

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2146212	(X3) Date Survey Completed 03/26/2021
Name of Provider or Supplier Skin Wellness Physicians Llc	Street Address, City, State 1300 Goodlette Rd, N, Naples, 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 recertification survey was conducted on 3/26/21 at Skin Wellness Physicians LLC, a clinical laboratory in Naples, Florida. Skin Wellness Physicians LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
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 histotechnologist, the laboratory failed to ensure the twice a year verification of accuracy testing for 2019 - 2020 for Scabies testing in the subspecialty of Parasitology for 3 out 3 Testing Personnel (#A, #B, and #C) and for potassium hydroxide (KOH) testing (for fungi) in the subspecialty of Mycology for 1 (#C) out of 3 Testing Personnel (#A, #B, and #C.) Findings included: Review of "Mycology and Parasitology Peer Review" records revealed that Testing Personnel #A and #B had performed Scabies verification of accuracy once (11/8 /2019) out of two years (2019 - 2020) and Testing Personnel #C had not performed Scabies peer review for two out of two years (2019- 2020). Testing Personnel #C had not performed (KOH) peer review testing for two out of two years (2019-2020). Interview on 3/26/21 at 09:40 a.m., the histotechnologist stated he did not know that verification of accuracy had to be performed even though there were no Scabies patient testing and confirmed that Testing Personnel #C had not performed (KOH) verification of accuracy testing.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observations, record review and interview with the histotechnologist, the laboratory failed to perform preventative maintenance on the microscope and cryostat for 1 (2020) out of 2 (2019-2021) years reviewed. Findings included: A tour of the laboratory on 3/26/21 at 9:15 a.m., the cryostat was observed with a preventative maintenance sticker on it that said it was performed on 2/2019 and that it was due 2/20, and there was no documentation of the preventative maintenance being performed in 2020. Also, there was no documentation for preventative maintenance for the microscope since last survey (9/10/2019). Record review of the "Mohs Lab General Maintenance" stated that the cryostat would have "Annually have a service provided conduct Preventative Maintenance (PM). " and the microscope would have "An annual PM should be done by a qualified microscope service representative.". Interview on 3/26/21 at 9:20 a.m., the histotechnologist confirmed the PM had not been performed for the cryostat and microscope and stated he did not know the laboratory's procedure stated that annual PM's would be performed.