

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D0951949	<b>(X3) Date Survey Completed</b> 01/19/2023
<b>Name of Provider or Supplier</b> Joslin Clinic Laboratory	<b>Street Address, City, State</b> One Joslin Place, Boston, 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 Joslin Clinic 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 proficiency testing (PT) record review and interview with the laboratory manager on 1/19/2023, the laboratory failed to enroll in an HHS approved PT program for the General Immunology subspecialty for which it seeks certification as evidenced by the following: The surveyor reviewed the College of American Pathologists (CAP) PT records from calendar years 2021 and 2022. The review revealed that the laboratory failed to enroll in an HHS approved PT testing program for the General Immunology subspecialty test Immunoglobulin A. The laboratory manager confirmed in an interview on 1/19/2023 at 11:42 AM that the laboratory failed to enroll in an HHS approved PT program for General Immunology for 2021 and 2022. The laboratory performs approximately 524 Immunoglobulin A tests annually. (Refer to D6041) .</p>
<b>D6041</b>	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) record review and interview with the laboratory manager on 1/19/2023 the Technical Consultant (TC) failed to ensure the laboratory enrolled in an HHS approved PT program for the General Immunology subspecialty as evidenced by the following: The surveyor reviewed the College of American Pathologists (CAP) PT records from calendar years 2021 and 2022. The review revealed that the TC failed to enroll in an HHS approved PT program for the General Immunology subspecialty test Immunoglobulin A. The laboratory manager confirmed in an interview 1/19/2023 at 11:42 AM that the TC failed to enroll in PT for General Immunology for calendar years 2021 and 2022. The laboratory performs approximately 524 Immunoglobulin A tests annually. (Refer to D2000).