

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D2011214	<b>(X3) Date Survey Completed</b> 03/02/2021
<b>Name of Provider or Supplier</b> Forefront Dermatology, Sc	<b>Street Address, City, State</b> 801 York St, Manitowoc, WI	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review and comparison of procedures and maintenance checklists and interview with the Director of Laboratory Operations, the laboratory has not documented required maintenance for the Celldyn Ruby hematology analyzer in 2019 and 2020. Findings include: 1. Review of the laboratory's "M-3300 CELLDYN Ruby" procedure showed requirements for daily, weekly, and monthly tasks for the laboratory. 2. Review of the "Celldyn Ruby Daily/Weekly/Monthly Start-Up &amp; Maintenance Checklist" showed requirements for daily, weekly, and monthly tasks. 3. Comparison of the maintenance procedure and the laboratory checklist shows the following maintenance tasks are not included or documented on the checklist but are in the procedure: Weekly: Check sample pump tubing Change diluent in test tubes 5. Interview with the Director of Laboratory Operations on March 2, 2021 at 3:45 PM confirmed that not all tasks required in the procedure are included on the checklist and documentation was not available to show the laboratory completed the required maintenance in 2019 and 2020.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> 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</p>

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature logs from 2019 and 2020 and interview with the Director of Laboratory Operations, the laboratory did not document corrective action on forty-one of eighty-two days when the temperature readings were outside the defined acceptable range on the Drying Oven. Findings include: Item 1: 1. Review of the Drying Oven temperature logs revealed testing personnel did not document corrective action on temperature readings outside the acceptable range (55-70 degrees Fahrenheit) on the following days: March 2019: 7-8, 12, 20-21, 26 April 2019: 4, 26 June 2019: 13 August 2019: 26-30 September 2019: 30 October 2019: 3-4, 8-10, 16-17 November 2019: 4-5, 20 January 2020: 3 February 2020: 13 April 2020: 28 May 2020: 14, 18, 20 June 2020: 4-5, 9-10, 30 July 2020: 1 August 2020: 19, 20, 24 September 2020: 21 2. Interview with the Director of Laboratory Operations on March 2, 2021 at 12:15 PM, confirmed testing personnel did not document corrective action when the temperature readings of the Drying Oven were outside the acceptable range on forty-one of eighty-two days in 2019 and 2020. Item 2: Based on surveyor review of temperature logs from 2019 and 2020 and interview with the Director of Laboratory Operations, the laboratory did not document corrective action on eleven of twenty-one days when the temperature readings were outside the defined acceptable range on the Clinical Refrigerator. 1. Review of the Clinical Refrigerator temperature logs revealed testing personnel did not document corrective action on temperature readings outside the acceptable range (2-8 degrees Celsius) on the following days: May 2019: 3 July 2019: 18, 24 August 2019: 19, 28 September 2019: 4, 6, 20, 23, 25, 26 2. Interview with the Director of Laboratory Operations on March 2, 2021 at 12:15 PM, confirmed testing personnel did not document corrective action when the temperature readings of the Clinical Refrigerator were outside the acceptable range on eleven of twenty-one days in 2019 and 2020.