

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0551024	(X3) Date Survey Completed 12/02/2025
Name of Provider or Supplier Simone A Mckitty, Md Inc	Street Address, City, State 3440 W Lomita Blvd Ste 442, Torrance, 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 observation of the Nikon Alphaphot microscope (serial number 152731), review of 2022 -2025 laboratory records including biopsy pathology reports and Mohs procedures records, the lack of laboratory records, and interview with the Laboratory Director and Laboratory Assistant-1, it was determined the laboratory failed to verify the accuracy of Pathology reports and Mohs procedures for the timeframe 2022 - 2024. Findings included: a. BIOPSY PATHOLOGY 1. Different Testing Persons reported Pathology, as follows: Date collected Patient Testing Person ID reporting pathology ----- 1/04/22 DL Dr. SM 1/09/23 PM Dr. SM 9/13/23 SL Dr. CM 11/02/23 MG Dr. CM 12/06/23 RL Dr. CM 2/28/24 JT Dr. CM 5/20/24 LA Dr. SM 6/19/24 CC Dr. CM 10/08/24 NK Dr. CM 2. The laboratory failed to have records documenting at least twice annual peer reviews of biopsy pathology reported by each Testing Person in 2022, 2023, and 2024. 3. The Laboratory Director and Laboratory Assistant-1 affirmed (12/02/25 at 12:00 PM) the aforementioned findings that both Dr. SM and Dr. CM reported biopsy pathology in 2022, 2023, amd 2024; and that no peer reviews had been done for either Testing Person during those calendar years. b. MOHS PROCEDURES 1. Mohs procedures were performed onsite beginning in 2023, by one Mohs Surgeon. Several records reviewed were, as follows: Date Patient ID ----- 1/18/23 SC 9/13/23 SL 12/06/23 RL 2/28/24 JT 6/19/24 CC 10/18/24 DM 2. The laboratory failed to have records for at least twice annual peer reviews of Mohs procedures performed in 2023 and 2024. 3. The Laboratory Director and Laboratory Assistant-1 affirmed (12 /02/25 at 12:00 PM) the aforementioned findings that Mohs procedures were performed during the timeframe 2023- 2024; and that no peer reviews had been done</p>

for either calendar year. c. The reliability and quality of Biopsy Pathology reported by all Testing Persons in 2022 - 2024 and Mohs procedures performed in 2023 -2024 could not be assured during this Survey. d. The laboratory reported a combined total of 2,400 Pathology reports and Mohs procedures annually (CMS116 CLIA Application, 12/01/25). .

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory records and lack of written policy and procedure, the deficiency cited, and interview with the Laboratory Director and Laboratory Assistant-1, it was determined the laboratory failed to have a written policy and procedure for ensuring the practice of peer reviews were performed to verify the accuracy of each Testing Person, at least twice each calendar year, who's reporting biopsy pathology or performing Mohs procedures. Findings included: a. The laboratory failed to have records of peer review for pathology reports during the timeframe 2022- 2024, and Mohs procedures during the timeframe 2023 - 2024. See D5217. b. The Laboratory Director and Laboratory Assistant-1 affirmed (12/02/25 at 12:45 PM) the lack of a routine process as well as the lack of a written policy/procedure, for ensuring peer reviews were performed at least twice within each calendar year for each Testing Person reporting biopsy pathology or performing Mohs procedures. c. The reliability of the laboratory to have an effective and complete laboratory manual to follow and ensure compliance with federal CLIA regulations could not be assured during this Survey. .

D5787

TEST RECORDS
CFR(s): 493.1283(a)

(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 review of Pathology Reports and interview with Laboratory Assistant-1, it was determined that the records failed to include the name of the Testing Person reporting the biopsy pathology. Findings included: a. Six out of 12 Pathology Reports randomly selected from the timeframe 2022 - 2025 for this Survey failed to identify the person who read the biopsy slide and reported the pathology: Date Collected Patient ID ----- 1/04/22 DL 1/09/23 PM 5/20/24 LA 1 /21/25 SA 2/15/25 DT, Right upper abdomen 6/17/25 JD b. The Laboratory Director and Laboratory Assistant-1 affirmed (12/08/25 at 11:09 AM) the pathologies were reported by Testing Person-1 and that the aforementioned reports failed to state the

name of the Testing Person after "Electronically Signe [sic]". c. As a consequence, the reliability of laboratory test records to document the responsible Testing Person could not be assured during this Survey. . .

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Review of laboratory records titled, "McKitty Dermatology Pathology Report", and interview with Laboratory Assistant-1 revealed the pathology reports failed to include the Report Date. Findings included: a. No Report Date was stated on 12 out of 12 McKitty Dermatology Pathology Reports randomly selected for this Survey, as follows: Date Collected Patient ID "Completed Date" or Report Date
----- 1/04/22 DL - blank - 1/09/23 PM - blank - 9/13/23 SL - blank - 11/02/23 MG - blank - 12/06/23 RL - blank - 2/08/24 JT - blank - 5/20/24 LA - blank - 6/19/24 CC - blank - 10/08/24 NK - blank - 10/18/24 DM - blank - 1/21/25 SA - blank - 6/17/25 JD - blank - b. Laboratory Assistant-1 affirmed (12/02/25 at 12:00 PM) the aforementioned findings, that the field labeled "Completed Date" was blank on all the McKitty Dermatology Pathology Reports. c. As a consequence, the dates when pathology results were reported could not be assured during this Survey. d. The laboratory reported a combined total of 2,400 histopathology reports annually for biopsy pathology and Mohs procedures (CMS116 CLIA Application, 12/01/25). . .

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on the serious and cumulative nature of deficiencies cited, the Laboratory Director is herein cited for not meeting the Condition to provide overall management and direction in accordance with CLIA regulations. Findings included: a. Under the Laboratory Director's management, the laboratory failed to establish the routine process of annual peer reviews to verify the accuracy of testing personnel to report pathology or perform Mohs procedures. See D5217. b. Under the Laboratory Director's management, the laboratory failed to ensure pathology reports identified the person reporting the pathology. See D5787. c. Under the Laboratory Director's management, the laboratory's Pathology Reports failed to state the Report Date. See D5805. d. Under the Laboratory Director's management, the laboratory failed to have

an effective Laboratory Manual complete with the written policy and procedure for ensuring peer reviews are established and maintained according to CLIA requirements.