

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2057857	(X3) Date Survey Completed 01/17/2020
Name of Provider or Supplier Sansum Clinic - Hitchcock	Street Address, City, State 215 Pesetas Ln, Santa Barbara, 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
D5463	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient test records, quality control testing records, and interview with the Laboratory testing personnel, the laboratory failed to rotate control material testing, over time, among all operators who perform the test. The findings include: a. The laboratory has a total of 16 testing persons who perform the testing of patient samples. However, a random review of last 2 years testing records of the quality control material showed that only testing person #1 had performed the testing. b. The laboratory testing person, on 1/17/2020 at 2:30 pm, affirmed that the laboratory did not rotate the quality control material among the testing persons for testing. c. The laboratory's testing declaration form, signed by the laboratory Director on 1/8/2020, stated that the laboratory performs 1,200 tests, annually.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, patient & quality control test records, testing personnel qualifications, training & competency records, and interview with the Laboratory testing personnel, it was determined that the laboratory director failed to ensure that the quality control and testing personnel competency assessment programs are maintained to assure the quality of laboratory services provided. See D5463 and D6046.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, patient test records, testing personnel competency evaluation records and interview with the testing personnel, the laboratory Technical Consultant failed to evaluate the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The findings include: a. The laboratory's testing personnel competency evaluation records for last 2 years showed that the evaluation was performed by the testing person #1, and not by the Technical Consultant. b. The laboratory testing personnel, on 1/17 /2020 at 2:40 pm, affirmed that the laboratory Technical Consultant just developed the competency evaluation form but never evaluated testing personnel competency. The competency was evaluated by the testing person #1, instead. c. The laboratory's testing declaration form, signed by the laboratory Director on 1/8/2020, stated that the laboratory performs 1,200 tests, annually.