

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0966538	(X3) Date Survey Completed 12/20/2021
Name of Provider or Supplier Sharp Rees-Stealy Clinics Laboratory-San Diego	Street Address, City, State 2929 Health Center Dr, 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
D2098	<p>ENDOCRINOLOGY 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 CAP (College of American Pathologists) proficiency testing (PT) results 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 each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed TSH which is in the list of subpart I of 42 CFR part 493, and enrolled with CAP PT program to ensure the accuracy, reliability, and timely of the testing results of TSH b. The laboratory attended a score of 0% for TSH in the Q1 2020 PT event which was unsatisfactory performance. c. The laboratory performed TSH in approximately 750 patient samples monthly. d. The laboratory testing personnel affirmed (12/20/21 @ 10:45 am) that the laboratory attained a score of 0% for TSH in Q1 2020 PT event which was unsatisfactory performance.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CAP (College of American Pathologists) proficiency testing (PT) results reports and interview with the laboratory testing</p>

personnel, it was determined that the laboratory failed to assure the evaluation of proficiency testing performance at least twice annually to verify the accuracy of any test or procedure, which is NOT listed in the subpart I of 42 CFR part 493, and the laboratory performed. The findings included: a. The laboratory performed Free T4 (FT4), which is NOT in the subpart I of 42 CFR part 493. b. To assure evaluation of proficiency testing performance at least twice annually, the laboratory elected to enroll a CAP PT program to verify the accuracy of FT4 testing procedure. c. The laboratory attained a score of 0 % for FT4 in the Q1 2020 PT event, which was unsatisfactory performance of that PT event. d. The laboratory performed FT4 in approximately 130 patient samples monthly. e. The laboratory personnel affirmed (12 /20/21 @ 10:50 am) that the laboratory attained a score of 0% for FT4 in the Q1 2020 PT event which was unsatisfactory performance.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's histology patient test result reports and its quality assurance records, and interview with the laboratory director and the laboratory staff, it was determined the laboratory failed to indicate, but are not limited to the following information, 1) the name and address of the laboratory location where the test was performed, 2) the test report date, 3) the test performed, 4) specimen source, when appropriate, 5) the test result and, if applicable, the units of measurement or interpretation, or both, 6)) any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. The findings included: a. The laboratory performed histopathology (frozen section) onsite. b. Review of an example of the "Anatomic Pathology Reports", 03-SP -21 -0000385 01-11-06-69, as a laboratory patient test result report. b. The laboratory failed to have a report title, except "Anatomic Pathology Report". c. The format of the report title failed to clearly indicate the laboratory's name and address where the test performed, including the laboratory director's name (CA State Clinical laboratory regulations). d. The laboratory failed to indicate the collection date or performed date and a report date in the final patient test result report.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Anatomic Pathology Report Quality Assurance records, and interview with the laboratory director and the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures to assure the consistency of its written policies and the procedures performed, and failed to assure an ongoing mechanism to monitor, assess, and to evaluate the testing personnel's proficiency testing performance, and to ensure the accuracy, reliability, and timely of the patient test result reports, and, when indicated, correct problems identified in the postanalytical systems. The findings included: a. The laboratory performed histopathology diagnoses while undergoing a frozen section procedure. b. To assure the evaluation of proficiency testing performance, and to ensure the accuracy, reliability, and timely of the laboratory's "Anatomic Pathology Report", the laboratory established written its quality assurance policies and procedures. c. The laboratory used a form identified as "Quality Assurance" to verify the accuracy of the testing results by peer review for consensus of the diagnosis and verify the accuracy of the patient demographics information, date, and site, if any, on the slide labeling, at least twice annually. d. The laboratory failed to document and indicate the "Quality Assurance" records with peer reviewer's initial or signature and/or proper date. .

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 results 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 for the analyte listed and not listed in the subchapter I of 42 CFR part 493. The findings included: a. The laboratory performed TSH which is in the list of subpart I of 42 CFR part 493 and enrolled with CAP (College of American Pathology) PT program to ensure the accuracy, reliability, and timely of the testing results. b. The laboratory failed to attend a score of 0% for TSH in the Q1 2020 PT event which was unsatisfactory performance see D-2098 c. The laboratory performed Free T4 (FT4), which is NOT in the subpart I of 42 CFR part 493. d. To ensure the accuracy of the testing performance at least twice annually, the laboratory elected to enroll a CAP PT program to assure the evaluation of proficiency testing performance of FT4. e. The laboratory attained a score of 0 % in the Q1 2020 PT event, which was unsatisfactory performance of that PT event, see D-5217

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's "Quality Assurance" records, the patient's final "Anatomic Pathology Report" reports, and interview with the laboratory director and the laboratory staff, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory performed histopathology (frozen section) on site. b. The laboratory performed evaluation of proficiency testing performance by peer review, at least twice annually, to verify the accuracy of the testing results for histopathology diagnosis and quality assurance to assure the final patient pathology report were accurate, reliable, and timely completed c. The laboratory failed to ensure that the quality assessment programs were performed and maintained to assure the quality of laboratory services provided, see D-5805 and D-5891