

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2005819	<b>(X3) Date Survey Completed</b>  11/05/2025
<b>Name of Provider or Supplier</b>  Novant Health Primary Care South Rowan	<b>Street Address, City, State</b>  1965 South Us Hwy 29, China Grove, NC	
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>D6073</b>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4)</p> <p>(b)(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2024 and 2025 temperature and humidity logs 11/5/25, testing personnel failed to follow the laboratory's corrective action policies for temperatures outside the acceptable limits. Findings: Review of the "Lab General Maintenance" policy revealed "... 3. Temperature and humidity must be recorded for the testing area and any refrigerators, freezers, and/or area outside of the testing area used for storage of reagents, controls, or patient specimens. ... 4. Temperatures and humidity must be within acceptable limits each day of patient testing. a. Corrective action is indicated when any temperatures or humidity readings are outside of acceptable range; this should be documented on the temperature/general maintenance log or in a quality assessment report. b. If the refrigerator, incubator, or freezer malfunction, or the room temperature or humidity is not acceptable after corrective action, reagents, controls, and/or patient specimens should be sent to another location for storage until the equipment is repaired or the problem is corrected. Document and monitor the temporary location. ..." 1. Review of 2024 and 2025 temperature and humidity logs revealed documented refrigerator temperatures below the acceptable range of 2-8 degrees Celsius on the following dates: a. 2024 - 3/6, 3/8, 4/23, 4/24, 4/25, 5/22, 5/29, 5/30, 6/5, 6/13; b. 2025 - 7/29, 7/30, 7/31, 9/18. 2. Review of 2024 and 2025 temperature and humidity logs revealed documented room temperatures above the acceptable range of 20-25 degrees Celsius on the following dates: a. 2024 - 8/9, 8/19. The technical consultant had noted the out-of-range temperatures during review and had documented patient look-backs as needed, but there was no documentation to</p>

indicate that testing personnel took any corrective action for the out-of-range temperatures.