Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2312374	12/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Paragon Skin Dermatology	1616 Route 72 West, Manahawkin, NJ	

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
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 the lack of the Biannual Assessments (BA) records and interview with the Office Manager (OM) the laboratory failed to verify the accuracy of Histopathology testing biannually from 10/10/24 to 12/17/25. The finding includes: 1. There was no documented evidence the laboratory verified the accuracy of histopathology testing. 2. The OM confirmed on 12/17/25 at 12:30 pm, the laboratory did not verify the accuracy of Histopathology testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of Histology reagents and interview with the Office Manager (OM), the laboratory usedf and failed to discard expired Histopathology reagents from 10/10/24 to 12/17/25. The findings include: 1. Platinumline Eosin Y Stain Solution 1% W/V in Alcohol Lot 1924210 Exp 2021-09-04. 2. Platinumline Hematoxylin Stain Soluaiton,GILL III Lot: 2002408 EXP: 2022-01-28 3. Platinumline Hematoxyulin Stain solution, Gill III Lot: 2105416 EXP: 2023-03-04 4. Platinumline Eosin Y Stain Solution 1% W/V in Alcohol Lot 2110308 Exp 2023-04-

	16. 5. Approximately 200 patients were tested with expired reagent. 6. The OM confirmed on 12/17/25 at 1:00 pm that the laboratory used and failed to discard expired reagents.
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. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing from 10/10/24 to 12/19/25. The findings include: 1. The laboratory did not document H&E stain QC reactions during the time period stated above. 2. The laboratory read and reported approximately 200 patients in the above time period. 3. The OM confirmed on 12/19/25 at 12:30 pm that the laboratory did not document H&E QC stain reaction.