Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2005542	09/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Parks Dermatology Center Llc	37 Old Kings Rd N, Palm Coast, FL	

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
D0000	At the time of the announced, onsite recertification survey, Parks Dermatology Center, LLC was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and staff interview, the facility failed to ensure that at least twice annually, the laboratory verify the accuracy of tests performed in the subspecialties of Mycology, Parasitology, and Histopathology for one of two years reviewed. (2021) The findings include: Record review of accuracy determinations in the facility-provided proficiency testing manual revealed no accuracy testing in 2021 for the 1 Nurse Practioner and the 1 Physician Assistant performing KOH (potassium hydroxide) and scabies patient testing. Record review of the Mohs testing peer review showed cases from October 2021 were sent out for review in August of 2022. There was no documentation showing peer review was performed twice in 2021. Interview at 8:44am on 9/9/22 with laboratory staff confirmed that the twice-yearly accuracy determinations had not been performed in 2021.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to maintain daily quality control (QC) slide documentation for Mohs testing for two days in March 2022. The findings include: The review of QC documentation showed no record for the quality of the Hematoxylin and Eosin stains used during MOHs testing performed on March 17th and March 23rd 2022. Review of the Mohs accession log showed 10 patients tested on 3/17/22 and 10 patients tested on 3/23/22. The interview with the testing person on 9/9/22 at 8:50am confirmed that the documentation for the two days was missing.