

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2180282	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier Northeast Men's Health	Street Address, City, State 333 Elm St, Dedham, 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	An initial CLIA certification survey was conducted for Northeast Men's Health 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 Technical Consultant (TC) on 6/8 /2021, 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 eight (8) patient final test reports between June 2020 through April 2021 in the Electronic Medical Record (EMR), AdvancedMD. The review revealed: The laboratory failed to indicate the correct name of the laboratory location where the test was performed for eight (8) out of eight (8) patient final test reports. The name of the laboratory on the patient final test reports in the AdvancedMD EMR was North East Mens Clinic. The laboratory's name on the CLIA certificate is Northeast Men's Health. The TC confirmed on 6/8/2021 at 11:38 AM that the patient final test reports did not indicate the correct name of the laboratory where the test was performed. The laboratory performs 2,000 PSA and 2,000 Total Testosterone tests annually.</p>