

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0691430	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Sharp Rees Stealy Clinics Laboratory	Street Address, City, State 525 3rd Ave, Chula Vista, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of reagent manufacturer's product insert, ten (10) random review of patients reports from 04/07/2017 to 02/26/2019, and interview with the technical supervisor and laboratory personnel, it was determined that for the years 2017, 2018 and 2019, the laboratory failed to follow manufacturer's instructions and disclose on patients reports limitations on test interpretation Prostate Specific Antigen (PSA) tests. The findings included: a. The laboratory performed Prostate-Specific Antigen (PSA) tests on the Beckman Access analyzer the Access Immunoassay systems reagents. The manufacturer's products insert states under PRINCIPLE, Warning: "The concentration of PSA in a given specimen determined with assays from different manufactures can vary due to differences in assay methods and reagents used. The results reported by laboratory to the physician must include the identity of the PSA assay used." b. On 02/26/2019 (survey date) the technical supervisor and staff personnel confirmed that the patients' electronic medical records (EMR) did not specify the manufacturer's assay on the patient's final report for PSA test results as mandated in the manufacturers package insert instructions. c. Based on the laboratory's annual testing declaration submitted on 02/26/2019, the laboratory analyzed and reported 1620 PSA test results.</p>