Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2007100	06/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology, Pa	912 Foster Lane #200, Weatherford, 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 found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicare and Medicaid Services) 209 form, laboratory policies, personnel records, and confirmed in staff interview, it was revealed the laboratory failed to perform competency assessments for one of one clinical consultant in 2023 and 2024. Findings included: 1. Review of the laboratory's submitted CMS 209 form identified one clinical consultant. 2. Review of the laboratory policy titled "Quality Assessment Plan" stated: "PROCEDURE ... 2. Personnel Competency: A formal competency program is an essential part of assuring quality in the anatomic pathology laboratory as well as maintaining regulatory compliance ... Written job descriptions will reflect assigned responsibilities and competency evaluations must be based on these job descriptions. The performance of each employee working in the laboratory will be reviewed at least annually. The written results of the review will be filed on site with laboratory paperwork in the location of the Laboratory Director's choosing." 3. A review of personnel records in 2023 and 2024 revealed there were no competency assessments for the clinical consultant. 4. During an interview on 06/13/2025 at 1:15 p.m., the laboratory representatives after review of records, confirmed the above findings.
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 Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policies, laboratory twice annual accuracy records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology procedures at least twice annually for 2 of 2 testing events in 2024. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed histopathology (frozen sections) procedures. 2. Review of the laboratory's "Quality Assessment, Proficiency Testing" policy stated: "PROCEDURE: Physicians ... 2. Proficiency shall be assessed at least semiannually." 3. Review of the laboratory's twice annual accuracy records revealed there were no twice annual accuracy assessment records for frozen sections for 2 of 2 events 2024. 4. During an interview on 06/13/2025 at 11:11 a.m., the Mohs Preceptor confirmed the laboratory failed to perform twice annual accuracy assessments for frozen sections in 2024.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 surveyor observations, review of laboratory policy, mycology and parasitology log, patient final reports, and confirmed in staff interview, the laboratory failed to ensure one of one Potassium Hydroxide (KOH) reagents did not exceed their expiration dates prior to patient testing on from July 2024 through June 2025. Findings included: 1. During a tour of the laboratory number two on 06/12/2025 at 12: 22 p.m., the surveyor observed the following expired reagent located on the counter: 1 bottle Delasco 20% Potassium Hydroxide with DMSO; lot# K215J6; expiration date 05/31/2024 2. Review of laboratory policy "Quality Assessment Plan" stated: "PROCEDURE ... 9. Environment, Instruments, Reagents, Materials, and Supplies ... The manufacturer's instructions for maintenance and function checks, storage conditions, and expiration dates must be followed to ensure consistent quality results throughout the laboratory in order to provide optimal patient care." 3. Review of the laboratory's Mycology & Parasitology Log" and patient final reports revealed five patients in 2024 and two patients in 2025 who were tested and reported using the expired KOH reagent on the following dates: 07/03/2024 Patient MRN: MM0001891367 07/12/2024 Patient MRN: MM0003009570 09/16/2024 Patient MRN: MM0003072643 10/08/2024 Patient MRN: MM0003090649 10/16/2024 Patient MRN: MM0001878632 05/28/2025 Patient MRN: MM000201366 06/11/2025 Patient MRN: MM0003398263 4. During an interview 06/13/2025 at 12:22 p.m. in the laboratory, the Histotechnician and Clinical Supervisor confirmed the KOH had exceeded its expiration date and was used in patient testing. Word Key: KOH - potassium hydroxide MRN - medical record number
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of CMS (Centers for Medicare & Medicaid Services) 209 form, laboratory policies, personnel records, and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for three of three testing persons (TP-2, TP-3, TP-4) engaged in the performance of moderate complexity testing. Findings included: 1. Review of CMS 209 form listed TP-2, TP-3, TP-4 as testing persons of moderate complexity testing. 2. Review of the laboratory policy titled "Quality Assessment Plan" stated: "PROCEDURE ... 2. Personnel Competency ... Written job descriptions will reflect assigned responsibilities and competency evaluations must be based on these job descriptions." 3. Review of the personnel records for TP-2, TP-3, TP-4 revealed there were NO delegation of duties for testing persons engaged in moderate complexity testing by the laboratory director. The laboratory director failed to specify in writing the responsibilities and duties of testing persons engaged in moderate complexity testing. 4. During an interview on 06/13 /2025 at 9:51 a.m., the Mohs Preceptor was asked to provide documentation of the delegation of duties for testing personnel and none was provided. This confirmed the above findings.