

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0890455	<b>(X3) Date Survey Completed</b> 02/16/2021
<b>Name of Provider or Supplier</b> Sharp Rees-Stealy Clinics	<b>Street Address, City, State</b> 5525 Grossmont Center Dr, La Mesa, 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>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in routing chemistry PT testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed routine chemistry including but is not limited to serum total protein (TP), which is in the list of subpart I of 42 CFR part 493. b. The laboratory enrolled with College of American Pathology (CAP) PT program. c. The laboratory attained a score of 0% in the Q3 2019 Chemistry PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed TP in approximately 2064 patient samples monthly. e. The laboratory testing personnel affirmed (2/16/2021 @ 12:35 PM) that the laboratory attained a score of 0% for TP in the Q3 2019 Chemistry PT event.</p>
<b>D2098</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) result reports, and interview with the laboratory testing</p>

personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in routing chemistry PT testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed endocrinology testing including but not limited to serum TSH and free T4, which are in the list of subpart I of 42 CFR part 493. b. The laboratory enrolled with College of American Pathology (CAP) PT program for TSH and FT4 c. The laboratory attained scores of 0% for TSH and FT4 in the Q1 2020 Endocrinology PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed TSH and FT4 each in approximately 500 patient samples monthly. e. The laboratory testing personnel affirmed (2/16/2021 @ 12:35 PM) that the laboratory attained a score of 0% for TSH and FT4 in the Q1 2020 Endocrinology PT event.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) result reports, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. The findings included: a. The laboratory enrolled with College of American Pathology (CAP) PT programs for its routing chemistry and endocrinology testing. b. The laboratory failed to attain at least 80 percent of acceptable responses for serum TP in the Q3 2019 routine chemistry PT testing (see D-2087). c. The laboratory failed to attain at least 80 percent of acceptable responses for serum TSH and FT4 in the Q1 2020 endocrinology PT testing (see D-2098).