

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0961471	<b>(X3) Date Survey Completed</b>  10/28/2021
<b>Name of Provider or Supplier</b>  Alden Lakeland	<b>Street Address, City, State</b>  820 W Lawrence Ave 3rd Floor Vent, Chicago, IL	
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 record review and interview, the laboratory failed to take corrective actions when the environmental conditions did not meet the manufacturer's established operating parameters for 291 out of 396 days of testing. Findings include: 1. The temperature and humidity log from January 2020 through September of 2021, the Optic CCA Blood Gas analyzer operator's manual, and corrective action reports were reviewed. 2. The laboratory used the Optic CCA Blood Gas analyzer to perform basic testing of pH, carbon dioxide partial pressure (PCO2), and oxygen partial pressure (PO2),. 3. The manufacturer's manual defined under 'Section 9.5.2-Test Conditions', the environmental requirement for Relative humidity as 5% - 95% (non-condensing). 4. The temperature/humidity logs revealed the laboratory failed to adjust the Relative humidity for 291 out of 396 days when below 5%. 5. The laboratory failed to establish and perform corrective action procedures to ensure environmental requirements were met prior to conducting control procedures and patient testing. 6. On a Recertification survey conducted on 10/28/2021 at 11:15 AM, the general supervisor confirmed the above findings.</p>