

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0874084	(X3) Date Survey Completed 01/08/2026
Name of Provider or Supplier Wingate University Health Center	Street Address, City, State 109 N Camden Rd, Wingate, 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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2025 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with technical consultant (TC), the laboratory failed to perform and document the review of ungraded PT results. Findings: Review of API PT 2025 Microbiology - 1st Event revealed the laboratory received 2 "Not Graded" results and "See Data Summary" for Febridx Bacterial/Non-Bacterial Assay, samples BIS-01 and BIS-02. Review of 2025 PT records revealed no documentation the laboratory reviewed the data summary to ensure the accuracy of the ungraded PT results. Interview with TC at approximately 12:00 p.m. confirmed the "Not Graded" PT results were not reviewed for accuracy. They stated they assumed if the Performance Summary results were 100% there was no further action necessary.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:
Based on review of employee records and laboratory policies, lack of documentation and interview with technical consultant (TC) 01/08/26, the laboratory director (LD) failed to establish a competency assessment policy/procedure for the duties and responsibilities of the TC. Findings: Review of employee records and laboratory policies revealed no documentation the LD established a competency assessment policy/procedure for the duties and responsibilities of the TC. Interview with TC at approximately 11:30 a.m. confirmed there was no policy or procedure for competency assessment of the TC.

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 employee records, lack of documentation and interview with technical consultant (TC) 01/08/26, the laboratory director (LD) failed to specify in writing the duties and responsibilities of the TC. Findings: Review of employee records for the TC revealed no documentation the LD specified in writing the duties and responsibilities of the TC. Interview with TC at approximately 11:30 a.m. confirmed the LD failed to specify in writing their duties and responsibilities. They stated they were unaware of this requirement.