

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1049111	(X3) Date Survey Completed 04/25/2022
Name of Provider or Supplier Dermath New England, Llc	Street Address, City, State 1380 Soldiers Field Road, Suite 3800, Brighton, 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 Dermath New England, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD) and the laboratory's general manager (GM) on 4/25/2022, the laboratory failed to indicate on the patient final test report the correct name of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed fifteen (15) patient final test reports between January 2020 and March 2022. The review revealed: The laboratory failed to indicate the correct name of the laboratory location where the test was performed for fifteen (15) out of fifteen (15) patient final test reports. The name of the laboratory on the patient final test reports was DermDX New England. The laboratory's name on the CLIA certificate is Dermath New England, LLC. The LD and GM confirmed on 4/25/2022 at 1:18 PM that the patient final test reports did not indicate the correct name of the laboratory where the test was performed. The laboratory reads 86,760 histopathology slides annually.</p>