

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2329038	(X3) Date Survey Completed 02/06/2026
Name of Provider or Supplier Rainbow Pediatrics Of Lumberton	Street Address, City, State 4300 Fayetteville Road, Lumberton, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on review of 2025 and 2026 laboratory temperature and humidity logs, and interview with Testing Personnel (TP #3) on 02/06/2026, the laboratory failed to monitor and document fridge and room temperatures, and humidity for 8 days of patient testing from 10/13/2025 to 10/17/2025 and 10/20/2025 to 10/22/2025. Findings: Review of the laboratory log "Temperature/Humidity Chart October 2025" revealed fridge and room temperatures, and humidity were not documented and recorded for the following eight days of patient testing: 10/13/2025 10/14/2025 10/15/2025 10/16/2025 10/17/2025 10/20/2025 10/21/2025 10/22/2025 During interview at approximately 12:22 p.m. TP #3 confirmed fridge and room temperatures and humidity were not recorded for 8 days. TP #3 said she had no idea why these days were missed.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient

identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of 7 random laboratory patient test reports from 2025 and 2026, and interview with Testing Personnel (TP #3) 02/06/2026, the laboratory test report failed to include the address where the test was performed. Findings: Review of 7 random test reports revealed the absence of the laboratory address for the following Identification (ID) numbers: 1. 245151 2. 250981 3. 270780 4. 317662 5. 319280 6. 319650 7. 320611 During interview at approximately 12:48 p.m. TP#3 confirmed the absence of the laboratory address on patient test reports.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of personnel records for 2025 and 2026, and interview with Testing Personnel (TP #3) 02/06/2026, the Laboratory Director (LD) failed to specify in writing the duties and responsibilities for the Clinical Consultant (CC) and Technical Consultant (TC) involved in the daily operation of the laboratory. Findings: Review of personnel records revealed the absence of a job description for the following positions: 1. CC 2. TC During interview at approximately 11:47 a.m. TP #3 confirmed no position descriptions were available for the CC and TC.