

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2005542	(X3) Date Survey Completed 08/29/2024
Name of Provider or Supplier Parks Dermatology Center Llc	Street Address, City, State 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.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to perform competency assessments on 3 out of 3 Testing Personnel who perform KOH (potassium hydroxide) and Scabies testing for two of two years reviewed. (2022-2024) The findings include: Review of Testing Personnel records showed no laboratory competency assessment was performed for testing persons A, B, and C. The laboratory Quality Assurance Program policy states "Our Quality Assurance Program has developed specific indicators that follow the pre analytical, analytical, and post analytical phases of testing to ensure quality. The established indicators are as follows: Competency evaluations of all laboratory personnel including physicians to evaluate their technical laboratory skills. Competency evaluations: new personnel are trained in the specific policies and procedures of this facility and documented within 30 days of assuming laboratory duties. Personnel are evaluated for competency on at least an annual basis. These evaluations may include but are not limited to personal observation, retesting of previously reported specimen or proficiency testing. The competencies also include a review of laboratory safety procedures." During an interview on 8/29/24 at 9:50 AM the Mohs Technician confirmed there was no documentation of laboratory competency assessments on the testing personnel who perform KOH and scabies testing.</p>

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 laboratory failed to send histopathology patient slides for peer review more than once annually in 2023. Findings include: The record review of documented peer review for 2023 showed that patient slides from 2023 were sent on 10/27/23 to ASMS (American Society of Mohs Surgery) to verify accuracy of results. There was no other documented peer review for 2022. The facility Quality Assurance Program policy states "Participation of Proficiency Testing (PT): Proficiency Testing samples are tested exactly like patient specimens. PT for histopathology slides are performed semiannually by submitting 5 randomly selected patients slides to an external reference laboratory where another Dermatopathologist reviews and diagnoses the process. Once the results are returned from the laboratory, they are reviewed to ensure that both diagnosis match. PT for Mohs cases are done semiannually also whereas 5 randomly selected cases are selected and sent to our reference lab to have another Dermatopathologist review them for absence or presence of tumor in the slides provided. Another selected case is sent to the ASMS for peer review to evaluate for certain criteria to maintain their fellowship membership status." The interview with the Mohs Technician on 8/29/24 at 9:33am confirmed that slides were only sent out once for peer review in 2023.