

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2028950	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Center For Dermatology, Pllc	Street Address, City, State 14275 N 87th St Suite 110, Scottsdale, AZ	
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
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on review of amended test reports for testing performed in the sub-specialty of Histopathology and interview with the facility personnel, the laboratory failed to maintain duplicates of the original report, as well as the corrected report. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology with an approximate annual test volume of 1,526. 2. During the survey conducted on 12/15/20, review of patient test report (Accession# YSF19-0021, reported on 11/13 /19), indicated the test report was amended. The operative note contained in the electronic record for this patient contained a page titled "Frozen Path info correction" and stated, "Frozen Section Path info was entered in wrong. The Rt Superior Occipital Scalp diagnosis should be 'Well Differentiated SCC' and the clinical description was 'Islands of atypical squamous cells invading the dermis' ". 3. The final, amended test report for accession YSF19-0021 included a Final Diagnosis of "Squamous Cell Carcinoma, Well-differentiated" and the Clinical Description stated, "Islands of atypical squamous cells invading the dermis." 4. The laboratory failed to provide documentation of the original diagnosis on the test report indicated above. The patient's test report only contained the amended diagnosis, and did not include the original diagnosis reported prior to the correction. 5. The facility personnel confirmed that the laboratory failed to maintain copies of the original test report, as well as the corrected test report.</p>

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the facility personnel, (A) the laboratory failed to follow policies and procedures for signing off on pathology test reports in a timely manner and (B) the laboratory failed to establish a policy and /or procedure for amending pathology test reports. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the sub-specialty of histopathology, with an approximate annual test volume of 1,526. The laboratory utilizes an electronic medical record (EMR) system to maintain patient records, including Mohs test reports which are electronically signed by the physician who made the diagnosis. A2. The laboratory's established policy titled, "Providers Chart Review" (policy# 100.003) states, " All physicians and Nurse Practitioners must review and sign off patients charts within 72 hours of patients being seen virtually or in person." A3. Review of Mohs test reports indicated the laboratory failed to follow the established policy and sign off on patients' test reports within 72 hours of the procedure as evidenced by the following cases reviewed during the survey: PSM19-186 - Date of Service (DOS) 7/15/19 - electronically signed on 7/28/19; YSM19-0614 - DOS 11/19/19 - electronically signed on 12/01/19; YSM20-0098 - DOS 2/19/20 - electronically signed on 3/01/20; PSM20-086 - DOS 5/11/20 - electronically signed on 5/23/20. A4. The facility personnel confirmed that the Mohs test reports reviewed during the survey were not signed in a timely manner by the physician who made the diagnosis. B1. No evidence was presented for review to indicate the laboratory established a policy or procedure for amending pathology test reports. B2. The facility personnel failed to provide documentation of an established policy and/or procedure for amending pathology test reports. The laboratory's policies and procedures are maintained in an electronic format and the surveyor requested the policy but no policy was presented for review by laboratory staff.