

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D1085689	<b>(X3) Date Survey Completed</b>  07/27/2018
<b>Name of Provider or Supplier</b>  Atrius Health Plymouth	<b>Street Address, City, State</b>  36 Shops At 5 Way, Plymouth, 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 PMG Physician Associates laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in an approved proficiency testing (PT) program for each specialty and subspecialty for which it seeks certification as evidenced by the following: 1. PT record review revealed the laboratory failed to enroll in a PT program for Hematology for calendar year 2017. The Technical Supervisor confirmed through interview at 10:30 AM that the laboratory was not enrolled in Hematology PT for calendar year 2017. The laboratory performs 5978 Hematology tests annually. 2. PT record review of the 3rd event from 2016, calendar year 2017, and 1st and 2nd events in 2018 revealed the laboratory failed to enroll in an Endocrinology PT program for Human Chorionic Gonadotropin (hCG) serum test. The Technical Supervisor confirmed through interview at 10:30 AM that the laboratory was not enrolled in Endocrinology PT. The laboratory performs 40 serum hCG tests annually.</p>