Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0912268	01/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Scpmg San Marcos Laboratory	400 Craven Rd, Bld #3, Ste 236, San Marcos, 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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, preventive maintenance (PM) documentation, fifteen patient records, and interviews with the pathology manager and staff, it was determined that the laboratory failed to ensure performed tests and function checks were documented or maintained prior to patient testing. The findings include: 1. The laboratory performed Mohs micrographic skin cancer surgeries and had an internal Mohs technician team responsible for the technical component and related documentation. The acceptable range for the cryostat equipment was between -27C to -18C wherein the laboratory either failed to document on specific dates or used the cryostat equipment when it was at an out-of-range temperature. 2. The surveyor reviewed fifteen Dermatopathology patient testing records and found that the laboratory used more than one cryostat equipment but no designation was indicated for which was used on a specific patient case. A total of three records were found to be documented in an out-of-temperature, while two other records had missing entries. The discrepancies are as followed: a. Out-of-range temperature: i. Patient 1, SDXS23-9826, examined on 3/30/2023 at -28C. ii. Patient 6, SMAS24-6769, examined on 4/18/2024 at -14C. iii. Patient 14, SMAS24-17236, examined on 10/8/2024 at -28C. b. Missing temperature entries: i. Patient 13, SMAS24-12602, examined on 7/23/2024 ii. Patient 15, SMAS24-12599, examined on 7/23/2024 3. Further review of the laboratory's "Daily Maintenance and Inspection for

	(YEAR)" revealed that the almost the entire month of July 2024 was missing entries and patient blocks were processed. Since there was no indication in the reports for which equipment was used for specific cases, the laboratory was unable to verify. In addition, the succeeding months from August to December 2024 had every single entries for cryostat with an out-of range temperature for the HM550, SN30836. 4. No corrective action was performed when the trend of the temperature started. Thus, the quality and reliability of patient samples processed could not be assured. 5. The pathology manager and staff affirmed in an interview on January 8, 2026 at approximately 11:50 a.m. that the laboratory failed to address the issue with their cryostat when it was operating at an out-of-range temperature and that the inconsistencies documentation were not corrected upon its occurrence. 6. According to the testing declaration form (Lab-144) submitted on January 8, 2026, the laboratory performed and reported approximately 571 cases annually including the period when the discrepancies with the cryostat temperature and documentation occurred.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 the surveyor's review of the laboratory's policy and procedure, preventive maintenance log, randomly selected patient test records and interviews with the pathology manager and staff on January 8, 2026; the laboratory director is herein cited due to failure to ensure that quality assessment programs were followed and maintained to assure the quality of laboratory services provided and to identify errors as it occur. See D5435