Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2140548	04/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Umdc - South Miami Dermatology	7000 Sw 62nd Ave, Ph-A,, Miami, 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	A recertification survey conducted from 03/28/2024 to 04/01/2024 found the UMDC - SOUTH MIAMI DERMATOLOGY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow the procedure manual for the Hematoxylin and Eosin (H&E) stain procedure at least since November 2021. Findings included: -During the tour of the laboratory on 03/28/2024 at 10:00 AM, the surveyor observed that the Linistat stainer displayed the solutions

	used and the order was: Hematoxylin, water, acid alcohol (100% alcohol), water, bluing, water, 100% alcohol, eosin, 100% alcohol, 100% alcohol, 100% alcohol, xylene substitute and xylene substitute. -Review of the procedure manual signed by the laboratory director on 01/08/2024 revealed that the procedure listed an H&E procedure different from the one displayed on the manual stainer with the following solutions and order: alcohol 100%, distilled water, Harris Hematoxylin, tap water, tap water, Scott's tap water, tap water, Eosin, 95% alcohol, 95% alcohol, 100% alcohol and Xylene. During an interview on 03/28/2024 at 11:30 AM, the consultant confirmed that the laboratory failed to follow the H&E stain procedure described in the procedure manual and via email the office manager confirmed on 04/01/2024 that the current method has been used at least since November 2021.
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 review of patient reports and staff interview, the laboratory failed to use the correct name for the laboratory where testing was performed for five out of five patient test reports reviewed. Findings included: Review of five final patient reports: P#1(date 03/14/2022), P#2 (dated 08/26/2022), P#3 (dated 02/27/2023), P#4 (dated 09 /18/2023), P#5 (dated 01/29/2024); revealed that the reports failed to use the correct name for the laboratory where the testing was done. During an interview on 03/28 /2024 at 11:30 AM, the office manager confirmed that the final reports reviewed did not include the correct name for the laboratory where testing was performed for the test reports reviewed.