

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2031978	<b>(X3) Date Survey Completed</b>  04/08/2026
<b>Name of Provider or Supplier</b>  Romagosa Barron Dermatology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Romagosa Barron Dermatology on March 25, 2026 to April 8, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, review of the laboratory procedure manual and safety data sheets (SDS), the laboratory failed to ensure protection from chemical hazards used in their Tissue Tek Vacuum Infiltration Processor (VIP) and Hematoxylin and Eosin (H&amp;E) stain from 02/02/2024 to 03/25/2026. Findings: 1. During a tour of the laboratory on 03/25/2026 at 9:45 AM, two containers used to store chemical waste used in their H&amp;E stain in the Mohs lab were seen in a cabinet in the laboratory and one large container used to store chemical waste used in their H&amp;E stain and in the Vacuum Infiltration Processor (VIP) was seen on the floor of the pathology laboratory. 2. Review of the procedure titled, Tissue Tek VIP Vacuum Infiltration Processor - Processing Program, signed and dated by the Laboratory Director on 02/18/2026, revealed the pathology laboratory used the following reagents in their VIP processors: Formalin, 50% Reagent Alcohol, 70% Reagent Alcohol, 95% Reagent Alcohol, 100% Reagent Alcohol, and Xylene. 3. Review of the procedure titled Routine Hematoxylin and Eosin Staining (H&amp;E) by the Leica Autostainer XL Procedure, signed and dated by the Laboratory Director on 02/18/2026, revealed the Pathology laboratory used the following reagents for the H&amp;E stain: Xylene, 100% Reagent Alcohol, 95% Reagent Alcohol, Harris Hematoxylin, Clarifier, Bluing Reagent, and Eosin. 4. Review of the procedure titled, Hematoxylin and Eosin Stain</p>

(Automatic Timetable), signed and dated by the Laboratory Director on 02/18/2026, revealed the Mohs laboratory used the following reagents for the H&E stain: 100% Reagent Alcohol, Hematoxylin, Eosin, and Histo-Clear. 5. Review of the SDSs for Avantik Reagent Alcohol 100%, Avantik Gill 3 Hematoxylin, Avantik Alcoholic Clarifier, Avantik Eosin Y, Stat Lab 100% Reagent Alcohol stain, and Stat Lab Xylene noted, "Store locked up." 6. Review of the SDSs for Avantik Eosin Y, Stat Lab Eosin - Y - Alcohol 0.25%, Stat Lab 95% Reagent Alcohol, Stat Lab Xylene, and Stat Lab Harris Hematoxylin noted, "Keep in fireproof place." 7. Review of the SDSs for Avantik Reagent Alcohol 100%, Avantik Gill 3 Hematoxylin, Avantik Alcoholic Clarifier, Avantik Eosin Y, Stat Lab 100% Reagent Alcohol, Stat Lab Xylene, Stat Lab Eosin - Y - Alcohol 0.25%, and Stat Lab 95% Reagent Alcohol revealed each SDS had the symbol for flammable. 8. During an interview on 03/25/2026 at 9:45 PM, the Mohs Technician acknowledged the flammable chemical waste was not locked up or in a fireproof place.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.

This STANDARD is not met as evidenced by:  
Based on review of the procedure manual, record review, and interview, the laboratory failed to document acceptability of the Hematoxylin and Eosin (H&E) quality control (QC) slide from 01/30/2024 to 08/19/2024. Findings: 1. Review of the procedure titled, H&E Quality Control Procedure, signed and dated on 02/18/2026 by the Laboratory Director noted, "If the slide meets the criteria for proper interpretation, the reviewer will then sign the "Path Lab H&E Staining Quality Control Log" and /or report any issues." 2. Review of Path Lab H&E Staining Quality Control Log Suite #204 revealed, the Dermatopathologist (Technical Supervisor B) failed to document the acceptability of the H&E stain for 124 of 124 days from 01/30/2024 to 08/19/2024. 3. During an interview on 03/25/2026 at 1:30 PM, Testing Personnel E acknowledged the stain quality control logs were not signed by the Dermatopathologist.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the procedure manual, review of personnel records, and interview, the Technical Supervisor (Laboratory Director) failed to document competency evaluation for two (Testing Personnel B and C) of three (Laboratory Director, and Testing Personnel B and C) Mohs Surgeons in 2024 and 2025. Findings included: 1.

Review of the procedure titled, Competency Assessments and Annual Review signed and dated by the Laboratory Director on 02/18/2026 noted, "All Romagosa Baron Dermatology laboratory employees will be subject to competency assessments." 2. Review of the personnel records for Testing Personnel B and C revealed there was no documentation of annual competency evaluations on the Mohs Surgeons for 2024 and 2025. 3. During an interview on 03/25/2026 at 12:39 PM, the Mohs Technician revealed they did not have competency assessments performed on the Mohs Surgeons.