

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0686672	(X3) Date Survey Completed 04/03/2026
Name of Provider or Supplier Huntington Dermatology Medical Group	Street Address, City, State 800 S Fairmount Ave, Ste 425, Pasadena, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's protocol for retention of records, a total of twenty patient test records, lack of preventive maintenance (PM) records, and interviews with the director of operations on April 3, 2026; it was determined that the laboratory failed to retain the PM records for the microscopes used in testing. The findings include: 1. The laboratory's policy was to perform PM for the microscopes annually through Western Scientific Co (WesCo). However, the only available record for review was for 2025. 2. The surveyor reviewed a total of twenty patient records that required the use of the microscope for test performance. Fourteen out of twenty were potentially affected due to lack of records from 2023, 2024 and 2026. 3. There was a lack of corrective action to address the failure of retaining PM records for the microscopes used in patient testing. 4. During an interview on April 3, 2026, at approximately 11:00 a.m., the director of operations confirmed that the laboratory lacked the microscope PM records for 2023, 2024 and 2026. In addition, the laboratory failed to perform a corrective action for the missing documentation. 5. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 10 Mycology tests and 1,300 Dermatopathology cases annually including the time when the laboratory failed to retain PM records for the microscopes. .</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(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 surveyor's review of the laboratory's eight selected patient records for Mycology, observation during the laboratory tour, examination of laboratory reagent materials and solutions, and interviews with the director of medical operations on April 3, 2026; it was determined that the laboratory failed in using the 20% potassium hydroxide (KOH) when it had exceeded its expiration date for patient testing. The findings include: 1. The surveyor's observations during the laboratory tour resulted in identifying three bottles of 20% KOH solution with Lot#K19424, expiration date: 4/30/2022 were used for patient testing that was used beyond its expiration date. 2. The surveyor selected eight random patient records for KOH test, subspecialty Mycology. All eight records were tested using the expired KOH solution covering 12/11/2023 to 3/25/2026. In addition, the patient log sheets available for review had 41 other patients examined from 2023 to 2026. 3. The director of medical operations affirmed by an interview on April 3, 2026, at approximately 4:28 p.m. that the laboratory used the 20% KOH solution beyond its expiration date for patient testing without noticing nor checking the label during their quality assessment checks. 4. According to the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 10 patient samples for Mycology annually during the time when the 20% KOH solution was used past its expiration date. .

D5821

TEST REPORT

CFR(s): 493.1291(k)

(k)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.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's quality assessment (QA) policy and procedure, twenty randomly chosen patient test records from 2023 to 2026, and an interview with the director of operations on April 3, 2026, it was determined that the laboratory failed to address errors in patient records prior to finalizing reports. The findings include: 1. The surveyor reviewed a total of twenty randomly selected patient test records for Mycology and Histopathology wherein seven records had a mismatch of patient information from several documentation checked such as the patient log, electronic chart notes, Mohs map, and slides. a. Mycology (four out of eight records had errors) i. Patient ELYO0001, examined and documented at left neck on 3/26/2024, negative findings for KOH and was omitted in the final report. ii. Patient ALBE0003, examined on 10/31/2025 was recorded in the patient log for positive findings in KOH but was omitted in the final report. iii. Patient DALA0005, examined and documented on 2/17/2026 in the patient log, negative for KOH at the feet and was recorded in the final report at the right third toe. iv. Patient DAJO0007, examined and documented on 3/25/2026 in the patient log at the feet and was reported in "2

locations: right foot" b. Dermatopathology (three out of twelve had errors) i. Patient 23-702, examined on 11/9/2023, was recorded in the Mohs patient log and slides at left ear. However, in the Mohs surgery map and final report, it was reported at the left ear - descending pinna. ii. Patient 24-577, examined on 9/26/2024, was recorded in the Mohs patient log and slides at right cheek. However, in the Mohs surgery map and final report, it was reported at the right cheek - buccal. iii. Patient 25-815, examined on 12/15/2025, was recorded in the Mohs patient log and slides at left ear. However, in the Mohs surgery map and final report, it was reported at the left ear - descending helix. 2. There was a lack of corrective action documentation for the seven out of twenty patient records reviewed as mentioned in statement #1. 3. During an interview on April 3, 2026, at approximately 3:30 p.m., the director of operations confirmed that the seven records with errors lacked a corrective action and/or addendum to provide the correct and matching anatomical locations across all records. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 10 Mycology and 1,300 Dermatopathology tests annually, including the time when the discrepancy in the patient record occurred that lacked the corrective action documentation.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and 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 the surveyor's review of the laboratory's policy and procedure, errors in selected patient test records, lack of preventive maintenance records, and interviews with the director of operations on April 3, 2026, this deficiency is herein cited for the laboratory director due to failure to ensure that the quality system assessment records were followed, documented and retained with the least frequency required in CFR493.1105. The findings include: 1. The laboratory failed to follow their policy to retain preventive maintenance records for the microscopes used in testing. See D3031. 2. The laboratory used the 20% potassium hydroxide solution beyond its expiration date for patient testing. See D5417. 3. The laboratory failed to ensure that the information matched in all their records prior to finalizing reports. See D5821.