| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D2053212 | 08/31/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Forefront Dermatology, Sc | 1610 Maxwell Drive Suite 210, Hudson, WI | |

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 |
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| **D5028** | HISTOPATHOLOGY<br>CFR(s): 493.1219<br><br>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of laboratory records and interview with the regional manager, staff A, the laboratory has not met the requirements specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory used expired Scott's tap reagent from January 26, 2023, to February 15, 2023. Expired reagents were previously cited during the last three surveys. See D5417. 2. The laboratory did not document temperatures for room temperature, humidity and cryostat temperature and did not document maintenance for the cryostat on the logs provided. This is a repeat citation from previous survey. See D5429. 3. The laboratory did not document quality control on days of patient testing. See D5601. This is a repeat deficiency from September 21, 2021. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and interview with the regional manager, staff A, the laboratory used expired Scott's tap reagent for the slide staining |

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| | process on thirty-three of thirty-three patients from January 26, 2023, through February 15, 2023. Findings include: 1. Review of the "2023 CHEMICAL LOG SHEET" showed the following: Product/Lot number/Expiration date/Date opened. Scott's tap/2202114/January 26, 2023/August 2, 2022 Scott's tap/2234327/December 21, 2023/February 15, 2023 Further review showed no documentation of another lot number of Scott's tap used between January 26, 2023, and February 15, 2023. 2. Review of "2023 Mohs Patient Log" showed thirty-three patients with Mohs testing between January 26, 2023, and February 15, 2023. 3. Interview with the staff A on August 31, 2023, at 1:50 PM via telephone call confirmed the laboratory used expired Scott's tap reagent for the slide staining process in January and February 2023. This is a repeat deficiency from September 21, 2021, July 31, 2019, and September 22, 2017. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and interview with the regional manager, staff A, the laboratory did not document cryostat maintenance and temperatures for one of nine patient testing days in August 2022 and one of eight patient testing days in February 2023. Findings include: 1. Review of the "Mohs Patient Log" showed patient testing occurred on the following days: August 2022: 2, 3, 9, 10, 16, 17, 24, 30, and 31. February 2023: 1, 7, 8, 14, 15, 21, 22, and 28. Further review showed six patient tests performed on August 17, 2023 and nine patient tests performed on February 15, 2023. 2. Review of the "Cryostat Maintenance & Temperature Log" showed maintenance and temperature recorded on the following days: August 2022: 2, 3, 9, 10, 16, 24, 30 and 31. February 2023: 1, 7, 8, 14, 21, 22, and 28. 3. Review of the Form "M-722-B Room Temp/Humidity" log showed temperature and humidity recorded on the following days: August 2022: 2, 3, 9, 10, 16, 24, 30 and 31. February 2023: 1, 7, 8, 14, 21, 22, and 28. 4. Interview with staff A on August 31, 2023, at 1:50 PM via telephone call confirmed the laboratory did not document maintenance and temperatures for all days of patient testing in August 2022 and February 2023. This is a repeat deficiency from September 21, 2021. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(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. (f) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and interview with the regional manager, staff A, the laboratory did not document Hematoxylin and Eosin (H&E) stain slide quality control (QC) for one of nine patient testing days in August 2022 |

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| | and one of eight patient testing days in February 2023. Findings include: 1. Review of the "Mohs Patient Log" showed patient testing occurred on the following days: August 2022: 2, 3, 9, 10, 16, 17, 24, 30, and 31. February 2023: 1, 7, 8, 14, 15, 21, 22, and 28. Further review showed six patient tests performed on August 17, 2023, and nine patient tests performed on February 15, 2023. 2. Review of the "Quality Control Assessment of Mohs Tissue Staining Procedure" showed QC recorded on the following days: August 2022: 2, 3, 9, 10, 16, 24, 30 and 31. February 2023: 1, 7, 8, 14, 21, 22, and 28. 3. Interview with staff A on August 31, 2023, at 1:50 PM via telephone call confirmed the laboratory did not document H&E slide stain QC for all days of patient testing in August 2022 and February 2023. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory records and slides and interview with the regional manager, staff A, the laboratory director did not ensure the established quality assessment program was sufficient to identify and correct failure in quality as they occur during patient testing for five of five patients reviewed in July 2023. Findings include: 1. Review of "2023 Mohs Patient Log", Mohs slides, Mohs map and patient chart for patient 1 showed the visit note in the chart and Mohs map showed the date of service as on July 25, 2023, and Mohs slides and log showed the date of service as July 24, 2023. Further review showed patients 2 through 5 with a date of service on the log as July 24, 2023, and Mohs map date of service as July 25, 2023. 2. Interview with staff A on August 31, 2023 at 11:50 AM via telephone confirmed the laboratory director did not ensure the established quality assessment program was sufficient to identify and correct failure in quality as they occur. This is a repeat deficiency from September 21, 2021. |