

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0294956	(X3) Date Survey Completed 09/02/2021
Name of Provider or Supplier Bradenton Dermatology Pa	Street Address, City, State 2919 26th St W, Bradenton, FL	
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
D0000	An announced CLIA recertification survey was conducted at Bradenton Dermatology PA on 09/02/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 record review and interview with the Laboratory Director, the laboratory failed to verify the accuracy of testing twice a year for 2 of 2 years (2019-2021) reviewed for the subspecialties of Mycology, Parasitology, and Virology. Findings Included: Review of quality assurance peer review revealed no peer reviews were completed for two out of two years (2019 - 2021) for fungi testing with Potassium hydroxide (KOH) in Mycology, Scabies testing in Parasitology, and Tzanck testing in Virology. Review of the "KOH/Tzanck/Scabies (K/T/S) " patient log revealed the statement "No longer reading KOH/Tzanck slides as of June 2019". On 09/02/21 at 09:15 AM, the Laboratory Director stated he wanted to keep his subspecialties of mycology, parasitology, and virology and reported that he had performed microscopic (KOH, Scabies, and Tzanck) testing but had not logged the patients. He also confirmed he had not performed peer review for two out of two years (2019 -2021) This is a repeat deficiency.</p>