

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D2180282	<b>(X3) Date Survey Completed</b> 04/09/2025
<b>Name of Provider or Supplier</b> Northeast Men's Health	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA recertification survey was conducted for the Northeast Men's Health laboratory on 04/09/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Persons #1 (TP1) and Testing Person # 2 (TP2) on 4/09/2025, the laboratory failed to have and follow written policies and procedures to evaluate the competency of the Technical Consultant (TC) as evidenced by the following: The surveyor reviewed the competency records on 4/09/2025 for the seven (7) laboratory personnel. The review revealed that an annual competency assessment was not performed for the former TC who was employed from 3/2024 to 3/2025. TP #1 and TP #2 confirmed in an interview on 4/09/2025 at 10:38 A.M. that an annual competency assessment had not been completed for the former TC who was hired from 3/2024 to 3/2025. The laboratory performs 2,000 PSA and 2,000 Total Testosterone tests annually. .</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>(c) 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</p>

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Testing Person #1 (TP1) and Testing Person #2 (TP2) on 4/09/2025, the laboratory failed to indicate on the patient final test report the correct address of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed eight (8) patient final test reports between September 2023 through April 2025 in the Electronic Medical Record (EMR), AdvancedMD. The review revealed that the laboratory failed to indicate the correct address of the laboratory location where the test was performed for four (4) out of eight (8) patient final test reports. For the four (4) patient final test reports one (1) indicated no laboratory address and three (3) indicated the laboratory's address as 11 Apex Drive, Marlborough, MA 01752. TP1 and TP2 confirmed on 4/09/2025 at 12:20 P.M. that the four (4) patient final test reports did not indicate the correct address of the laboratory where the test was performed. The laboratory performs 2,000 PSA and 2,000 Total Testosterone tests annually.