

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0544561	(X3) Date Survey Completed 07/29/2024
Name of Provider or Supplier Tower Dermatology	Street Address, City, State 8631 W 3rd St Ste 1035e, Los Angeles, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures manual, a review of three randomly chosen Dermatopathology patient test records, and interviews with the office manager (OM) and medical assistant (MA), it was determined that the laboratory failed to have an approved written policy and procedure for documentation and slide retention and storage. The findings include: 1. Based on the survey at approximately 12:15 p.m. on July 29, 2024, no written policy and procedure manual was found for the retention and storage of documents and slides. 2. The deficient practice was affirmed by interviews with the OM and MA on July 29, 2024, at approximately 12:15 p.m. as mentioned on statement #1. 3. According to the laboratory's testing declaration form submitted at the time of the survey and a review of three randomly chosen Dermatopathology patient test records covering the period of January 2023 to January 2024, the laboratory performed 3,000 tests annually for Dermatopathology during the time the laboratory had no written and approved retention and storage policy and procedure for documentation and slides.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on the lack of documentation, review of testing personnel competency assessment records, patient records review, and interviews with the office manager (OM) and medical assistant (MA) on July 29, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish a written policy and procedure to assess the testing personnel competency for the years 2023 and 2024. Findings include: 1. Based on the lack of the laboratory's policy and procedure and competency evaluations' records, the laboratory failed to have an approved written policy and procedure for competency assessment of the testing personnel (TP) for the subspecialties of Mycology and Parasitology. 2. Based on the review of patient records, the laboratory failed to provide documentation of training and competency assessment for the TP who performed the tests for KOH and scabies consisting of sample processing, testing, and reporting at the laboratory for the years 2023 and 2024. 3. This deficient practice was affirmed by interviews with the OM and MA on July 29, 2024, at approximately 12:00 p.m. 4. According to the laboratory's testing declaration submitted at the time of the survey, the laboratory performed 50 KOH tests for the subspecialty of Mycology and 10 scabies tests for the subspecialty of Parasitology annually, for which the competencies of the testing personnel were not performed.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (ii) Perform and document the function checks, including 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 the surveyor's review of the written policy and procedure manual for equipment quality control and maintenance, an interview with the medical assistant (MA), and a review of six (6) randomly selected patient test results for KOH, scabies, and Dermatopathology, it was determined that the laboratory had missed recording the microscope preventive maintenance (PM) since 2022. The findings include: 1. Based on the survey on July 29, 2024, at approximately 12:30 p.m. and the review of the laboratory's equipment quality control policy and procedure manual and PM log, the surveyor observed that since June 20, 2022, no record for the microscope PM was found. 2. The MA affirmed by interview on July 29, 2024, that although the microscope PM is performed every time there is a patient slide to be reviewed, the facility had missed recording the PM performed as mentioned in statement #1. 3. Based on the laboratory's testing declaration submitted on July 29, 2024, and review of 6 randomly selected patient test records for KOH, scabies, and Dermatopathology, the laboratory performed 3,060 tests annually during the time that no PM was recorded.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on the surveyor's review of patient test records and interviews with the laboratory director (LD) and medical assistant (MA), the laboratory failed to maintain a system that identified the records and dates of all specimens tested, including the identities of the personnel who performed the test. Findings include: 1. Based on the interviews with the LD and MA at approximately 12:30 p.m. on July 29, 2024, it was determined that the practice of the laboratory is to directly enter the results upon patient visitation into the electronic health records (EHR) for those seen by the LD. 2. Based on the findings during the patient test record review, it was found that only the testing personnel (TP) kept records for KOH tests performed. However, no signature or initials of the TP who performed the test were found on the patient log sheet. Since most of the tests were performed by the LD, all tests performed for KOH and scabies in 2023 were not documented in the patient record log sheet. 3. The LD and MA affirmed by interview on July 29, 2024, at approximately 12:30 p.m. that the laboratory failed to keep documentation for every patient tested for KOH and scabies seen by the LD. 4. According to the laboratory testing declaration submitted at the time of the survey, the laboratory performed 50 KOH and 10 scabies tests annually during the time the laboratory failed to maintain a record system for all specimens tested, including the identities of the personnel who performed the test on the patient log sheet.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the deficiency cited, a review of the laboratory's quality assessment (QA) policy and procedure manual, and an interview with the medical assistant (MA), it was determined that the laboratory failed to perform and document preanalytic, analytic, and postanalytic systems for quality assessment necessary to prevent the recurrence of problems identified and to conduct discussion reviews with appropriate staff. Findings include: 1. Based on the surveyor's review of the laboratory's policy and procedure manual for QA, no records were provided by the facility as none were performed for the years 2023 and 2024 for any QA activities consisting of Quality Control Review, Personnel Training Evaluation, Test Tracking, Communication, Compliance Assessment, etc. 2. The MA affirmed by interview on July 29, 2024, at

approximately 12:00 p.m. that the laboratory failed to perform and document the preanalytic, analytic, and postanalytic systems QA necessary to monitor and prevent the recurrence of identified problems and to conduct discussion reviews with appropriate staff as mentioned in statement #1. 3. According to the laboratory testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 3,060 patient tests annually for the subspecialties of Mycology, Parasitology, and Dermatopathology.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must 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 interviews with the office manager and medical assistant, review of the laboratory's policies and procedures, observations during the tour of the facility, the review of six randomly chosen patient records, and the preventive maintenance log on July 29, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. Findings included: 1. No retention and storage policies and procedures. See D3043. 2. No Personnel Competency Assessment records. See 5209. 3. Missing records for preventive maintenance. See D5435. 4. Missing documentation for test records. See D5787. 5. No quality assessment documentation found. See D5793.