

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1044440	(X3) Date Survey Completed 01/23/2020
Name of Provider or Supplier Cpn, Inc DbA Atrium Health Lc Indian Trail	Street Address, City, State 6030 Highway 74 West, Suite F, Indian Trail, NC	
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
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 review of the laboratory's Temperature and Humidity Requirements for all instruments, the manufacturer's Operator's Manual, a review of 2019 Temperature and Humidity Log, and interview with TC (Technical Consultant) 1/23/20, the laboratory failed to take and document corrective action for humidity readings outside the acceptable limits. The laboratory's "Temperature and Humidity Requirements' reads, ... Beckman AcT Diff: 20-85% non-condensing." The manufacturer's Operator Manual read on page 1-2. "...Ambient Temperature and Humidity, Keep room temperature between 16 degrees C (Celsius) and 35 degrees C (Celsius) (61 degrees F (Fahrenheit) and 95 Degrees F (Fahrenheit) and humidity to between 20 and 85% percent without condensation...". Review of 2019 Temperature and Humidity Logs revealed recorded humidity readings below acceptable limits on the following days with no corrective action documented: a. March 2019: 14% humidity reading was documented on 3/5 and 4/4; b March 20019: 9% humidity readings was documented on 3/6-8, 3/19-20; c. March 2019: 19% humidity reading was documented on 3/12; d. March 2019: 17% humidity reading was documented on 3/18; e. March 2019: 15% humidity reading was documented on 3/27; f. March 2019: 12% humidity reading was documented on 3</p>

/28; g. March 2019: 17% humidity reading was documented on 3/29; h. April 2019: 10% humidity reading was documented on 4/2; During interview at approximately 4:00 p.m., the TC verified the low humidity readings and the absence of an acknowledgement or corrective action.