Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2302186	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Partners - Lancaster	150 Farmington Lane, Suite 4, Lancaster, PA	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Director of Training and Compliance (DTC), the laboratory failed to obtain a permit from the Pennsylvania Department of Health (PA DOH) and CLIA Certificate of Compliance in order to operate a clinical laboratory in Pennsylvania prior to the start of patient testing from 03/27/2024 to 04/30/2024. Findings: 1. On the date of the survey, 08/14/2024 at 11:00 am, review of 1 of 1 MOHS surgery diagrams revealed the laboratory began patient testing on 03/27/2024. 2. Further review of laboratory records and the CMS ASPEN database revealed the laboratory's inital application for a PA Clinical Laboratory permit and CLIA Certificate of Compliance was processed on 04/05/2024 by the PA DOH. 3. The letter sent to the laboratory from the PA DOH on April 5, 2024 stated, "Your facility is being granted provisional approval to perform patient testing. Your facility must receive the Certificate of Registration prior to starting patient testing." 4. The laboratory's Certificate of Registration was mailed to the facility on 04/30/2024 by CMS. 5. The DTC confirmed the findings above on 08/14/2024 at 11:00 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with the Director of Training and Compliance (DTC), the laboratory failed to perform and document maintenance/function checks for 1 of 1 microscope used to perform MOHS microscopic slide examinations in 2024. Findings include: 1. On the day of survey, 08 /16/2024 at 11:00 am, observation of the laboratory revealed the maintenance sticker on 1 of 1 microscope used to perform MOHS micrographic slide examinations in 2024 stated the following: - Microscope serial number (S/N) 290447. - Maintenance completed on 6-14-2023. - Maintenance due 6-2024. 2. The laboratory failed to provide maintenance records for 1 of 1 microscope (S/N 290447) for maintenance due 06/2024. 3. The DTC confirmed the findings above on 08/16/2024 at 11:00 am.
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 patient test reports and interview with the Director of Training and Compliance (DTC), the laboratory failed to include the address of the location where MOHS microscopic slide examinations were performed on the patient test report from 03/27/2024 to the date of survey. Findings include: 1. On the date of survey, 08/14 /2024 at 11:15 am, review of 1 of 1 MOHS micrograhpic surgery diagram (Case # LH 001-24) revealed the documentation of MOHS micrographic slide examination test results did not include the address of where the tests were performed from 03/27/2024 to 08/14/2024. 2. The DTC confirmed the finding above on 08/14/2024 at 11:15 am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance (QA) policies and records, lack of documentation, and interview with the Director of Training and Compliance (DTC), the laboratory director (LD) failed to ensure quality assessment (QA) programs were maintained to assure the quality of laboratory services and to identify failures in quality as they occur from March 2024 to July 2024. Findings Include: 1. The laboratory's Quality Assurance procedure stated, "The lab director or their assigned designee will also review and sign off the checklist quarterly." 2. On the day of survey, 08/14/2024 at 10:00 am, review of the laboratory's Monthy QA checklists revealed technical supervisor #2 (TS) (CMS 209 personnel # 2) completed and signed

	off on 5 of 5 montly QA reports reviewed from March 2024 to July 2024. 3. The laboratory failed to provide a delegation of duties signed by the LD for TS #2. 4. The DTC confirmed the findings above on 08/14/2024 at 10:00 AM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel training records, test reports, and interview with the Director of Training and Compliance (DTC), the laboratory director (LD) failed to ensure that 1 of 2 testing personal (TP) received the appropriate training and demonstrated their ability to perform MOHS microscopic slide examinations reliably to provide and report accurate results before testing patient specimens from 03/27 /2024 to 4/18/2024. Findings include: 1. On the day of the survey, 08/14/2024 at 10: 45 am, review of personnel training records revealed the LD failed to ensure that 1 of 2 TP (CMS 209 personnel #2) received the appropriate training to ensure MOHS microscopic examinations results were performed reliably and accurately before patient testing from 03/27/2024 to 04/18/2024. 2. Further review or personnel training and patient test reports (MOHS Surgery Diagram) revealed the following: - TP # 2 performed MOHS micrographic slide examinations starting from 03/27/2024. - Training records for TP # 2 were completed by the LD on 04/18/2024. 3. The DTC confirmed the findings above on 8/14/2024 at 10:45 AM.