

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0712932	(X3) Date Survey Completed 07/15/2025
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.
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>(a) The laboratory must be constructed, arranged, and maintained to ensure the following: (a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory failed to use chemicals under a fume hood when required for an undetermined amount of time. The findings include: During the tour of the laboratory on 7/15/25 around 1:10pm, the chemical stain line used for Mohs surgery (a procedure used to treat skin cancer) was observed. The stains used in the stain line included 100% alcohol and Eosin. A review of the chemical's safety data sheets (SDS) was performed. 1. The SDS for the 100% Alcohol stated "Use only outdoors or in a well-ventilated area. Do not breathe dust /fume/gas/mist/vapors/spray." 2.. The SDS for the Eosin stated "Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation." During the interview with the Histotechnologist on 7/15/25 at 1:20pm, it was confirmed the room does not have a ventilation system and a fume hood over the stain line is required for respiratory safety.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and staff interview, the laboratory failed to ensure the potassium hydroxide (KOH) was not expired prior to patient testing. Findings include:

Observations made during a tour of the laboratory on 7/15/25 at 1:30 PM, showed one bottle of "Potassium Hydroxide" with lot number 2906-02 expired 12/31/2023. During an interview on 7/15/25 at 1:35 PM with the Histotechnologist, it was confirmed the bottle of KOH was expired.