

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0467077	(X3) Date Survey Completed 03/20/2026
Name of Provider or Supplier Prime Medical Group Pllc	Street Address, City, State 9601 Baptist Health Drive, Little Rock, AR	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instruction, temperature and humidity logs, and interview with staff, the laboratory failed to follow manufacturer's instructions for operational environment relative humidity for the HistoStar. Findings follow: A) Review of the HistoStar instrument manual (HistoStar Operator Guide, A81010100 Issue 10, September 2020), revealed the operating environment for relative humidity is " Max. 80% RH up to 31C decreasing linearly to 50% RH at 40C". B) Upon request the laboratory was unable to provide humidity measurements for the laboratory. C) During an interview on 2/25/26 at 10:28 am the testing personnel #3 (as listed on the CMS-209 form) confirmed that humidity was not recorded in the laboratory.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p>

This STANDARD is not met as evidenced by:
Based on a review of the quality control records and through interviews with laboratory personnel, the laboratory failed to document quality control of histological staining. Findings follow: A. A review of the "Consolidated Complete Staining Run" log for February 2026 revealed 123 stains performed and no documentation of quality control checks. B A review of the "Monthly Hand Stain QC" log from July through December of 2025 revealed 44 stains performed and no documentation of quality control checks. B. Upon request the laboratory was unable to provide alternative documentation of quality control checks for the above tests. C. In an interview at 10:48 a.m. on 3/20/26, testing personnel #3 (as listed on the form CMS-209) confirmed that documentation of stain quality control for the above tests was not available.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on policy, lack of documentation, and interview the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in analytic systems. Finding follow: A. The laboraotry's Quality Assurance Manual states "The Laboratory Director reviews all quality control charts and logs on a regular basis." B. Upon request, no documentation showing Laboratory Director Review of "Monthly Hand QC Stain" logs for July through December 2025 and "Consolidated Completed Staining Run" logs for February 2026 was available. C. At 10:38am on 3/20/26 testing personnel #3 (as listed on the CMS-209 form) confirmed that documentation of laboratory director review for the above quality control logs was not available.