Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2087620	08/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Csi Medical Group	1127 Wilshire Blvd, Ste 600, Los Angeles, 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 the lack of the laboratory's policies & procedures, review of three (3) randomly chosen patients' Mohs reports, three (3) Histopathology slides, quality control records, peer review records, and interviews with the laboratory director (LD) and office manager (OM) on August 24, 2022 at approximately 12:15 p.m.; it was determined that the laboratory failed to verify, at least twice annually, the accuracy of its Mohs and Histopathology tests for the years 2020 and 2021 for two (2) out of two (2) Mohs and Histopathology testing diagnosing physicians. The findings included: 1. The laboratory did not have any documentation showing that it had verified its Mohs and Histopathology tests' accuracy for the years 2020 and 2021 for two (2) out of two (2) Mohs surgeons and dermatopathologists performing slide reading and providing patients' diagnosis. Therefore, the accuracy of the laboratory's test results for patients for Mohs and Histopathology procedures, cannot be assured. 2. The LD and OM confirmed at approximately 12:45 p.m., that the laboratory did not have any record to verify its Mohs and Histopathology test accuracy for the years 2020 and 2021 for two (2) testing physicians. 3. The laboratory's testing declaration form signed by the laboratory director, stated that the laboratory performs 500 Histopathology and Mohs tests annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyors' interviews with the laboratory director (LD) and the laboratory's office manager (OM) and record review of pre-analytic, analytic, and postanalytic remedial action records on August 24, 2022; the laboratory failed to establish written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's systems. Findings included: 1. According to laboratory LD and OM, during preanalytic, analytic, and postanalytic review of patients' processed Mohs and Histopathology slides, if a patient specimen was received or a report was issued that did not meet the laboratory's criteria for acceptability, a description as to why the specimen or report did not meet the laboratory's criteria for acceptability would be documented, appropriate corrective actions would be taken and noted, and the incident would be captured for quality assessment review. 2. Based on surveyor review of policies and procedures on 8/24/2022 at approximately 2:15 p.m.; it was determined that the laboratory failed to maintain written policies and procedures detailing the quality assessment process described. 3. According to the LD declaration statement, the laboratory performed approximately 530 patient tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the laboratory director (LD); it was determined that the laboratory failed to update protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey August 24, 2022, at approximately 11:45 a.m. the procedure manual in place had not been approved, signed, and dated by the laboratory director. 2. The LD affirmed on August 24, 2022, that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 530 patients test 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 the surveyors' observation, examination of laboratory reagents, and interview with the office manager (OM); it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings

	included: 1. On the day of inspection, August 24, 2022, at approximately 11:40 a.m. the surveyor found the KOH reagent used for microscopic examination for the presence of yeast and fungal elements grossly contaminated, no lot number indicated, and used beyond its expiration date (10/2014). In addition, two other bottles of KOH shown by OM were also expired. Other reagents such as Chlorazol Black E Lot # 8094 were also expired (4/4/2020). 2. The OM affirmed on 8/24/2022 at approximately 11:45 a.m. testing personnel using the KOH reagent beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 30 KOH mycology samples 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 review of the laboratory's records for policies and procedures, peer review records, use of expired reagents in Mycology, lack of a Quality Asseesment plan, and interview with the laboratory director and office manager on August 24, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D5217, D5391, D540, and D5417.