

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2031978	(X3) Date Survey Completed 02/02/2024
Name of Provider or Supplier Romagosa Barron Dermatology	Street Address, City, State 2220 Se Ocean Blvd Ste 204, Stuart, 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	Recertification survey was conducted from 1/23/2024 to 2/2/2024. Romagosa Barron Dermatology clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to have unexpired mineral oil in use for scabies testing for 1 out of 1 scabies patient reviewed. Findings Included: On 1/23/2024 at 1 PM, one bottle of mineral oil with expiration date of 8/2021 in a cabinet. Review of procedure policy revealed there was no policy for how to perform scabies and no policy for reagent storage and expiration. Review of scabies patient records revealed patient 1 was tested for scabies on October 9th, 2023. On 1/25/2024 at 4:45 PM, MOHS Lab Manager and IHC Lab Manager confirmed the mineral oil used for Scabies testing was expired for 1 out of 1 scabies patient reviewed.</p>