

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0306704	(X3) Date Survey Completed 05/20/2026
Name of Provider or Supplier Premier Medical Group	Street Address, City, State 490 Dunlop Lane, Clarksville, TN	
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
D0000	During a recertification survey performed on May 19 and May 20, 2026, the laboratory was found out of compliance with the following conditions: 493.801 Condition: Enrollment and testing of samples.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (FORM CMS-116), American Proficiency Institute (API) 2025 and 2026 Proficiency Testing (PT) records, API 2025 and 2026 Program Catalogs, and staff interviews, the laboratory failed to enroll in PT for the detection of the presence or absence of bacteria in urine culuture in 2025 and 2026, with approximately 229 patient urine cultures reported in 2025, and approximately 76 urine cultures reported in 2026. The findings included: 1. A review of the laboratory's FORM CMS-116 revealed that the laboratory performed urine culture for the presence or absence of bacteria and colony count using the Aidian Uricult media. 2. A review of the laboratory's 2025 and 2026 API PT records revealed the laboratory was not enrolled in PT for detection of bacteria in urine culture. 3. A review of the API 2025 and 2026 PT Program catalogs revealed the availability of Urine Culture Program 314, that included five urine culture samples per event with three shipments per year</p>

that was compatible with the Uricult method. 4. Technical Consultant Two stated on May 19, 2026, at 2:45 p.m. that the laboratory performed 229 urine cultures in 2025 and 76 urine cultures in 2026. 5. Technical Consultants Two and Three confirmed the findings on May 20, 2026, at 2:30 p.m.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's API PT records and staff interviews, the laboratory failed to retain one of twenty-five PT attestation statements (2024 Hematology Event Two) and failed to retain one of twenty-five PT performance evaluation reports (2025 Hematology Event One). The findings included: 1. A review of the laboratory's API PT records revealed that the attestation statement from 2024 Hematology, Event Two, was not retained; the Performance Evaluation report for 2025 Hematology, Event One, was not retained. 2. Technical Consultants Two and Three confirmed the findings during an interview on May 20, 2026, at 2:30 p.m.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), a review of competency assessment records, a lack of documentation, and staff interview, the laboratory failed to follow the policy for performing annual competency assessment for two of eleven established testing personnel who performed urine culture using the Aidian Uricult media in 2025. The findings included: 1. A review of the laboratory's policy titled "Competency Assessment" stated that each laboratory employee would be evaluated upon initial hire, semi-annually during the first year of employment, and each calendar year thereafter for procedures that the employee is qualified to perform. 2. A review of the FORM CMS-209 revealed that eleven of the laboratory's testing personnel performed urine culture and urine colony count testing. 3. A review of the laboratory's annual competency assessment forms revealed that the laboratory lacked documentation of competency assessment for testing persons thirteen and twenty one as listed on FORM CMS-209 for urine culture and colony count testing in 2025. 4. Technical Consultant Two stated that in 2025, testing person eleven performed four urine colony count tests and testing person nineteen performed two urine colony count tests during an interview on May 19, 2026, at 2:45 p.m. 5. Technical Consultants Two and Three confirmed the findings on May 20, 2026, at 2:30 p.m.