

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2129545	<b>(X3) Date Survey Completed</b>  01/26/2023
<b>Name of Provider or Supplier</b>  Innovative Dermatology And Mohs Surgery Llc	<b>Street Address, City, State</b>  8800 Bernwood Pkwy Unit 6, Bonita Springs, FL	
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>D0000</b>	An announced CLIA recertification survey was conducted at Innovative Dermatology and Micrographic Surgery (Mohs) Surgery LLC on 1/26/23 a clinical laboratory in Bonita Springs, Florida. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 mycology (fungi) for two (2021 - 2022) out of two (2021 - 2022) years for one Testing Personnel (#B) out of 2 Testing Personnel ( #A and #B) , and failed to verify the accuracy of parasitology (scabies), virology ( herpes simplex virus and varicella zoster virus) testing for two (2021 - 2022) out of two (2021 - 2022) years for two Testing Personnel ( #A and #B) out of two Testing Personnel (#A and #B), and failed to verify the accuracy of histopathology (hematoxylin and eosin) testing twice annually for two (2021 - 2022) out of two years reviewed (2021 - 2022) for one Testing Personnel ( #A) out of one Testing Personnel (#A). The findings included: Record review of the Laboratory Personnel Report (Form CMS 209) completed and signed by the Laboratory Director on 1/26/23 revealed that the Laboratory Director (Testing Personnel #A) performed high complexity testing: hematoxylin and eosin testing, and includes fungi, scabies, herpes simplex virus and varicella zoster testing. Testing Personnel #B performed moderate complexity: fungi, scabies, herpes simplex virus, and varicella zoster virus testing. Record review of the "Proficiency Testing/Verification of Accuracy" revealed "Provider Performed Microscopy (PPM) Proficiency testing (PT) will be performed</p>

every 6 months by using a Clinical Laboratory Improved Amendment (CLIA) approved outside organization such as American Academy of Family Practitioners (AAFP)...." Record review of the AAFP proficiency testing revealed the laboratory was enrolled in "Clinical Microscopy" proficiency testing for two (2021 - 2023) out two (2021 - 2022) years and one (Testing Personnel #A) out of two (Testing Personnel #A and #B) Testing Personnel #A performed the testing for 6 (A, B, and C Events 2021, and A, B, and C Events 2022) out of 6 (A, B, and C Events 2021, and A, B, and C Events 2022) proficiency testing events. Record review of the AAFP revealed that the "Clinical Microscopy" proficiency testing only tested for scabies for two proficiency testing events (2021 B Event and 2022 A Event) out of 6 A, B, and C Events 2021, and A, B, and C Events 2022) and 6 (A, B, and C Events 2021, and A, B, and C Events 2022) out of 6 (A, B, and C Events 2021, and A, B, and C Events 2022) did not test for herpes simplex or varicella zoster virus. On 1/26/23 at 10:45 a. m., the laboratory director stated he did not know each testing personnel needed to perform verification of accuracy and precision twice annually for each analyte tested. He confirmed the twice annual verification of accuracy and precision had not been performed for scabies and herpes simplex virus and varicella zoster virus. Also he stated he thought being enrolled in AAFP covered him for the requirement even though he had not tested for herpes simplex virus or varicella zoster virus and had tested scabies once per year. Record review of the "Proficiency Testing/Verification of Accuracy" revealed "Mohs surgery (PT) will be done by sending at least 2 cases semi - annual every 6 months to an outside Mohs surgeon or Pathologist for proficiency testing review. Record review of the "MOHS PT Cases for Review (Bi-Annual)" logs revealed 2 ( both logs dated 12/20/22 but one log had specimens from 2021 and the other had specimens from 2022) out of 4 (two for 2021 and two for 2022) bi - annual proficiency testing had been performed. On 1/26/23 at 10:50 a.m., the Certified Nursing Assistant stated she thought she could pull Mohs cases once per year with Mohs cases with different dates.