

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0712932	(X3) Date Survey Completed 06/02/2023
Name of Provider or Supplier Parks Dermatology Center Llc	Street Address, City, State 400 Lakebridge Plaza Dr, Ormond Beach, 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 the Clinical Manager, the laboratory failed to perform competency assessments on 4 out of 4 Testing Personnel who perform KOH (potassium hydroxide) and Scabies testing for two of two years reviewed. (2021-2022) The findings include: Review of Testing Personnel records showed no laboratory competency assessment was performed for testing persons A, B, C, and D. During an interview on 6/2/23 at 10:30 AM the Clinical Manager confirmed there was no documentation of laboratory competency assessments on the testing personnel since 2019.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to send</p>

histopathology patient slides for peer review more than once annually in 2022 and failed to perform twice annual verification of accuracy for the subspecialties of Mycology and Parasitology in 2021 and 2022. Findings include: 1. The record review of documented peer review for 2022 showed that patient slides from 2022 were sent on 3/13/2023 to ASMS (American Society of Mohs Surgery) to verify accuracy of results. There was no other documented peer review for 2022. 2. The review of the MLE (Medical Laboratory Evaluation) proficiency testing results for KOH (potassium hydroxide) and Scabies testing showed the laboratory participated in the first testing event in 2021 and the second testing event in 2022. The laboratory could not locate records showing participation in the second testing event of 2021 or the first testing event of 2022. The interview with the Clinical Manager on 6/2/23 at 10:30am confirmed that slides were only sent out once for peer review in 2022. She stated that she was unable to locate the KOH and Scabies results for the missing MLE testing events in 2021 and 2022.