Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0673421	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Physicians Inc	2106 Harrisburg Pike Suite 314, 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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on lack of documentation, observation of the laboratory, and interview with the laboratory director (LD), the laboratory failed to monitor the room temperature of paraffin blocks storage to ensure proper conditions for preservation for 2019, 2020 and 2021. Findings include: 1. On the day of survey, 11/17/2021 at 10:40 a.m., the surveyor observed paraffin blocks were stored at room temperature in a office behind the laboratory. 2. The LD could not provide room temperature records for the office behind the laboratory from 11/17/2019 to 11/17/2021. 3. The laboratory could not provide a procedure for the storage of paraffin blocks. 4. The LD confirmed the findings above on 11/17/2021 at 10:45 a.m.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to retain QC records for Potassium Hydroxide (KOH) mycology and scabies microscopic examinations from 11/17/2019 to 07/21/2020. Findings include: 1. On the day of survey, 11/17/2021 at 09:35 a.m.,

	the laboratory could not to provide QC records for KOH mycology and scabies microscopic examinations performed from 11/17/2019 to 07/21/2020. 2. The LD confirmed the above finding on 11/17/2021 around 11:00 a.m.
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 competency assessment records and interview with the Laboratory Director (LD), the laboratory failed to assess 2 of 3 testing personnel (TP) for each assay in microbiology microscopic examinations performed for 2019, 2020, and 2021. Findings Include: 1. On the day of Survey 11/17/2021 at 09:15 a.m., review of the competency assessment records revealed, the forms used to document competency did not separate the two microscopic examinations (Potassium Hydroxide (KOH) Mycology and Scabies) for 2 of 3 TP from 11/17/2019 to the day of survey. 2. The LD confirmed the finding above on 11/17/2021 at 11:00 a.m.
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), the LD failed to ensure that 3 of 3 Testing personnel (TP) performed the verification of accuracy of Potassium Hydroxide (KOH) for mycology and scabies microscopic examination in 2019, 2020, and 2021. Findings Include: 1. The laboratory's Peer Review Procedure manual states: "Each physician will review separately and then document their observation /interpretation. The forms are compared by the laboratory director." 2. On the day of survey, 11/17/2021 at 09:26, The Laboratory could not provide documentation of the verification of accuracy performed by 3 of 3 TP for KOH mycology and scabies from 11/17/2019 to the day of survey. 3. The LD confirmed the findings above on 11/17 /2021 around 11:00 am.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of quality control (QC) slide evaluation records and interview with the Laboratory Director (LD), the laboratory failed to document a positive and negative reactivity every day of patient testing for 5 of 5 special stains performed in 2019, 2020, and 2021. Findings include: 1. On the day of survey 11/17/2021 at 10:15 a.m., review of special stains records revealed, that a positive and negative controls were not documented for Periodic acid-Schiff (PAS), Colloidal Iron, Gram, acid-fast bacteria (AFB), and Giemsa stains in 2019, 2020 and 2021. 2. The laboratory performed the following number of special stains: - From 11/17/2019 to 12/31/2019: 70 special stains. - From 01/01/2020 to 12/31/2020: 345 special stains. - From 01/01 /2021 to 11/17/2021: 508 special stains. 3. The LD confirmed the findings above on 11 /17/2021 around 11:00 a.m.