02/01/2021 StatLab Blue Tissue Marking Dye, Lot #085852; expiration date 08/31/2021 StatLab VioletTissue Marking Dye, Lot #077435; expiration date 02/02/2021 StatLab Black Tissue Marking Dye, Lot #078797; expiration date 03/01/2021 2. During an interview on 09/24/2021 at 02:35 pm, the medical assistant reviewed and confirmed the used tissue marking dyes had expired.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Review of the submitted Centers for Medicare and Medicaid (CMS) 209 form, competency assessment records and laboratory representative interview, it was revealed the laboratory's technical supervisor failed to evaluate the competency

	assessment for testing personnel for 2019 and 2020. Findings included: 1. Review of CMS-209 form revealed 1 testing person performing high complexity MOHS testing. (Testing Person-1) and 1 Technical Supervisor. 2. Review of the laboratory records titled "Competency Assessment Checklist Mohs Surgery" revealed that Testing Person-1 were assessed by an individual other than the Technical Supervisor listed on the CMS-209 for 2019 and 2020. 3. The above findings were confirmed in an interview with the laboratory representative on 09/24/2021 at 02:05 pm in the laboratory area.