Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2295804	12/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Eastside Dermatology	32743 23 Mile Road Suite 230, Chesterfield, 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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to follow its maintenance and function checks policy prior to putting its cryostat and linear hematoxylin and eosin staining system into use for nine (March 2024 to December 2024) of nine months since the laboratory started testing. Findings include: 1. The surveyor toured the laboratory on 12/3/24 at 9:11 am and noticed the laboratory was using one Leica cryostat and an Epredia linear hematoxylin and eosin staining system. 2. A review of the laboratory's "Equipment" policy revealed a section stating, "All new, used or loaner equipment must be validated and have a "Method Validation Evaluation" form filled out prior to using the instrument. This form must include the following: laboratory name, address, contact person, and phone number; name of the instrument, serial number, installation and validation date. The laboratory director must validate and approve the instrument for accuracy in accordance with manufacturer's instructions. The form must be kept on file with the quality control for the instrument." 3. An interview on 12/3/24 at 10:18 am with Testing Personnel #2 revealed the laboratory had not validated its Leica cryostat and Epredia linear hematoxylin and eosin staining system in accordance with the laboratory's policy.
D5805	TEST REPORT

	CFR(s): 493.1291(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 Testing Personnel #2 (TP2), the laboratory failed to ensure final report date was included on 9 (#1-9) of 9 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed the final report date was not included for the following patients: a. Patient 1 had testing performed on 03/12/2024 b. Patient 2 had testing performed on 04/02/2024 c. Patient 3 had testing performed on 05/14/2024 d. Patient 4 had testing performed on 06/18 /2024 e. Patient 5 had testing performed on 07/02/2024 f. Patient 6 had testing performed on 08/06/2024 g. Patient 7 had testing performed on 9/17/2024 h. Patient 8 had testing performed on 10/08/2024 i. Patient 9 had testing performed on 11/12/2024 2. An interview conducted on 12/03/2024 at 10:55 am with TP2 confirmed patient test reports did not include final report dates.