

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2123702	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier Leominster Dermatology, Llp	Street Address, City, State 308 West Broadway, Suite 3, Gardner, 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, LLP dba Clearview Dermatology 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.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and record review, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date as evidenced by the following: a) During a tour of the laboratory on 5/2/23 at 10:35 AM, the surveyor observed the following expired item in the laboratory area where Physician Performed Microscopy Procedures (PPMP) are performed: * One (1) bottle of Potassium Hydroxide (KOH), expiration date 7/31/2020. b) There were no other in-date reagents available in the laboratory. Based on this evidence the accuracy and reliability of microscopic examinations, utilizing this reagent, could not be assured. Twenty four (24) patient sample for KOH were tested between 1/11/23 and 4/27/23. c) The laboratory performs approximately 1000 KOH preparations annually.</p>