

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2071666	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier Su And Chang Dermatology Associates Apmc	Street Address, City, State 3600 N Verdugo Rd, Ste 210, Glendale, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation of testing personnel competency assessment records and interviews with the office manager (OM) and medical assistant (MA) on September 11, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish written policies and procedures to assess the testing personnel competency for the years 2022, 2023, and 2024. Findings include: 1. Based on the interviews with the OM and MA, it was determined that the scope of responsibilities of the MA involved duties as a histotechnologist, such as operating the cryostat, creating, staining, and labeling slides for Dermatopathology. 2. Based on the lack of the laboratory's policies and procedures and competency evaluations' records, it was determined that the laboratory failed to have an established written policies and procedures for competency assessment of the MA for Dermatopathology. 3. Based on the review of records, the laboratory failed to provide documentation of training and competency assessment for the MA performing tests for Dermatopathology for the years 2022, 2023, and 2024. 4. This deficient practice was affirmed by interviews with the OM and MA on September 11, 2024, at approximately 12:45 p.m. 5. Based on the declared annual testing volume submitted at the time of the survey, the laboratory processed and reported an estimated total volume of 2,103 Dermatopathology test samples for which competencies of the MA were not performed.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on the lack of the laboratory personnel competency evaluations for the years 2022, 2023, and 2024 and the interviews with the manager and medical assistant, the laboratory director is herein cited for failure to ensure that policies and procedures were established and followed to monitor individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens and perform test procedures promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209