

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0694769	(X3) Date Survey Completed 06/13/2022
Name of Provider or Supplier Gh Bendheim Laboratory	Street Address, City, State 77 Lafayette Pl, Ste 202-A, Greenwich, CT	
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
D2000	<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 staff interview, the laboratory failed to enroll in an approved Proficiency Testing (PT) program in a timely manner for 2021 and 2022 in the specialty of Hematology. Findings include: 1. Record review on 6/13/2022 of the American Association of Bioanalysts (AAB) PT records for 2021 and 2022 for 'Non-Chemistry and Hematology' revealed the lack of PT scores from AAB for Q1 event in 2021 and 2022 for the regulated analytes in the specialty of Hematology. 2. Record review on 6/13/2022 of the laboratory's 'Proficiency testing review' document revealed "Samples were received late and not submitted on time due to unpaid invoice. Graded according to the peer group by AAB." 3. Staff interview with the laboratory's general supervisor and administrative director (AD) on 6/13/2022 at 11:30 AM confirmed the above findings. The AD further stated that the corrective action in place from 2021 was not effective as the deficient practice recurred in 2022. 4. The laboratory performs 38,607 tests annually in the specialty of Hematology.</p>