| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 52D2053212 | 09/21/2021 |
| **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 |
|---|---|
| **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, observation in the laboratory, and interview with the regional manager, 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 was using expired stains or dyes at the time of this and the two previous surveys. See D5417. 2. The laboratory did not document maintenance for the cryostat on the 'Cryostat Maintenance & Temperature Logs'. See D 5429. 3. The laboratory did not document corrective actions when cryostat temperatures were not within the established acceptable range. See D5781. |
| **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 observation of supplies in the laboratory, review of laboratory records, and interview with the regional manager, the laboratory had two expired Surgipath Tissue Marking and Margin Dyes and used expired green dye from August 28, 2021 through September 21, 2021. Findings include: 1. Observation on September |

| | |
|---|---|
| | 21, 2021 at 12:45 PM of the marking dyes used for patient testing in the laboratory revealed two Surgipath Tissue Marking and Margin Dyes used in Mohs procedures were past their expiration dates. Black dye expired August 12, 2021 Green dye expired August 27, 2021 2. Review of laboratory records showed Mohs procedures were performed after August 27, 2021 on September 1, 8, 14, 15, and 21. 3. Interview with the regional manager (staff A) on September 21, 2021 at 12:45 PM confirmed the dyes had exceeded their expiration dates and confirmed the green dye was used for patient testing after August 27, 2021. This is a repeat deficiency previously cited on 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 the 'Cryostat Maintenance & Temperature Logs' from May through September 2021 and interview with the regional manager, the laboratory did not document cryostat maintenance on the forms as required. Findings include: 1. Review of the 'Cryostat Maintenance & Temperature Logs' from May through September 2021 showed the log included a column to document maintenance. The form states, "A checkmark in the Maintenance column indicates that maintenance (per cryostat procedure) is done daily when Mohs is performed". No checkmarks are present in the maintenance column on the forms. The form from September 2021 included dashes on dates when the laboratory did not process Mohs samples, the same dashes are present in the maintenance column on dates when the laboratory processed Mohs samples. 2. Interview with the regional manager (staff A) on September 21, 2021 at 11:45 AM confirmed the laboratory did not document performance of maintenance on the 'Cryostat Maintenance & Temperature Logs' as required by the instructions on the form. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the 'Cryostat Maintenance & Temperature Logs' and interview with the regional manager, the laboratory did not document corrective actions taken when all the recorded cryostat temperatures were outside the identified acceptable operating parameters from June through September 2021. Findings |

| | |
|---|---|
| | include: 1. Review of the 'Cryostat Maintenance & Temperature Logs' showed the recorded temperatures were not in the stated acceptable range of -20 C (Celsius) to -30 C from June to September 2021. Other instructions on the log included: "If the temperature is out of range, the temperature is adjusted, rechecked and documented in "comments/correction column," and, "If the temperature continues to be out of range service will be performed on the cryostat." The logs showed no corrective actions documented for any of the unacceptable temperatures. 2. Interview with the regional manager (staff A) on September 21, 2021 at 11:45 AM confirmed corrective actions were not documented when the cryostat temperatures were outside the established acceptable operating parameters. |
| **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 interview with the regional manager, the laboratory director did not ensure quality assessment programs were maintained through review of temperature and maintenance logs in July and August 2021 or identification of unacceptable parameters on the logs in June 2021. Findings include: 1. Review of 'Cryostat Maintenance & Temperature Logs' from June through August 2021 showed personnel did not document any corrective actions when all recorded temperatures were not acceptable. Further review revealed the log included a section to document review of the log by the team leader or laboratory director. The section stated, "Reviewed temperatures are in range" and included a space for the reviewer's signature and date. The log from June was reviewed and showed no evidence the review identified the unacceptable temperatures recorded on the form or the lack of corrective action documentation. The logs from July and August showed no evidence of review. 2. Interview with the regional manager (staff A) on September 21, 2021 at 11:45 AM confirmed the review of the June log did not identify the missing corrective action documentation, the July and August forms were not reviewed, and that the quality assessment program was not maintained. |
| **D6096** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(7)<br><br>The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of cryostat temperature records and interview with the regional manager, the laboratory director did not ensure remedial actions were documented when the director identified slide quality issues and the laboratory took remedial actions including adjusting the cryostat operating temperature in May 2021. Findings include: 1. Review of the monthly 'Cryostat Maintenance & Temperature Logs' from 2021 showed temperatures are recorded in Celsius (C). The log includes the following, "Cryostat temperature must be between -20 C and -30 C". From June |

| | |
|---|---|
| | through September 2021, all the recorded temperatures were outside the acceptable range; records for most days showed the recorded temperature was either -17 or -18 degrees C. 2. Review of laboratory records showed no documentation of a change of operating parameters for the cryostats. 3. Interview with the regional manager (staff A) on September 21, 2021 at 11:45 AM revealed the laboratory had changed the target temperature setting for the cryostat to -18 degrees in May 2021 to address issues with artifacts seen on slides. The manager confirmed the issues and the corrective actions taken were not documented. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of cryostat maintenance logs and procedures and interview with the regional manager, the laboratory procedures did not include a procedure referenced on the maintenance log to identify what maintenance steps were required for the cryostat. Findings include: 1. Review of the 'Cryostat Maintenance & Temperature Log' used in September 2021 showed cryostat maintenance was to be completed "per cryostat procedure". 2. Review of the procedure manual showed no evidence of a "Cryostat Procedure" to identify what maintenance steps were required. 3. Interview with the regional manager (staff A) on September 21, 2021 at 11:45 AM confirmed the procedure manual approved by the director did not include the cryostat procedure referenced on the maintenance log. |