

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2224791	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Sc Medical Inc	Street Address, City, State 27550 Newhall Ranch Rd Unit 203, Valencia, 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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (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.</p> <p>This STANDARD is not met as evidenced by: Based on the deficiency cited for the technical consultant, a review of staff competency, delegation of responsibility documentation, and interviews with the managing director and medical assistant on December 17, 2025, the laboratory director is herein cited for failure to ensure that the established delegation of responsibilities documentation and policy were followed. The findings include: 1. The laboratory failed to follow the established policy and delegation of responsibilities documentation regarding the competency assessment of staff which were performed by medical assistants. See D6046 . .</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:

Based on the review of laboratory's policy and procedure, competency assessment documentation for the years 2023, 2024 and 2025, patient records, and an interview with the managing director and medical assistant (MA) on December 17, 2025; it was determined the technical consultant is herein cited for the deficient practice in failure to perform or document the personnel competency assessment to ensure that individuals maintained the necessary competency to conduct test procedures in a timely, accurate, and proficient manner. The findings include: 1. The surveyor reviewed the laboratory's policy and procedure and found the document entitled "Delegation of Tasks" that stated both the laboratory director and technical consultant are responsible for competency review of staff wherein this was not adhered to. 2. Ten records were reviewed by the surveyor and found that medical assistants were considered as testing staff. Also, their competency was not performed by either the technical consultant or the laboratory director. Thus, the accuracy and reliability of patient testing cannot be assured. 3. The managing director and MA stated in an interview on December 17, 2025, at approximately 11:30 a.m. that staff competency were performed by medical assistants and are later signed by the technical consultant and laboratory director. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported 1,500 Hematology tests annually including the period when competencies of staff were performed by an unqualified personnel under 493.1405 or 493.1411