Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0605631	02/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Csi Medical Group	204 Green Valley Rd, Freedom, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on interview with Laboratory Regional Director and review of laboratory's Proficiency Testing (PT) records on February 7, 2025, it was determined that the Laboratory failed to ensure that the accuracy of the Mohs test was verified at least twice annually in 2024. The findings include: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery, which is not listed in subpart I of 42 CFR part 493. For test procedure not listed in subpart I, the laboratory must verify the accuracy of the test procedure at least twice annually. 2. According to the laboratory's written procedures for Mohs Micrographic Surgery proficiency testing, the laboratory selects three Mohs slides -one case every other month -twice annually, for a total of six cases per year for peer review. 3. On February 7, 2025, at approximately 10:00 am, the Laboratory Regional Director affirmed that the laboratory maintained no documentation to show it verified the accuracy of the Mohs procedure at least twice annually for the year 2024. The laboratory selected three cases from 1/3/2024, 3/20 /2024, and 5/15/2024, and slides were reviewed on 6/11/2024. The laboratory failed to verify the accuracy of the Mohs test for the second required event. 4. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 310 Mohs procedures annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems

	identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Laboratory Regional Director on February 7, 2025, the laboratory failed to follow its own written policies and procedures for Quality Assessment (QA) in 2022, 2023, and 2024. The findings include: 1. It was the practice of the laboratory to perform histopathology testing and prepare Mohs slides in-house. 2. According to the laboratory's written policies and procedures for quality control assessment, the Laboratory Director (LD) shall review all quality control logs at least quarterly. 3. On February 7, 2025, at approximately 11:00 am, the Laboratory Regional Director affirmed that the laboratory maintained no documentation to show that the LD reviewed the logs for 3 of 3 years. 4. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 310 Mohs procedures annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory documents, and interview with the Laboratory Regional Director, it was determined that the laboratory failed to maintain written policies and procedures for Provider Performed Microscopy (PPM) including potassium hydroxide (KOH) and direct wet mount preparation testing to examine the skin samples for fungal and scabies infections. The findings included: 1. The laboratory is a dermatology laboratory, currently performs moderate complexity KOH preparation, PPM testing, for the examination of the presence or the absence of yeast and parasites such as scabies, plus high complexity testing of histopathology including Mohs procedures. 2. On February 7, 2025, at approximately 9:30 am, the Laboratory Regional Director affirmed that the laboratory maintained no written procedures manual for potassium hydroxide (KOH) and direct wet mount preparation testing. 3. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 25 Mycology and 10 parasitology tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of reagents used for Mycology and Parasitology and interview

	with the Laboratory Regional Director on February 7, 2025, the laboratory failed to ensure testing personnel did not use expired reagents. The findings include: 1. It was the practice of the laboratory to perform Mycology and Parasitology using potassium hydroxide (KOH) reagent and mounting medium. 2. Observation on 02/07/2025 at approximately 11:00 am, showed the KOH reagent solution (lot number K215J6) had expired on 05/13/2024, and the Mounting medium solution (lot number 12380) had expired in 09/2024. The Laboratory Regional Director confirmed the expired outdates of the two solutions. 3. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 15 Mycology and 10 Parasitology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Regional Director and lack of documentation on February 7, 2025, it was determined that the laboratory failed to perform and document maintenance and calibration of the microscopes as defined by the manufacturer for the years 2022, 2023, and 2024. The findings include: 1. The laboratory performs microscopic review of histopathology slides as well as performing KOH and wet mount preparation. The laboratory microscopic testing performed on Olympus CH microscope. 2. On February 7, 2025, at approximately 11: 00 am, the Laboratory Regional Director affirmed that the laboratory maintained no documentation indicating the maintenance or cleaning performed on the microscope for 3 of 3 years. 3. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 335 microscopic tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on interview with Laboratory Regional Director, observation of reagents used in the laboratory, review of laboratory's policies and procedures manuals, quality assessment (QA) records, and Proficiency Testing (PT) records, it was determined that the Laboratory Director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart. See D5217, D5291, D5401, D5417, D5429.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)

	(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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. This STANDARD is not met as evidenced by: Based on review of competency assessments for Mohs Technicians and interview with the Laboratory Regional Director on February 7, 2025, the Technical Supervisor (TS) failed to ensure that Mohs Technicians received appropriate training and maintained their competency to prepare Mohs slides for the years 2022, 2023, and 2024. The findings include: 1. It was the practice of the laboratory to perform histopathology testing and prepare slides in-house. The Mohs Technicians were responsible for preparing slides for histological analysis. 2. On February 7, 2025, at approximately 11:00 am, the Laboratory Regional Director affirmed that the laboratory maintained no documentation for the training and competency assessments for 3 of 3 Mohs Technicians regarding preparation of Mohs slides. 3. The laboratory's testing declaration form, signed by the laboratory director on January 13, 2025, stated that the laboratory had performed 310 Mohs procedures annually.