

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0972782	(X3) Date Survey Completed 01/12/2026
Name of Provider or Supplier Ramakrishna P Kanuri Md Pa	Street Address, City, State 12190 Cortez Blvd, Brooksville, FL	
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
D0000	<p>An announced CLIA initial survey was conducted at Ramakrishna Kanuri MD, PA on 01/12/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows: (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, it was found the Laboratory failed to monitor the room temperature and humidity where histology equipment is used and stored from 11/27/2024-01/12/2026 in two of two rooms (Room #1 and Room #2). Findings Include: 1) During tour of lab at 11:50am on 1/12/26, it was noted the lab has a Thermoscientific thermometer in Room #1. No thermometer was observed in Room #2 and confirmed by Laboratory director at 11:56am on 1/12/26 by</p>

Laboratory Director (LD). 2) Review of the laboratory's charts revealed no chart(s) or logs kept for Room #1 or Room #2 monitoring the temperature and humidity. According to the "Policy and Procedure" manual signed by LD on 11/24/2025, lab policy states, "To ensure accuracy of the temperature and humidity, utilized in the laboratory. Satisfactory functioning of all equipment depends on daily monitoring. The FDA regulatory guidelines an optimal temperature for labs as being between 68 degrees and 77 degrees F, with a humidity levels between 30% and 50%." 3) Interview with the Laboratory Director and TP#A at 12:15pm confirmed that no temperature or humidity is recorded for either Room #1 or Room #2.