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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>05D0968426               | <b>(X3) Date Survey Completed</b><br><br>07/30/2025 |
| <b>Name of Provider or Supplier</b><br><br>J Robert West Md Inc  | <b>Street Address, City, State</b><br><br>9201 W Sunset Blvd Ste 602, West Hollywood, CA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>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:<br/>Based on the surveyor's review of the laboratory's policies and procedures, peer review records, eight (8) randomly selected patient records, and interviews with the office managers (OMs); the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the year 2023. The findings include:<br/>1. The laboratory's policy and procedure for proficiency testing stated that two cases are sent to another facility to verify the accuracy of results for Dermatopathology. However, only one case per year was available for review for the year 2023. Therefore, the accuracy of patient results could not be assured. 2. The OM s confirmed by interview the day of the survey July 30, 2025, at approximately 12:30 p. m., that the laboratory failed to verify the accuracy of the dermatopathology Mohs procedure at least twice per year as stated in #1. 3. The laboratory's testing declaration form submitted at the time of the survey stated that 144 Dermatopathology Mohs samples were processed and reported annually during the time that laboratory failed to verify the accuracy of the Mohs test results.</p> |
| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>(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.</p>   |

This STANDARD is not met as evidenced by:  
 Based on the lack of laboratory written policies and procedures for parasitology and preparation for the detection of *Sarcoptes scabiei* (scabies) and interviews with the laboratory managers (OMs) it was determined that the laboratory failed to have available and follow written procedures for parasitology test performed in the laboratory. The findings included: 1. On the day of the survey on July 30, 2025, at approximately 11:45 a.m. the laboratory failed to provide written policies and procedures for parasitology (scabies) microscopic test performed in the laboratory. 2. The OMs confirmed on 07/30/2025 at approximately 11:50 a.m. that the laboratory did not have written policies and procedures available for parasitology tests performed in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 07/01/2025, the laboratory processes and reports 5 parasitology samples annually.

**D5779**

**CORRECTIVE ACTIONS**  
 CFR(s): 493.1282(a)

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of policies and procedures, eight (8) randomly selected patient records, and interviews with the laboratory's office managers (OMs); the laboratory failed to follow an established and approved policy and procedure for corrective action. Findings include: 1. Based on review of policies and procedures, no corrective documentation since the year 2022 was found at the time of inspection. 2. Based on the review of five (5) randomly selected Mohs patient records, and three (3) mycology and parasitology test results records; (1) for one out of eight (8) records reviewed a discrepancy was found between the test results documented in the test log and test results documented in the patient chart for the year 2025. 3. The laboratory documented in the test log a test positive for KOH, however, the patient chart was reported as scabies positive. The MO affirmed it was a scabies test performed, reported, and treatment given for scabies documented. However, no corrective action was documented since 10/21/2022. 4. The OMs confirmed by interview on July 30, 2025, at approximately 1:00 p.m. that the laboratory did not follow the policy and procedure for corrective action documentation as mentioned in statement #1. 4. Based on the testing declaration submitted at the time of the survey, the laboratory performed and reported 144 tests annually during the time that no corrective action was documented; thus, the quality and accuracy of patient records cannot 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 peer review records, policies and procedures, randomly selected patient test records, and interviews with the laboratory's managers on July 30, 2025; the laboratory director is herein cited due to failure to ensure that several aspects of the pre-analytic, analytic and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Missing one out of two times per year peer review for the year 2023. See D5217. 2. No procedure for processing and reporting microscopic test for *Sarcoptes scabiei* (scabies) found in the laboratory. See D5401. 3. Fail to document corrective actions for the years 2023, 2024, and 2025. See D5779.