

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2216358	(X3) Date Survey Completed 03/09/2023
Name of Provider or Supplier Leominster Dermatology, Llp	Street Address, City, State 101 Coolidge Street, Hudson, 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 Leominster Dermatology, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 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, the laboratory failed to follow policies and procedures for twice annual verification of testing it performs that is not included in subpart I of this part as evidenced by the following: a) A review of the laboratory's policies for histopathology skin slide case reviews for MOHS surgery indicated that the laboratory performs semiannual case reviews of 2 randomly selected cases. b) A review of histopathology skin slide case reviews performed for calendar year 2022 revealed that skin slide case reviews for accuracy verification were not performed semiannually during calendar year 2022. There was only one documented case review performed on 11/10/22. c) The pathology consultant interviewed on 3/9/23 at 9:00 AM confirmed that twice annual accuracy verification for histopathology cases had not been performed semiannually during calendar year 2022. The laboratory performs approximately 1,300 MOHS slide exams annually.</p>