

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2314546	<b>(X3) Date Survey Completed</b>  01/27/2026
<b>Name of Provider or Supplier</b>  Forefront Dermatology Sc Corp	<b>Street Address, City, State</b>  2305 Vidina Dr Ste 102, Melbourne, 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 initial certification survey was conducted at Forefront Dermatology SC Corp on January 27, 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, the laboratory failed to ensure protection from chemical hazards used in their Hematoxylin and Eosin (H&amp;E) stain from 04/19/2025 to 1/27/2026. Findings: A1. During a tour of the laboratory on 01/27/2026 at 9:50 AM, the container used to store the chemical waste used in their H&amp;E stain was seen on the floor of the laboratory. A2. Review of the procedure titled Automatic Stainer Hematoxylin and Eosin noted the laboratory used the following reagent: 95% Reagent Alcohol, Hematoxylin, Acid Alcohol, Bluing Reagent (Scott's Tap Water), Eosin, 100% Reagent Alcohol, and Xylene Substrate. A3. Review of the Safety Data Sheets for the Stat Lab 100% Reagent Alcohol stain noted, "Store locked up." Review of the Safety Data Sheets for the Stat Lab Eosin - Y - Alcohol 0.25% and the Stat Lab XS-3 Xylene Substitute noted, "Keep in fireproof place." A4. During an interview on 01/27/2025 at 11:10 PM, the Clinical Lead stated the chemical waste was not stored in a flammable cabinet. B1. During a tour of the laboratory on 11/12/2025 at 9:20 AM, there was no fume hood over the automated stainer and there were no respirators seen. B2. Review of the Safety Data Sheets showed the following chemicals included the respiratory hazard symbol: Stat Lab 100% Reagent Alcohol, Stat Lab Gill 3 Hematoxylin, and Stat Lab XS-3 Xylene Substitute. B3. Review of the Safety Data</p>

Sheets for Stat Lab 100% Reagent Alcohol noted, 100% Reagent Alcohol - "Inhalation: May cause drowsiness or dizziness." The Safety Data Sheets for Stat Lab Gill 3 Hematoxylin noted, "May cause respiratory irritation." Review of the Safety Data Sheets for Stat Lab XS-3 Xylene Substitute noted, "Inhalation: High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headaches, and similar narcotic symptoms." Review of the Safety Data Sheets for Cancer Diagnostics Reagent Alcohol 95% noted potential health effects as "Inhalation: Alcohols are absorbed through the mucous membranes and will produce irritation as well as the same effects as ingestion. Ingestion: Ingestion will produce CNS (Central Nervous System) disturbance, dizziness, photophobia, headache, stupor, coma and death." B4. Review of the Safety Data Sheets for Stat Lab 100% Reagent Alcohol and Stat Lab Gill 3 Hematoxylin noted, "Use NIOSH (National Institute for Occupational Safety and Health) approved full faced piece negative pressure respirators equipped with appropriate cartridges or canisters within the use limitations of these devices." The Safety Data Sheets for Stat Lab Eosin - Y - Alcohol 0.25% noted, "If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn." Review of the Safety Data Sheets for Cancer Diagnostics Reagent Alcohol 95% noted "Special PPE Requirements: If ventilation hood not available wear respirator." B5. During interview on 11/12/2025 at 9:25 AM, the Laboratory Manager acknowledged there was no fume hood.

**D5413**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to document the room temperature and humidity for seven (05/23/2025, 08/22/2025, 08/23/2025, 09/27/2025, 10/10/2025, 12/15/2025, 01/13/26) of 42 days that Mohs surgical procedures were performed. Findings: 1. Review of the Room Temp/Humidity log and the Mohs Daily Quality Control Worksheet showed the room temperature and humidity for the laboratory was not documented on 05/23/2025, 08/22/2025, 08/23/2025, 09/27/2025, 10/10/2025, 12/15/2025, and 01/12/2026. 2. Review of the Mohs Accession Log showed the following number of Mohs surgical procedures: 05/23/2025 - 9 surgical procedures 08/22/2025 - 7 surgical procedures 08/23/2025 - 10 surgical procedures 09/27/2025 - 18 surgical procedures 10/10/2025 - 8 surgical procedures 12/15/2025 - 6 surgical procedures 01/12/2026 - 9 surgical procedures 3. During an interview on 01/27/2025 at 11:10 PM, the Clinical Lead acknowledged the room temperature and humidity of the laboratory was not recorded.

**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 review of quality control documents and interview, the laboratory failed to document the daily maintenance activities from 05/23/2025 to 11/21/2025. Findings: A1. Review of the Hematoxylin & Eosin (H&E) Staining Maintenance Log showed the laboratory failed to document the maintenance of the reagents used in the H&E stain on 5/23/25, 7/25/25 7/26/25, 10/10/25, 10/24/25 and 10/25/25. A2, Review of the Mohs Accession Log showed the following number of Mohs surgical procedures: 05/23/2025 - 9 surgical procedures 07/25/2025 - 9 surgical procedures 07/26/2025 - 10 surgical procedures 10/10/2025 - 8 surgical procedures 10/24/2025 - 6 surgical procedures 10/25/2025 - 14 surgical procedures A3. During an interview on 01/27/2025 at 11:30 PM, the Clinical Lead acknowledged stain maintenance was not recorded. B1. Review of the Cryostat Maintenance and Temperature Log and the Mohs Daily Quality Control Worksheet showed the laboratory failed to document the cryostat maintenance and temperatures for 5/23/25, 8/22/25 8/23/25, 10/10/25, and 11/21/25 B2. Review of the Mohs Accession Log showed the following number of Mohs surgical procedures: 05/23/2025 - 9 surgical procedures 08/22/2025 - 7 surgical procedures 08/23/2025 - 10 surgical procedures 10/10/2025 - 8 surgical procedures 11/21/2025 - 10 surgical procedures B3. During an interview on 01/27/2025 at 11:30 PM, the Clinical Lead acknowledged the cryostat temperature and maintenance were 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 record review and interview, the laboratory failed to document acceptability of the Hematoxylin and Eosin (H&E) control slide for 3 (09/13/2025, 10/10/2025, 11/21/2025) of 42 days that Mohs surgical procedures were performed. Findings: 1. Review of the Mohs Daily Quality Control Worksheet showed the Previous Laboratory Director failed to indicate the stain quality was acceptable on 09/13/2025 and 10/10/2025, and the Laboratory Director failed to indicate the stain quality was acceptable on 11/21/2025. 2. Review of the Mohs Accession Log showed the following number of Mohs surgical procedures: 09/13/2025 - 17 surgical procedures 10/10/2025 - 8 surgical procedures 11/21/2025 - 10 surgical procedures 3. During an interview on 01/27/2025 at 11:30 PM, the Clinical Lead acknowledged the worksheet was not completely filled out.

**D5609**

**HISTOPATHOLOGY**

CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on interview and review of the procedure manual, and quality control records, the laboratory failed to document quality control information including lot numbers, expiration dates, and open dates for all the reagents used in their Hematoxylin and Eosin (H&E) stain from 04/19/2025 to 01/18/2026. Findings: 1. Review of the procedure titled, Automatic Stainer Hematoxylin and Eosin noted the laboratory used the following reagent: 95% Reagent Alcohol, Hematoxylin, Acid Alcohol, Bluing Reagent (Scott's Tap Water), Eosin, 100% Reagent Alcohol, and Xylene Substrate. 2. Review of the Chemical Log Sheet and the Laboratory Reagent Log showed the first day the reagents were listed as being opened on the logs are the following: 95% Reagent Alcohol - 01/18/2026 Hematoxylin - 06/13/2025 Acid Alcohol - 12/17/2025 Bluing Reagent - 11/21/2025 Eosin - 08/07/2025 100% Reagent Alcohol - 06/13/2025 Xylene Substrate - 07/11/2025 3. Review of the Mohs Accession Log showed the first day of testing was 04/19/2025. 4. During an interview on 01/27/2025 at 11:54 PM, the Clinical Lead acknowledge there was not a chemical log from when the laboratory started testing.