

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0555281	(X3) Date Survey Completed 06/14/2021
Name of Provider or Supplier Csi Medical Group	Street Address, City, State 289 Huntington Dr, Ste 208, Arcadia, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Evaluation of Proficiency Testing Performance (PT) documents, and interview with the laboratory personnel, it was determined that the laboratory failed to perform and document the PT and to verify the accuracy of the histopathology testing PT at least twice annually in 2019. The findings included" a. The laboratory performed Mohs surgery onsite and examined the histologic tissue slides to ensure the total removal of the skin malignancy in Mohs procedures. Histopathologic examination is NOT listed in the subpart I of 42 CFR part 493. b. In order to ensure and verify the accuracy of the histologic examinations, the laboratory elected to use peer review/split samples to have a second qualified personnel to examine the tissue slides with a "consent" or "agree" for the final findings. c. The laboratory failed to perform and document the PT twice in 2019 period. c. The laboratory affirmed (6/14/2021 @ 11:05 am) that the laboratory failed to perform and document the PT in 2019 to verify the accuracy of histopathology testing performance. d. The laboratory performed Mohs surgery in approximately 90 patients monthly.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's peer review records, and interview with the laboratory personnel, it was determined that the laboratory failed to follow its written policies and procedures (P&P) for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: a. The laboratory must follow its written P&P, an ongoing mechanism, to monitor, assess and verify the accuracy, consistency, and reliability of its laboratory operations, including pre-analytic, analytic, and post-analytic system. b. Review of nine (9) evaluation of proficiency testing performance records, one of the "Mohs Micrographic Surgery Quality assurance Review Histologic Interpretation of Mohs Slides" between the year of 2019 and 2021, one of the peer reviewer had dated 6/10 /2021 for the "DATE OF REVIEW: 03/01/2020" record, which is inconsistent in the record.

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 review of the laboratory records, and the Evaluation of Proficiency Testing Performance (PT) documents, and interview of the laboratory personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory performed Mohs surgery and examined the histologic tissue slides to ensure the total removal of malignant tissues. b. The laboratory failed to perform and document twice annually for PT in 2019 to verify the accuracy of the histologic testing performance, see D-5217 c. The laboratory failed to follow its quality assurance policies and procedures to verify the accuracy of the laboratory operations including preanalytical, analytic, post-analytic systems, see D-5891