

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0958479	<b>(X3) Date Survey Completed</b>  04/15/2025
<b>Name of Provider or Supplier</b>  Kopelson Clinic	<b>Street Address, City, State</b>  414 N Camden Dr Ste 640, Beverly Hills, 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>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's quality assessment policies and procedures, lack of personnel competency documentation, fifteen (15) patient records, and an interview with the office manager (OM) on April 15, 2025, at approximately 9:15 a. m., as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to follow an established policy and procedure to perform competency assessment for the testing personnel 2 (TP2) for the years 2022, 2023, and 2024. The findings include: 1. No competency evaluation records were found for TP2 who was performing moderate complexity tests for the years 2022, 2023, and 2024. Seven (7) out of 15 patient records reviewed were performed by TP2. 2. The OM affirmed by interview on April 15, 2025, at approximately 9:15 a. m. that the laboratory had no records of any competency assessment for TP2 as specified in statement #1 for the years 2022, 2023, and 2024. 3. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 40 tests for KOH and scabies tests for which competency assessments of the TP2 were not performed. Thus, the accuracy and reliability of patient results cannot be assured.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)</p>

Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory's tour and an interview with the office manager (OM); it was determined that the laboratory failed to label various reagent materials used in the laboratory to indicate, as appropriate, the identity, opening, and expiration dates when such materials are used in the laboratory. The findings include: 1. Each provider at the laboratory had their own bottle for the reagent materials used throughout testing. During the observations from the tour on April 15, 2025, at approximately 10:40 a.m., it was noted that the laboratory lacked labeling for the reagent materials for identity (name, titer, strength, or concentration), received, opening, and/or expiration dates, as appropriate. Some specific examples include: a. 20% potassium hydroxide (KOH) with DMSO, lot number 000496 with 5/23/2026 expiration date had no opening date. b. A bottle containing aliquoted mineral oil reagent, which did not have opening or expiration dates. 2. The laboratory's OM affirmed in an interview on April 15, 2025, at approximately 10:40 a.m., that the reagent materials mentioned in statement #1 above were not labeled with the opening, preparation, and/or expiration dates, as applicable. The OM also added that the original bottle for the mineral oil was not at the laboratory anymore. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 40 KOH and scabies tests for which various reagents materials were not labeled as appropriate.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on the lack of documentation of competency assessments for the years 2022, 2023, and 2024, along with insights from an interview with the office manager, it was concluded that the laboratory director, who also served as the technical consultant, did not perform or document the competency assessment for one of the testing personnel. This oversight resulted in a failure to ensure that the individual maintained the necessary competency to conduct test procedures in a timely, accurate, and proficient manner. See D5209.