Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2220431	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pa Dermatology Partners - King Of Prussia	200 Mall Blvd, King Of Prussia, 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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of Mohs surgery diagrams and interview with the Laboratory Manager (LM), the laboratory failed to indicate on 2 of 2 patient Mohs surgery diagrams, the correct address where tests were performed from 09/22/2021 to the day of survey. Findings include: 1. On the day of survey, 08/22/2023 at 10:47 am, review of patient Mohs surgery diagrams (2 of 2 reviewed) revealed that the laboratory did not include the correct address where patient tests were performed. 2. The Mohs surgery diagram stated "2913 Windmill Road, Suite 7, Sinking Spring, PA 19608" when patient tests were performed at "200 Mall Blvd, King of Prussia, PA 19406." 3. The LM confirmed the findings above on 08/22/2023 around 11:05 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 and interview with the Laboratory Manager (LM), the laboratory failed to perform and document maintenance on 1 of 1 thermometer used for monitoring room temperatures and room humidity from 09/22 /2021 to 08/22/2023. Findings include: 1. On the day of survey, 08/22/2023 at 11:00 am, an observation of the laboratory revealed that the following thermometer used to record room temperatures and room humidity expired on 17 December 2022. -Thomas Scientific - S/N- 200818360. 2. The LM confirmed the findings above on 08/22/2023 around 11:05 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 quality assurance procedure, lack of quality assurance documentation and interview with the Laboratory Manager (LM), the laboratory director (LD) failed to ensure quality assessment (QA) programs were maintained and documented to ensure the quality of services provided by the laboratory from 11/30 /2021 to 01/31/2023. Findings include: 1. The quality assurance procedure states, "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist." 2. On the day of survey, 08/22/2023 at 10:36 am, the laboratory could not provide documentation of monthly QA activities performed to assess the laboratory's pre-analytic, analytic and post analytic phases of testing from 11/30/2021 to 01/31/2023. 3. The LM confirmed the findings above on 08/22/2023 around 11:05 am.