

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2242874	(X3) Date Survey Completed 07/22/2024
Name of Provider or Supplier Commonwealth Dermatology Pllc	Street Address, City, State 100 Mlk Jr Blvd, Worcester, MA	
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 CLIA initial survey was conducted on 07-22-2024 for Commonwealth Dermatology laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director on 07-22-2024, the laboratory failed to follow the procedure and policy for twice annual verification of testing that is performed that is not included in subpart I of this part as evidence by the following: The surveyor reviewed the laboratory's procedure for Proficiency Testing policy for review of Mohs histopathology skin tissue slide cases. The review revealed that semi-annually, the Mohs histology technician or Laboratory director will select and send two cases to a reference laboratory. The reference laboratory to send the histopathology slide cases is Informed Diagnostics, Irving TX. A review of records from 12-05-2023 through 07-22-2024 revealed no cases had been sent and no cases were in the process of being sent to Informed Diagnostics. The Proficiency Testing procedure had not been implemented. The Laboratory Director was interviewed at 12:15pm on 07-22-2024 and confirmed that twice annual accuracy verification procedure for Mohs dermatology histopathology tissue slide cases had not been implemented and was not being performed. Laboratory performs (610) histopathology Mohs skin slide examination cases annually.</p>