

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1028878	(X3) Date Survey Completed 06/02/2025
Name of Provider or Supplier Academic Dermatology & Cosmetic Surgery Center	Street Address, City, State 51189 Shelby Pkwy, Shelby Township, MI	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with histology technician (HT), the laboratory failed to ensure histopathology reagents were not used beyond expiration date for 1 (red) of 3 reagents observed. Findings include: 1. During a tour of the laboratory on 06/02/2025 at 10:40 am, the surveyor observed three MOHS tissue stains (1 red, 1 blue, 1 green) dispensed in unlabeled containers. 2. During an interview with the HT on 06/02/2025 at 10:41 am, when asked to confirm the supply source of the dispensed stains, the HT stated that the red stain bottle had been discarded earlier that morning during setup, as the final portion was used and stated the red stain expired on May 31, 2025.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, record review and interview with the Office Manager (OM), the laboratory failed to establish and follow a preventative maintenance protocol for laboratory equipment for 24 (April 2023 to May 2025) of 24 months reviewed. Findings include: 1. The surveyor conducted a tour of the laboratory at 9:30 am on 6/2/2025 and observed the following equipment did not have a service tag: a. Microscope: Leicia DM E b. Cryostat: Lecia CM1900 c. Tissue Embedder: Leicia EG1160 2. A review of laboratory records revealed that annual preventative maintenance records were not present for the Microscope, Cryostat and Tissue Embedder. 3. A review of the laboratory's policies and procedures revealed that a maintenance procedure for annual preventative maintenance of laboratory equipment had not been established. 4. An interview with the OM at 11:25 am on 6/2/2025 confirmed that annual preventative maintenance had not been conducted on instruments listed above. 5. A record review of user manuals for the equipment confirmed that annual preventative maintenance was to be performed as follows: a. Microscope: "...professional maintenance every 1-2 years"... b. Cryostat: "...the instrument inspected by a qualified service engineer...once a year." c. Tissue Embedder: "...annual maintenance is recommended..."

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Medical Assistant (MA), the laboratory failed to indicate the laboratory name and address on the patient test report for 3 (10,11,12) of 3 MOHS patient test reports reviewed. Findings include: 1. A record review of MOHS patient test reports revealed the name and address of the laboratory was not listed for the following reports: a. Patient 10: 05/06/2023 b. Patient 11: 04/07/2024 c. Patient 12: 03/13/2025 2. An interview on 06/02/2025 at 11:40am with the MA confirmed the location of the laboratory was not listed on the patient test reports.