

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0900158	<b>(X3) Date Survey Completed</b>  12/09/2020
<b>Name of Provider or Supplier</b>  Idaho Dermatologic Surgery & Laser Center	<b>Street Address, City, State</b>  999 N Curtis Rd #505, Boise, ID	
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>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 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 a record review of cryostat temperature logs and an interview with the laboratory technician on 12/09/2020, the laboratory failed to document corrective actions when the cryostat was performing outside of the laboratory's established temperature parameters. The findings include: 1. A record review of the Avantik cryostat temperature/cleaning logs for 2019 and 2020 revealed that the laboratory failed to document corrective actions for temperatures below the laboratory's established temperature range of -25C to -30C for the following: 2 days in September of 2019, 3 days in July of 2020, 1 day in August 2020, 2 days in September of 2020, 2 days in October of 2020, and 2 days in November of 2020. 2. An interview with the laboratory technician on 12/09/20 at 11:15 am confirmed that the laboratory failed to document corrective actions documented for out of range temperatures for the Avantik cryostat for the above days in 2019 and 2020. 3. The laboratory reports performing 500 Moh's micrographic surgery cases per year.</p>