

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2175385	(X3) Date Survey Completed 03/17/2026
Name of Provider or Supplier Sebastian - Iconic Dermatology	Street Address, City, State 8745 Us Hwy 1, Sebastian, 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	An announced CLIA recertification survey was conducted at Sebastian - Iconic Dermatology on March 17, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D3011	<p>FACILITIES 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, review of the laboratory procedure manual and safety data sheets (SDS), and interview, the laboratory failed to ensure protection from chemical hazards used in their Hematoxylin and Eosin (H&E) stain from 03/13/2024 to 03/17/2026. Findings Included: Review of the procedure titled, H&E Staining signed and dated by the Laboratory Director on 1/2026 noted the laboratory used the following chemicals in their H&E stain: 100% Reagent Alcohol, Hematoxylin, Eosin, Xylene Substitute, and Scott's Tap Water. A1. During tour of the laboratory on 03/17/2026 at 3:10 PM, there was no fume hood over the automated stainer and there were no respirators seen. A2. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol, Mercedes Scientific Hematoxylin Stain Solution, Gill III, Mercedes Scientific Eosin Y Solution, 1% w/v (weight per volume) in Alcohol, and Mercedes Scientific Xylene Substitute, noted, "if exposure limits are exceeded or irritation is experienced, NIOSH/MSHA Approved respiratory protection should be worn." A3. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol and Mercedes Scientific Eosin Y Solution, 1% w/v (weight per volume) in Alcohol, also noted, "Do not breathe dust/fume/gas/mist/vapors/spray" and "Wear protective gloves /protective clothing/eye protection/face protection." A4. Review of the SDS's for the Mercedes Scientific Hematoxylin Stain Solution also noted, "Ensure adequate</p>

ventilation, especially in confined areas." A5. Review of the SDS's for the Mercedes Scientific Xylene Substitute also noted "May cause respiratory irritation" and "Avoid breathing dust/fume/gas/mist/vapors/spray" A6. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol, Mercedes Scientific Hematoxylin Stain Solution, Gill III, Mercedes Scientific Eosin Y Solution, 1% w/v (weight per volume) in Alcohol, and Mercedes Scientific Xylene Substitute revealed, showed each had the symbol for respiratory tract irritant. A7. During an interview on 03/17/2026 at 3:20 PM, the Laboratory Supervisor acknowledged there was no fume hood over the stainer, and the laboratory was small and probably did not have adequate ventilation. B1. During tour of the laboratory on 03/17/2026 at 3:20 PM, one large containers used to store the chemical waste in their H&E stain was seen on the floor of the storage room. B2. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol, Mercedes Scientific Eosin Y Solution, 1% w/v in Alcohol, and Mercedes Scientific Xylene Substitute noted, "Store locked up." B3. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol, and Mercedes Scientific Eosin Y Solution, 1% w/v in Alcohol noted "Store in an approved Flammable Liquids storage area." B4. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol, and Mercedes Scientific Eosin Y Solution, 1% w/v in Alcohol showed the each had the symbol for flammable. B5. During an interview on 03/17/2026 at 3:20 PM, the Laboratory Supervisor acknowledged the chemical waste from the H&E stain had been stored on the floor of the storage room. Word Key NIOSH - National Institute for Occupational Safety and Health MSHA - Mine Safety and Health Administration

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual, observation of patient specimen slides and interview, the laboratory failed to ensure positive identification of patient specimen slides for seven (#1 - 7) of eight (#1 - #8) patient slides reviewed. Findings: 1. Review of the procedure titled Mohs Slide Preparation noted, Slides are labeled as following: First, the date is across the very top of the white portion of the slide, then the patient's last name and first name Initial, Site, Mohs accession number and Stage." 2. Observation of the patient's slides on 03/17/2026 at 5:10 PM revealed the slides for Patients #1 and #6 listed the last name and not the initial of the first name, and the slides for Patients #2 - #5 and #7 listed the first name and not the last name. 3. During an interview on 03/17/2026 at 5:15 PM, the Laboratory Supervisor revealed she noticed the inconsistency in the labeling of the slides when she pulled the patients' slides.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section.

Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document maintenance and function checks for 4 days on the maintenance logs reviewed from 3/13/2024 to 03/17/2026. Findings included: 1. Review of Mohs Daily Quality Control Worksheet revealed it was used to document the H&E stain control slide, microscope verification and maintenance, cryostat maintenance, cryostat temperature, room temperature, room humidity, technician's initials, and doctors initials. The worksheet was not filled out for 01/29/2026 and 03/05/2026. 2. Review of the Mohs Accession Logs revealed, there were 16 Mohs surgical procedure on 01/29/2026, and 13 on 03/05/2026. 3. Review of the Hematoxylin and Eosin Staining Maintenance Log revealed, it was used to document the changing, rotation, filtering and adding of the reagent, and it was not filled out for 03/28/2025. 4. Review of the Mohs Accession Logs revealed, there were 17 Mohs surgical procedures on 03/28/2025. 5. Review of Daily Mohs Laboratory Log revealed the form was used to document the cryostat temperature, room temperature, room humidity, eye wash station check, fume hood check, daily maintenance, change/rotation of stain maintenance, and the quality control of the stain. 6. Review of Daily Mohs Laboratory Log revealed the log for 09/12/2024 was missing. 7. Review of the Mohs Accession Logs revealed, there were 16 Mohs surgical procedure on 09/12/2024. 8. During an interview on 03/17/2026 at 4:32 PM, the Laboratory Supervisor acknowledged the maintenance was not recorded.

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 the acceptability of the Hematoxylin and Eosin (H&E) control slide for 12 days (09/12/2024, 01/08/2026, 01/15/2026, 01/22/2026, 01/29/2026, 02/05/2026, 02/13/2026, 02/13/2026, 02/19/2026, 02/26/2026, 03/05/2026, and 03/06/2026) on the daily control log reviewed from 03/13/2024 to 03/17/2026. Findings: 1. Review of the procedure titled, H&E Staining signed and dated by the Laboratory Director on 1/2026 noted, for quality control, "Each slide is examined by a doctor and the quality of the cutting and the staining are documented daily." 2. Review of Daily Mohs Laboratory Log revealed the Laboratory Director's initials on the log indicating the quality of the H&E stain was acceptable. 3. Review of Daily Mohs Laboratory Log revealed the log for 09/12/2024 was missing. 4. Review of the Mohs Accession Logs revealed, there were 16 Mohs surgical procedure on 09/12/2024. 5. Review of the Mohs Daily Quality Control Worksheet revealed, the Laboratory Director failed to initial the log indicating the quality of the H&E stain was acceptable for 01/08/2026, 01/15/2026, 01/22/2026, 01/29/2026, 02/05/2026, 02/13/2026, 02/13/2026, 02/19/2026, 02/26/2026, 03/05/2026, and 03/06/2026. 6. Review of the Mohs Accession Log showed there were 11 Mohs surgical procedure

on 01/08/2026, 14 on 01/15/2026, 13 on 01/22/2026, 16 on 01/29/2026, 14 on 02/05/2026, 15 on 02/12/2026, 17 on 02/13/2026, 16 on 02/19/2026, 14 on 02/26/2026, 13 on 03/05/2026, and 16 on 03/06/2026 7. During an interview on 03/17/2026 at 4:32 PM, the Laboratory Supervisor acknowledged the daily log for 09/12/2024 was missing, and the Laboratory Director failed to initial all of the quality control worksheets.