

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2321543	(X3) Date Survey Completed 05/14/2026
Name of Provider or Supplier Prime Med Laboratory Inc	Street Address, City, State 14504 Friar St, Van Nuys, CA	
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, review of the documentation provided for the Respiratory Panel 2.1 verification of performance specifications, and interviews with the technical consultant (TC) and testing personnel (TP) on May 14, 2026, it was determined that the laboratory failed to provide completed and established verification of performance specifications when a new test system was introduced, as required by 493.1253(b). The findings include: 1. Surveyors reviewed the laboratory's verification of performance records for the BioFire Respiratory Panel 2.1 and determined that the documentation was incomplete and invalid. a. The TC and TP were only able to provide a summary of the concordance study, a summary of pooled sample results, and a quality control documentation that was dated at the end of the performance verification. b. The laboratory was not able to present the original raw data, including specimen level accuracy results (expected vs. observed), replicate data for precision, or operator level data. c. Lack of raw data prevents confirmation that the accuracy and precision to meet performance specifications as required under 493.1253(b). 2. Surveyors reviewed the laboratory's written policy, which states that verification will be conducted in accordance with manufacturer instructions and FDA cleared requirements for accuracy, precision, reportable range (if applicable), and reference

	range (if applicable). However: a. Documentation of laboratory director review and approval of the verification was not found, despite policy language requiring the laboratory director to make final acceptance decisions. b. The documentation available at the time of survey was limited to summary sheets only, without any underlying data to demonstrate the performance elements listed in the policy. 3. During an interview on May 14, 2026, at approximately 10:50 a.m., the TC and TP affirmed that they were unable to provide complete documentation of the verification of performance specifications for the Respiratory Panel 2.1. They confirmed that no raw data was retained beyond the summary tables. 4. According to the testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 48,000 tests for Microbiology annually that included the Respiratory Panel 2.1 wherein the verification of performance specifications for the test was incomplete and invalid
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on the deficiency cited, the technical consultant is herein cited for insufficient responsibility for verifying and documenting test system's accuracy, precision, reportable range, and reference range prior to testing patients specimen. See D5421