Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0946352	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Csi Medical Group	2420 Samaritan Dr, San Jose, 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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: . Based on the surveyor's review of ten Histopathology patient records, lack of personnel competency documentation, and interviews with the laboratory administrators (LAs) and director of operations (DO); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessments for all testing personnel involved in patient testing. The findings include: 1. The laboratory failed to provide competency records for one out of three histology technicians (HT) for the years 2023 and 2024. 2. The LAs and DO stated in an interview on October 8, 2025, at approximately 10:50 a.m. that no competency records were found for the years 2023 and 2024. 3. According to the testing declaration form submitted at the time of the survey, the laboratory reported and performed approximately 70,754 Histopathology patient samples annually including the time when competency assessment for one of the testing personnel was missing for the years 2023 and 2024. . . .
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 the surveyor's review of the laboratory's policy and procedure, randomly chosen patient records, lack of proficiency testing records, and interviews with the laboratory administrators (LAs) and director of operations (DO); it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the years 2023 and 2024. The findings include: 1. The laboratory lacked proficiency testing records for all testing personnel (TP) performing the Provider-performed microscopy (PPM) and Histopathology tests for the years 2023 and 2024. 2. The surveyor reviewed ten patient records for PPM and Histopathology. Nine out of ten records were performed by different TP lacked PT records for the years 2023 and 2024. 3. The LAs and DO affirmed by interviews on October 8, 2025, at approximately 10:09 a.m., that the laboratory failed to locate PT records for all providers as mentioned in the statements above. 4. The laboratory's testing declaration form submitted at the time of the survey stated that 180 PPM and 70,754 Histopathology patient test samples were performed annually including the time when PT records were missing for the years 2023 and 2024. Thus, the reliability and accuracy of patient tests reported cannot be assured.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) (h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. (a) The laboratory must check the following for positive and negative reactivity using control organisms: This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedure, patient test records, and interviews with the laboratory administrators (LAs) and director of operations (DO), it was determined that the laboratory failed to document the performance of alternative control procedures. The findings include: 1. The laboratory routinely entered the results of potassium hydroxide (KOH) and scabies tests directly into the electronic medical record (EMR) system without maintaining separate documentation to monitor test performance and alternative control procedures. 2. The reviewed policy and procedure for KOH and ectoparasite lacked to specify an alternative control procedure to meet quality control requirement. 3. A review of five randomly selected patient records from 2023 to 2025 revealed that none included documentation for alternative controls. 4. According to the testing declaration form (Lab-144) submitted on October 8, 2025, the laboratory performed and reported 150 KOH and 30 scabies test samples annually during the time when no alternative control procedure was performed nor recorded. 5. The quality and reliability of patient test results reported cannot be assured.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or

(b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of ten Histopathology patient records and interviews with the laboratory administrators (LAs) and director of operations (DO); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessment for all personnel involved in patient testing. The findings include: 1. The laboratory performed Histopathology testing, not limited to gross examination and technical preparation of all specimens received. Grossing, a high complexity test, was performed by the three histology technicians (HT) who were unqualified under Code of Federal Regulations (CFR) 493.1489. 2. The LAs and DO stated in an interview on October 8, 2025, at approximately 9:30 a.m. that all three HTs were unlicensed and performed gross examinations, sometimes without supervision. 3. The quality and reliability of patient samples processed and reported could not be assured. 4. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 70,754 Histopathology patient samples annually wherein gross examination were performed by unlicensed personnel.