

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1079398	(X3) Date Survey Completed 07/14/2021
Name of Provider or Supplier Sharp Rees Stealy Clinics Laboratory	Street Address, City, State 10670 Wexford St, San Diego, CA	
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
D2100	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CAP (College of American Pathologists proficiency testing (PT) report and the CMS 0096D (CLIA Application and Survey Summary) on 07/14/2021 at 10:30 a.m. for 2019 and 2020 PT results, fifteen (15) randomly selected patients test records from 01/20//2020 to 04/23/2021 and an interview with the laboratory technical supervisor (TS); it was determined that the laboratory failed to participate in the proficiency testing event for endocrinology 1st event (Q1-2020) for free thyroxine (Free TY) and thyroid-stimulating hormone (TSH) resulting in a 0% score. The findings included: 1. The laboratory received a score of 0% for the 1st (Q1) CAP event of 2020 in the subspecialty endocrinology for the following analytes: Free thyroxine (Free TY) and thyroid-stimulating hormone (TSH). The technical supervisor affirmed 07/14/201 at 12:00 a. m. (survey date) that the CAP Q1-2020 PT 0% score was received for endocrinology. 2. Based on the laboratory's annual testing declaration submitted 07/13/2021 the laboratory analyzed and reported approximately 7,316 endocrinology (which included Free TY, TSH) test results reported.</p>