

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0667379	(X3) Date Survey Completed 03/01/2022
Name of Provider or Supplier Forefront Dermatology Sc DbA Henghold Dermatology,	Street Address, City, State 530 Fontaine St, Pensacola, 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	A recertification survey was conducted on February 18, 2022. The survey continued through 3/01/2022 to gather additional documentation. Forefront Dermatology SC DBA Henghold Dermatology clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and laboratory staff interview, the laboratory failed to document corrective actions for temperatures out of range for the refrigerator and cryostats during the years 2020 and 2021. Findings included: Record review of the "Cryostat Maintenance & Temperature Log" showed the acceptable temperature range to be -20 to -30 Celsius (C). For Cryostat #1 Serial #61614, the following dates had temperatures out, with no corrective action documented: February 3, 2020 - documented temperature of -32 (C) February 4, 2020 - documented temperature of -32 (C) February 5, 2020 - documented temperature of -32 (C) February 6, 2020 - documented temperature of -32 (C) February 7, 2020 - documented temperature of -32 (C) February 10, 2020 - documented temperature of -32 (C) February 11, 2020 -</p>

documented temperature of -31 (C) March 2, 2020 - documented temperature of -32 (C) March 3, 2020 - documented temperature of -32 (C) March 4, 2020 - documented temperature of -32 (C) March 5, 2020 - documented temperature of -32 (C) March 6, 2020 - documented temperature of -31 (C) March 9, 2020 - documented temperature of -31 (C) March 10, 2020 - documented temperature of -31 (C) March 11, 2020 - documented temperature of -31 (C) March 12, 2020 - documented temperature of -31 (C) March 13, 2020 - documented temperature of -31 (C) March 16, 2020 - documented temperature of -31 (C) March 17, 2020 - documented temperature of -31 (C) March 18, 2020 - documented temperature of -31 (C) March 19, 2020 - documented temperature of -31 (C) March 20, 2020 - documented temperature of -31 (C) March 23, 2020 - documented temperature of -32 (C) March 24, 2020 - documented temperature of -31 (C) March 25, 2020 - documented temperature of -31 (C) March 26, 2020 - documented temperature of -31 (C) March 27, 2020 - documented temperature of -31 (C) March 30, 2020 - documented temperature of -31 (C) April 1, 2020 - documented temperature of -32 (C) April 2, 2020 - documented temperature of -32 (C) April 3, 2020 - documented temperature of -32 (C) April 6, 2020 - documented temperature of -32 (C) April 7, 2020 - documented temperature of -32 (C) April 8, 2020 - documented temperature of -32 (C) April 9, 2020 - documented temperature of -32 (C) April 10, 2020 - documented temperature of -32 (C) April 13, 2020 - documented temperature of -32 (C) April 14, 2020 - documented temperature of -32 (C) April 15, 2020 - documented temperature of -32 (C) April 16, 2020 - documented temperature of -32 (C) April 17, 2020 - documented temperature of -32 (C) April 20, 2020 - documented temperature of -32 (C) April 21, 2020 - documented temperature of -32 (C) April 22, 2020 - documented temperature of -32 (C) April 23, 2020 - documented temperature of -32 (C) April 24, 2020 - documented temperature of -32 (C) April 27, 2020 - documented temperature of -32 (C) April 28, 2020 - documented temperature of -32 (C) April 29, 2020 - documented temperature of -32 (C) April 30, 2020 - documented temperature of -32 (C) May 1, 2020 - documented temperature of -32 (C) Record review of the "Refrigerator, Freezer & Oven Log" showed the acceptable refrigerator temperature range to be from 35 to 45 Fahrenheit (F) or from 2 to 8 Celsius (C). For January of 2020, comments of "decreased temp" were documented, but the temperature continued to be out of acceptable range until January 31, 2020 at 45 (F). January 1, 2020 - documented temperature of 46 (F) January 2, 2020 - documented temperature of 47 (F) January 3, 2020 - documented temperature of 48 (F) January 6, 2020 - documented temperature of 46 (F) January 7, 2020 - documented temperature of 46 (F) January 8, 2020 - documented temperature of 47 (F) January 9, 2020 - documented temperature of 46 (F) January 10, 2020 - documented temperature of 47 (F) January 13, 2020 - documented temperature of 46 (F) January 14, 2020 - documented temperature of 46 (F) January 15, 2020 - documented temperature of 47 (F) January 16, 2020 - documented temperature of 47 (F) January 17, 2020 - documented temperature of 47 (F) January 20, 2020 - documented temperature of 46 (F) January 21, 2020 - documented temperature of 47 (F) January 22, 2020 - documented temperature of 47 (F) January 23, 2020 - documented temperature of 47 (F) January 24, 2020 - documented temperature of 46 (F) January 27, 2020 - documented temperature of 47 (F) January 28, 2020 - documented temperature of 47 (F) January 29, 2020 - documented temperature of 47 (F) January 30, 2020 - documented temperature of 48 (F) January 31, 2020 - documented temperature of 45 (F) For the "Fridge Temp", the following dates had temperatures out, with no corrective action documented: January 27, 2021 - documented temperature of 9 (C) February 8, 2021 - documented temperature of 9 (C) October 19, 2021 - documented temperature of 9 (C) October 20, 2021 - documented temperature of 9 (C) October 21, 2021 - documented temperature of 9 (C) October 22, 2021 - documented temperature of 9 (C) November 22, 2021 -

documented temperature of 9 (C) November 23, 2021 - documented temperature of 9 (C) November 24, 2021 - documented temperature of 9 (C) January 12, 2022 - documented temperature of 9 (C) January 13, 2022 - documented temperature of 9 (C) January 14, 2022 - documented temperature of 9 (C) January 24, 2022 - documented temperature of 9 (C) January 28, 2022 - documented temperature of 9 (C) January 31, 2022 - documented temperature of 9 (C) Interview with lab staff on 2/18/2022 at approximately 1345 confirmed corrective actions had not been documented.