

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0950271	(X3) Date Survey Completed 01/23/2024
Name of Provider or Supplier Paul J Mcandrews, Md	Street Address, City, State 50 Alessandro Pl Ste 115, 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
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 the lack of the laboratory's histopathology reports peer review, review of five (5) randomly chosen histopathology patient's reports, and interviews with the laboratory's medical assistant (MA) on January 23, 2024; it was determined that the laboratory failed to verify, at least twice annually, the accuracy of its histopathology tests for the years 2022 and 2023. The findings included: 1. The laboratory did not have any documentation showing that it had verified its histopathology tests' accuracy for the years 2022 and 2023 for the dermatopathologist performing slide reading and providing patients' diagnosis. Therefore, the accuracy of the laboratory's test results for patients' histopathology procedures, cannot be assured. 2. The MA confirmed at approximately 11:00 a.m., that the laboratory did not have any record to verify its histopathology test accuracy for the years 2022 and 2023. 3. The laboratory's testing declaration form signed by the laboratory director in 1/22/2024, stated that the laboratory performs approximately 200 histopathology tests annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on the lack of laboratory written policies and procedures and interview with the medical assistant, it was determined that the laboratory failed to have available and follow written procedures for histopathology test performed in the laboratory. The findings included: 1. On the day of the survey on January 23, 2024, at approximately 11:00a.m., the laboratory failed to provide written policies and procedures for histopathology test procedures performed in the laboratory. 2. For five (5) out of five (5) random patient test results reviewed covering period from 11/19/2021 to 9/27 /2023, all the patients had histopathology test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The medical assistant confirmed on 01/23/2024 at approximately 11:30 a.m. that the laboratory did not have written policies and procedures available for histopathology tests performed in the laboratory.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (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 observation, review of the laboratory records, and interview with the medical assistant; it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to 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. The findings included: See D5217.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
 Based on direct observation and interview with the medical assistant; it was determined that the laboratory director failed to ensure that a signed and dated approved written procedure manual is always available to all personnel responsible for any aspect of the testing process. See D5401.