

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1088600	(X3) Date Survey Completed 10/23/2018
Name of Provider or Supplier North Shore Women's Center	Street Address, City, State 288 Groveland St, Haverhill, 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 Merrimack Valley Women's Health Services laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview the laboratory failed to authorize the proficiency testing (PT) program to release to Health and Human Services (HHS) as evidenced by the following: A review of the CMS CLIA Application and Summary report revealed no proficiency testing results for Immunohematology D (Rho) Typing. A review of PT documents for the third event in 2016 and calendar years 2017 and 2018 revealed that the laboratory's CLIA number was not listed on the American Proficiency Institute (API) PT reports. One testing person confirmed through interview at 10:30 AM that the API PT reports did not contain the laboratory's CLIA number therefore Immunohematology PT results were not released to HHS.</p>