

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2167404	<b>(X3) Date Survey Completed</b>  12/17/2025
<b>Name of Provider or Supplier</b>  Sharp Rees Stealy Clinics	<b>Street Address, City, State</b>  2020 Genesee Ave, San Diego, CA	
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>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 review of Proficiency Testing (PT) records and an interview with the Laboratory Director on December 17, 2025, it was determined that the laboratory failed to enroll in an approved PT program for peripheral smear slide review in specialty of hematology. The findings included: 1. It was practice in the laboratory to review peripheral hematology smear. The laboratory did not enroll in an approved PT program in 2023, 2024 and 2025. 2. On December 17, 2025, at approximately 10:00 am, the laboratory director affirmed that the laboratory did not enroll in an approved PT program for CBC differential. 3. The laboratory's testing declaration form, signed by the laboratory director on December 8, 2025, stated that the laboratory performed approximately 739 hematology tests annually.</p>