

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2071661	(X3) Date Survey Completed 04/29/2019
Name of Provider or Supplier Bethany Medical Center	Street Address, City, State 495 Arbor Hill Road Suite M, Kernersville, 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
D6095	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, review of 2017, 2018, and 2019 "Room Humidity and Temperature Log Sheet" records, and interview with TP (testing personnel) on 4/29/19, the laboratory director failed to ensure the establishment and maintenance of acceptable ranges for room temperature and humidity that were consistent with manufacturer's instructions for accurate and reliable test performance. Findings: 1. Room temperature Review of manufacturers' instructions for the Tissue Tek VIP, Tissue Tek TEC, Tissue Tek DRS, Tissue Tek SCA, ELGA, Tissue baths, and Ventana revealed various operating temperature ranges between 5 and 40 degrees Celsius (41-104 degrees Fahrenheit). For example, the Ventana specifies an acceptable operating range of 20-32 degrees Celsius (68-89.6 degrees Fahrenheit). Review of the laboratory's "Room Humidity and Temperature Log Sheet" revealed an acceptable room temperature range of 59-77 degrees Fahrenheit which was not consistent with the manufacturers' instructions for all equipment. 2. Room humidity Review of manufacturers' instructions for the Tissue Tek VIP, Tissue Tek TEC, Tissue Tek DRS, Tissue Tek SCA, ELGA, and Ventana revealed various operating humidity levels between 0 and 90%. Review of the "Room Humidity and Temperature Log Sheet" revealed an acceptable range of 20-80% for Room Humidity which was not consistent with the manufacturers' instructions for all equipment. For example, the Tissue Tek SCA specifies an operating humidity of 30-70%. During interview at approximately 2:30 p.m. TP #1 confirmed the laboratory was using the documented range of 20-80% for humidity. TP #1 stated the acceptable range was updated after the last survey based on manufacturer's instructions for the Ventana, but specifications for all other equipment might not have been reviewed. Random review of "Room</p>

Humidity and Temperature Log Sheet" records revealed room humidity readings were documented below 30% on 40 of 162 days in January, February, and March 2019.