

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0708670	(X3) Date Survey Completed 11/14/2024
Name of Provider or Supplier Jeffrey A Klein Md	Street Address, City, State 30280 Rancho Viejo Rd, San Juan Capistrano, 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 interview with Office Manager (OM) and review of laboratory's Proficiency Testing (PT) records on November 14, 2024, it was determined that the Laboratory failed to ensure that the accuracy of the Mycology and Parasitology testing were verified at least twice annually for the years 2022, 2023 and 2024. The findings include: 1. It was the practice of the laboratory to perform Parasitology using wet mounts and Mycology using Potassium Hydroxide (KOH) and Dermatophyte Test Medium (DTM) testing, which are not listed in the subpart I of the 42 CFR part 493. For the test procedure not listed in subpart I the laboratory must verify the accuracy of the test procedure twice annually. 2. On November 14, 2024, at approximately 12:00 pm, the laboratory office manager affirmed that the laboratory maintained no documentation to show it verified the accuracy of Mycology and Parasitology testing at least twice annually for 3 of 3 years. 3. The laboratory's testing declaration form, signed by the laboratory director on November 4, 2024, stated that the laboratory had performed 175 Mycology and Parasitology testing annually.</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on interview with Office Manager, review of laboratory's policies and procedures manuals, and Proficiency Testing (PT) records on November 14, 2024, it was determined that the Laboratory Director (LD) failed to ensure that testing system developed and used for Mycology and Parasitology provide quality laboratory services for all aspects of test performance. The findings include: The laboratory failed to establish and follow written policy and procedure to ensure at least twice annually the accuracy of Mycology and Parasitology testing were verified. See D5217.