Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D2087795	**(X3) Date Survey Completed** 04/15/2021
Name of Provider or Supplier Philadelphia Center For Dermatology	**Street Address, City, State** 361 Highland Ave, Suite 204, Jenkintown, 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**
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 Laboratory procedure manuals, interview with laboratory director (LD) and coordinator, the laboratory failed to establish a complete competency assessment procedure to assess 1 of 2 testing personnel (TP) who performed Potassium Hydroxide (KOH) and scabies microscopic examinations from September of 2020 to the day of survey. Findings include: 1. On the day of survey, 04/15/2021, the laboratory could not to provide a complete competency assessment procedure to assess the competency of 1 of 2 TP performing KOH and scabies microscopic examinations in 2020 and 2021. 2. The LD could not provide training or the 6 month competency records for TP#2 analyzing KOH and scabies microscopic examinations from September 2020 to April 2021. 3. The LD and coordinator confirmed the findings above on 04/15/2021 around 09:20 am.
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 the laboratory procedure manual, review of peer review records and interview with the Laboratory director (LD) and coordinator, the laboratory failed

	to ensure 2 of 2 Testing personnel (TP) performed in the verification of accuracy at least twice annually for Mohs and scabies microscopic examinations in 2019 and 2020. Findings Include: 1. On the day of survey, 04/15/2021, the laboratory could not provide verification of accuracy performed at least twice annually for the following tests in 2019 and 2020: - Mohs microscopic examination for 1 of 2 TP (TP#1). - Scabies microscopic examination for 2 of 2 TP. 2. The LD and coordinator confirmed the findings above on 4/15/2021 around 10:00 am.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of tissue inking dyes in use, review of the laboratory procedure manual and interview with the laboratory director (LD) and coordinator, the laboratory failed to label 5 of 5 - 56 ml bottles of Thermo Scientific Shandon Tissue Marking dyes to indicate their open and expiration dates. Findings include: 1. The laboratory procedure manual, under QC/QA Procedures for Histology on Frozen Sections, quality control, 3. Test methods, Equipment, Reagents, Material and Supplies, 3.5 - "All reagents, solutions, culture media, control material, calibration material and others supplies will be labeled to indicates": 3.5.3 states, "Received, open and check expiration date". 2. On the day of survey, 04/15/2021, observation of the laboratory's tissue marking dyes revealed 5 of 5 - 56 ml bottles of Thermo Scientific Shandon Tissue Marking dyes in use, did not indicate open or expiration dates: - Red - Reference #3120127 - Lot#714046. - Blue - Reference #3120124 - Lot#714146. - Yellow - Reference #3120126 - Lot#710919. - Black - Reference #3120125 - Lot#714006. - Green - Reference #3120128 - Lot#709344. 3. The LD and coordinator confirmed the findings above on 04/15/2021 around 9:40 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 microscopes and interview with the laboratory director (LD) and coordinator, the laboratory failed to perform maintenance /calibration for 2 of 2 microscopes used to analyze Mohs, Potassium Hydroxide (KOH) and scabies microscopic examinations from 02/2020 to the day of survey. Findings include: 1. The Laboratory Procedure Manual, under section 5 Quality assurance/ quality control, Quality Control, 7. Equipment quality control, 7.1 Microscopy, 7.1.4. states, "All microscopes are tested, calibrated and aligned by Micronix Systems Yearly." 2. On the day of survey, 04/15/2021, observation of microscopes used to analyze Mohs, KOH and scabies microscopic examinations

	revealed the following microscopes were due for calibration on February of 2020: - Nikon Eclipse Ci - Serial #951210. - Lecica DMLB - Serial #241029. 3. The laboratory was unable to provide documentation of calibration performed on 2 of 2 microscopes after February of 2020. 4. The LD and coordinator confirmed the findings above on 4/15/2021 around 9:50 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 procedure manual, interview with the Laboratory director (LD) and coordinator, the LD failed to ensure quality assessment (QA) programs were established and documented to assure the quality of laboratory services provided from 2019 to the day of survey. Findings Include: 1. On the date of survey, 04/15/2021, the LD could not provide a complete QA procedure or documentation of periodic evaluation of the laboratory, that assess the laboratory's pre analytical, analytical, and post analytical processes from April 15, 2019 to April 15, 2021. 2. The LD and coordinator confirmed the finding above on 4/15/2021 around 9: 30 am.