

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2089691	(X3) Date Survey Completed 05/06/2025
Name of Provider or Supplier Wakemed Urology	Street Address, City, State 210 Ashville Ave, Cary, 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 laboratory policy, review of 2024 and 2025 temperature and humidity logs, and interview with technical consultant (TC) 05/06/25, the laboratory failed to document corrective action when humidity was out of range for approximately 10 days in 2024 and approximately 22 days in 2025. Findings: Review of laboratory policy "Quality Assurance Pathology" revealed under Section VI. Quality Control, "f. Temperature and humidity are reviewed and documented each day of patient testing. i. If temperature and humidity are outside of range, corrective action must be taken before patient testing can be performed.'. The policy fails to state what corrective actions should be performed if temperature and/or humidity are out of range. Review of 2024 and 2025 temperature and humidity logs revealed the following the following dates in which humidity was out of range and no corrective action was noted. The dates had an asterisk and the monthly logs had a notation for the asterisk stating "Frigid temperatures outside". a. 6 days in January of 2024; 01/05, 01/17, 01/19, 01/22 and 01/23. b. 4 days in February of 2024; 02/07, 02/08, 02/19 and 02/20. c. 17 days in January of 2025; 01/03, 01/06 - 01/10, 01/13 - 01/17, 01/20 - 01/24 and 01/27. d. 4 days in February of 2025; 02/18, 02/19, 02/21 and 02/24. e. 1 day</p>

in March of 2025; 03/03. Interview with TC at approximately 11:00 a.m. confirmed the humidity ranges were out of range and no corrective action was documented.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of testing personnel (TP) education documentation 05/06/25 and the deficiency cited at D6065, the laboratory failed to verify that 2 of 10 TP met the minimum education requirements for performing moderate complexity testing.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) education documentation 05/06/25 and course transcript sent via email 05/19/25, the laboratory failed to verify that 2 of 10 TP met the minimum education requirements for performing moderate complexity testing. Findings: Review of TP #6 education documentation at time of survey revealed a foreign diploma and a transcription into English of the foreign diploma, there was no documentation of a foreign equivalency for the diploma. Review of TP #8 education documentation at time of survey revealed a foreign diploma and an associates degree in medical assisting, there was no documentation of a foreign equivalency for the diploma. Review of transcript for TP #8 associates degree in medical assisting sent 05/19/25 revealed the courses taken failed to meet the minimum requirements in biology and chemistry needed for the performance of moderate complexity testing.