

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2140871	(X3) Date Survey Completed 08/19/2021
Name of Provider or Supplier Artius Dermatology Associates, Pc	Street Address, City, State 573 W Putnam Ave, Porterville, 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 patients test records, the lack of laboratory documents, and interview with a laboratory person, it was determined that the laboratory had failed to verify the accuracy of Mohs procedures in 2019 - 2020. Findings included: 1. The laboratory's Mohs Log and records registered procedures performed in 2019, 2020, to present 2021. 2. The laboratory was unable to provide for review 2019 and 2020 documents verifying the accuracy of the Mohs procedures to clear tumor at final stage. 3. The laboratory person affirmed (8/19/21 @ 4pm) the aforementioned lack of laboratory documents and that the laboratory policy required at least twice annual review of Mohs slides by a dermatopathologist. 4. And thus the reliability and quality of Mohs procedures performed in 2019 and 2020 could not be assured. Based on the stated annual test volumes (CMS116, 8/18/21), the laboratory performed approximately 400 Mohs procedures annually.</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> <p>This STANDARD is not met as evidenced by: Based on review of patients electronic medical records (Visit Notes) and laboratory</p>

Mohs records and slides, and interview with a laboratory person, it was determined that the laboratory failed to maintain an ongoing postanalytic process to monitor and assess records and slides for discrepancies, and correct problems as they occur. Findings included: 1. On 3/19/20, Mohs procedures were performed on the patient RH: a. the Mohs maps and slides recorded the following: Slide # Site ----- 20 - 26 Left Anterior Crown 20 - 27 Central Anterior Crown 20 - 28 Left Posterior Crown 20 - 29 Left Central Crown b. the Visit Note, "Mohs Operative Note" failed to match the Maps and Slides: 1. (the Mohs Case Number was not stated) Right superior medial forehead 2. Mohs Case Number: 20- 26 Left superior medial forehead 3. Mohs Case Number: 20- 29 Left superior parietal scalp 4. Mohs Case Number: 20- 28 Left central parietal scalp 2. On 2/11/21, Mohs procedures were performed on the patient DB: a. the Mohs maps recorded the following: Slide # Site Stages ----- 21 - 22 Left Medial Forehead III 21 - 23 Right Postauricular Crease I b. The label of 1 out of 5 Mohs slides failed to match the Mohs map. The slide was originally labeled as "L med FH, 21- 22", but was crossed out and relabeled as "R post aur crease, II, 21- 23". 3. The laboratory person affirmed (8/19/21 @ 5pm) the aforementioned findings identified errors post-Mohs surgeries. And thus, the laboratory had failed to maintain an ongoing process to assure the quality of records after Mohs surgeries were completed. 4. The reliability and quality of the medical records, "Mohs Operative Note", and slide labels could not be assured. Based on the stated annual test volume, the laboratory performed approximately 400 Mohs procedures annually.

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 findings and cumulative deficiencies cited, the Laboratory Director is herein cited for deficient practice in ensuring quality assessment processes were maintained to assure quality and identify failures as they occur. Findings included: 1. The Laboratory Director was deficient in monitoring and identifying failures to at least twice annually verify the accuracy of Mohs procedures performed. 2. The Laboratory Director was deficient in monitoring, assessing, identifying, and addressing errors in postanalytic records of completed Mohs procedures.