Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2164178	03/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Csi Medical Group	3311 Mission Drive, Santa Cruz, 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
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the Policies and Procedures documents, interviews with the office manager (OM) and compliance officer (CO), and lack of quality assessment documentation records on March 14, 2024; it was determined that the laboratory failed to perform and document analytic and postanalytic systems quality assessment necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. 1. Although the laboratory established a policy on Quality Assessment with a predetermined schedule of quality assurance activities consisting of QC Review, Personnel Training Evaluation, Test Tracking, Communication, Compliance Assessment, etc., no documentation of such activities was found. 2. The OM and CO confirmed on 03/14/2024 at approximately 12:00 p.m. that the laboratory fail to perform and document quality assurance /assessment activities. 3. According to laboratory testing declaration, the laboratory performs and reports approximately 1,004 patient tests annually.
D5821	TEST REPORT CFR(s): 493.1291(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 six (6) Mohs surgery records an interview with the office manager (OM) and the compliance officer (CO) two (2) out of six (6) Mohs patient reviews was discrepant in their findings and report. The findings included: 1. The survey team reviewed six (6) Mohs patient records. Two (2) out of six (6) records were discrepant as follow: a) One (1) patient had an incomplete file where no notes or mapping of the Mohs surgery records was found. b) The second discrepant patient had various descriptions of the location where the Mohs surgery was performed (medial pretibial region, calf, pretibial). Description of the site did not match the mapping area recorded. 2. The OM and CO affirmed during interview that the discrepancy described in number 1 (a,b) above was recorded erroneously. Further investigation is needed to be performed. No corrective action was available at the time of the survey. 3. The laboratory reported approximately 1,000 Mohs surgery cases performed annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of patients' Mohs test results records, inaccurate patient documentation, and interviews with the office manager and the compliance officer on March 14, 2024; the laboratory director failed to ensure that laboratory personnel are properly trained and competent for accurate and reliable reporting of test results. See D5821.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 surveyors' team review of laboratory's policy and procedure, quality assessment records, and interview with office manager and the compliance officer on March 14, 2024, the laboratory director failed to ensure that the laboratory maintained and documented quality assessment activities as stated on their policy. The findings include See D5793.