

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2148484	<b>(X3) Date Survey Completed</b>  01/07/2026
<b>Name of Provider or Supplier</b>  Csi Medical Group	<b>Street Address, City, State</b>  1934 Via Centre Ste B, Vista, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(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.</p> <p>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, ten patient records, and interviews with the practice manager (PM), regional director (RG) and interim director of operations (IDO), 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 used an external Mohs technician company for processing wherein both the doctor and technician were responsible for documenting all phases of testing. 2. The surveyor reviewed ten patient records and found the following discrepancies: a. 6/20/2023 surgery date was missing an entry on the cryostat temperature affecting Patient 23-084. Further review of the patient log revealed that a total of seven patients including Patient 23-084 underwent surgeries on the same date. b. 6/11/2025 surgery date had no entry for the stain preventive maintenance affecting Patient 25-075 from reviewed records. 3. The PM, RG and IDO affirmed by interviews on January 7, 2026, at approximately 10:45 a.m. that the preventive maintenance entries were overlooked during the daily quality assessment check. 4. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 355 Dermatopathology cases annually, which included the period when errors in the preventive maintenance occurred as mentioned in this deficiency.</p>

**D5821**

**TEST REPORT**

CFR(s): 493.1291(k)

(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's quality assessment (QA) policy and procedure, randomly chosen patient test records, and interviews with the practice manager (PM), regional director (RG) and interim director of operations (IDO), it was determined that the laboratory failed to address errors in patient records prior to finalizing reports. The findings include: 1. The surveyor reviewed ten randomly selected patient test records for Dermatopathology dated from June 20, 2023, to November 14, 2025 and one out of ten had a mismatch of patient information from several documentation checked such as the patient log, electronic chart notes, Mohs map, and slides. 2. There was a lack of corrective action documentation for Patient 25-180, examined on November 14, 2025 wherein the patient's name was inconsistent across records. 3. During an interview on January 7, 2026, at approximately 10:45 a. m., the PM, RG and IDO stated in an interview that the current responsibility of ensuring the completion of the documentation and integrity of records was to the doctor and Mohs technician and that no corrective action was performed as mentioned in the statements above. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 355 Dermatopathology tests annually, including the time when the discrepancy in the patient record 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 an interviews with the practice manager (PM), regional director (RG) and interim director of operations (IDO) on January 7, 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. The findings include: 1. The laboratory failed to document quality assessment activities. See D5435. 2. The laboratory failed to follow their policy to address and correct errors promptly. See D5821.