Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2281375	02/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Define Dermatolgoy, Pllc	4327 Barnett Rd, Wichita Falls, 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.
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 manufacturer's instructions, quality control (QC) logs, and confirmed in interview, the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for eight of eight months reviewed in February 2024 (June 2023-January 2024). Findings Included: 1. Review of manufacturer's instructions, "MER 41311GL Mercedes Scientific Eosin Y Stain Solution Specifications" (Revised 2019) revealed the following: "Eosin Y is most commonly used cytoplasmic stain because of vivid pink color development." Review of manufacturer's instructions, "Mercedes Scientific Hematoxylin Stain Solution, Gill 3" (Revised 2019) revealed the following: "Hematoxylin Gill III used with Eosin Y Stain Solution produces the following results: Nuclei- Stained Blue Cytoplasm- Stained Pink." 2. Review of laboratory QC logs, "Quality control Analysis Log Sheet for Histopathology (Mohs Surgery)" from June 2023-January 2024, revealed the laboratory failed to define and document H & E intended reactivity to ensure predictable staining characteristics for eight of eight months reviewed. The

	surveyor requested documentation of intended H & E staining reactivity, and none was provided. 3. During an interview on 02/27/2024 at 1:48 PM in the laboratory, the Laboratory Director confirmed the above findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on CMS (Center for Medicare and Medicaid Services)- 209 form, surveyor observation, personnel records, patient annual volumes, and confirmed in interview, the Technical Supervisor failed to ensure training was performed in high complexity testing for one of one testing persons reviewed in 2024. Findings Included: 1. Review of CMS-209 form submitted at time of survey, revealed one of one testing persons (TP-1) performing high complexity histopathology testing. The date of hire for this facility was June 2023. 2. During a tour of the facility on 02/27/2024 at 1:03 PM, the surveyor observed TP-1 performing histopathology testing. 3. Review of personnel documentation from June 2023-January 2024, revealed no documented training for TP-1 in high complexity histopathology testing. The surveyor requested documentation of the above training, and none was provided. 4. Review of laboratory patient volumes, revealed the laboratory performed 967 histopathology tests from June 2023-January 2024. 5. During an interview on 02/27/2024 at 1:31 PM in the laboratory, the Laboratory Director confirmed the above findings.