

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0686425	(X3) Date Survey Completed 02/20/2025
Name of Provider or Supplier Greenbrae Dermatology Amc	Street Address, City, State 501 Sir Francis Drake Blvd, Ste 200, Greenbrae, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, examination of laboratory reagent materials and solutions, and interviews with the laboratory assistant (LA); it was determined that the laboratory failed in using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's observations during the laboratory tour, multiple reagent materials and solutions were found to have exceeded its expiration date and were continuously used for patient testing. Reagent / Solution Lot # Expiration date a. 1% Toluidine Blue 1319 11-2013 b. 10% KOH 9301 10-25-2021 c. 10% KOH 1824011 8-28-2019 d. Chlorazol Black E K213P1 3-31-2022 e. Chlorazol Black E K18API 10-31-2019 2. The LA affirmed by interview on February 20, 2025 at approximately 10:35 a.m. that the laboratory used the reagent materials and solutions listed on #1 beyond its expiration date for patient testing. 3. Based on the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 9 tests samples for Mycology and Parasitology during the time when reagent materials and solutions used were past its expiration date. Thus, the quality and accuracy of patient results cannot be assured.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including</p>

background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's preventive maintenance (PM) documentation, five (5) randomly selected patient test records, and an interview with the office manager (OM), it was determined that the laboratory failed to ensure performed tests and function checks were documented properly prior to patient testing. The findings include: 1. Based on the surveyor's review of 5 randomly selected patient test records, no corrective action was found for the one out of 5 record that lacked PM documentation. Thus, the accuracy and quality of patient reports from November 11, 2022, cannot be ascertained. 2. The OM affirmed by interview at approximately 9:50 a.m. on February 20, 2025, that the laboratory missed checking the log sheet when quality assessment was performed as mentioned in statement #1. 3. Based on the annual testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 98 patient tests for Dermatopathology, including the time the missing entry for PM occurred. Thus, the quality and accuracy of patient reports cannot be assured.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of patient records for Mohs procedures and interview with the office manager (OM), it was determined the laboratory failed to test and assess the quality of staining materials on each day of Mohs. Findings include: 1. Based on the surveyor's review of 2022-2024 Mohs patient records, it was determined that four out of five records were missing quality control (QC) slides as followed: Date ----- 05-28-2022 04-15-2023 10-14-2023 03-23-2024 2. The OM affirmed by interview conducted on February 20, 2025, at approximately 9:50 a.m., that the records mentioned in statement #1 lacked QC slides, which were likely part of the quality assessment and acceptance process carried out by the Mohs surgeon or testing personnel on each date of the Mohs procedure. 3. Based on the testing declaration form submitted at the time of survey, the laboratory performed approximately 98 Mohs cases including the dates when QC slides were missing. Thus, the quality of staining and the reliability of the Mohs records could not be assured.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) 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 the surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and interviews with the laboratory assistant and office manager on February 20, 2025, it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the analytical and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Use of expired reagents. See D5417. 2. Missing preventive maintenance record. See D5435. 3. Missing quality control slides. See D5473.