

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1060453	(X3) Date Survey Completed 06/08/2023
Name of Provider or Supplier Premier Medical Center, Inc	Street Address, City, State 5390 Dorchester Road, Charleston, SC	
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	A Recertification Survey was initiated on 06/08/2023 and concluded on 06/08/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on policy review, interview, and document review, it was determined the Laboratory Director (LD) failed to ensure the competency of the Technical Consultant (TC) was assessed. Findings included: A review of the policy titled, "Personnel Competency Assessment," reviewed 01/19/2023, revealed, "Summary and Explanation /Intended Use: Laboratory staff who conduct the pre-analytical, analytical, and post-analytical phases of testing will be monitored to assure that they are competent and maintain their competency to process specimen, perform test procedures and report test results promptly and proficiently." The policy further indicated, "Other staff members are also required to prove their competency in relationship to the specific duties they are required to perform." A review of the "Laboratory Personnel Report (CLIA) [Clinical Laboratory Improvement Amendments]," signed by the LD and dated 06/08/2023, indicated the laboratory had one TC who function in chemistry. A review of the TC's personnel folder, revealed there were no competency evaluations. During an interview with the LD and TC on 06/08/2023 at 3:45 PM, both stated the TC had not had any competency evaluations.</p>