

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0077881	(X3) Date Survey Completed 04/09/2021
Name of Provider or Supplier Newton Wellesley Dermatology Associates Pc	Street Address, City, State 65 Walnut Street Suite 302, Wellesley, 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 recertification survey was conducted for the Newton Wellesley Dermatology Assoc 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 on 4/9/2021, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: The surveyor reviewed the laboratory's quality assurance records for twice annual peer slide review of Mohs histopathology cases, Potassium Hydroxide (KOH) preparations, and wet mounts for scabies for calendar years 2019 and 2020 on 4/9/2021. The review revealed that laboratory did not verify accuracy twice annually for Mohs histopathology slides or wet mounts for scabies in 2019 and verified accuracy of KOH preparations once in July 2019. The laboratory director interviewed on 4/9/2021 at 4:15 PM stated that Mohs twice annual peer slide review was performed but not documented for calendar year 2019. The laboratory director confirmed that twice annual accuracy checks for scabies wet mounts were not performed in calendar year in 2019 and that KOH preparation accuracy checks were performed once in calendar year 2019. The laboratory performs 600 Mohs cases and 150 KOH/wet mounts annually. .</p>