

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0890455	(X3) Date Survey Completed 09/27/2018
Name of Provider or Supplier Sharp Rees-Stealy Clinics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2087	<p>ROUTINE CHEMISTRY 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) results reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attain a score of 80 % for each analyte in each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed routine chemistry including BUN for its patient samples. b. The laboratory enrolled its PT with CAP (College of American Pathologists) to ensure the accuracy of the testing system and meet the CLIA requirements. c. The laboratory attained a score of 40 % for BUN in the 1st 2018 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed BUN in approximately 3905 patient samples monthly. e. The laboratory testing personnel affirmed (09/27/18 @ 11:15 AM) that the laboratory attained a score of 40 % for BUN in the 1st 2018 PT event which was unsatisfactory analyte performance for the testing event.</p>
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory testing persons and the laboratory director, it was determined that the laboratory failed to provide, construct</p>

and maintain to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. The findings included: a. The laboratory area was limited to the area of 22 ft X 35 ft approximately. b. The laboratory performed in approximately total test volume of 974,232 in certified for 8 specialties and subspecialties with various size of instruments. c. The area also provides spaces for non-technical personnel to process the patient samples and prepare for send out samples. d. By observation of the laboratory operations, the technical people flow and non-technical personnel logistic movements in a rectangular space 22 X 35 sq ft approximately, the total area for this laboratory appears to be insufficient to provide well and quality laboratory operations.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory facility, review of the laboratory records, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to be 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. The findings included: See D-3001,

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 proficiency testing (PT) results reports and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of this 42 CFR 493. The findings included: See D-2089