Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0297851	03/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Myers & Fotopoulos Mds Pa	5534 Gulf Dr Ste 1, New Port Richey, 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 CLIA recertification survey was conducted at Myers & Fotopoulos on 03/26/2024-03/27/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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, review of the procedure manual and interview, the laboratory failed to have a step-by-step procedure for the preparation of 70 % alcohol and 95 % alcohol used in the Hematoloxylin and Eosin (H&E) stain for Mohs specimen from 11

	/27/2023 to 03/26/2024. Findings Included: During a tour of the laboratory on 03/26 /2024 at 10:20 am, only 100 % alcohol was observed in the flammable cabinet. Review of the Staining Procedure showed the laboratory used 70 % alcohol and 95 % alcohol in their H&E stain. Review of the procedure manuals signed by the Laboratory Director on 11/27/2023 showed there was no procedure with a step-by-step procedure for the preparation of 70% alcohol and 95% alcohol. On 03/26/2023 at 12:46 PM, the Mohs Technician stated there were no instructions for the making of the alcohol dilutions.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and quality control (QC) records, and interview, the laboratory failed to document the preparation of the 70 % and 95 % alcohol solution used in the Hematoxylin and Eosin (H&E) stain for Mohs specimens from 02/02/2022 to 2/26/2024. Findings included: Review of the staining Procedure showed the laboratory used 70 % and 95 % alcohol in the H&E stain. Review of the laboratory's QC records revealed there were no records of the documentation the preparation of the 70 % and 95 % alcohol. On 03/26/2024 at 12:44 PM, the Mohs Technician stated there were no records documenting the preparation of the 70 % and 95 % alcohol.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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. This STANDARD is not met as evidenced by: Based on observation and interview with the Mohs Technician and Quality Assurance (QA) Manager, the laboratory failed to discard and continued to use expired bottles of Richard Allen Scientific Mounting Media (2 of 2), EDM3 KOH (1 of 1), and Swan mineral oil (1 of 1). Findings included: -During the tour of the laboratory on 03/26/24 at 10:20 a.m., a bottle of TBS Mounting Media was observed on the benchtop with an expiration date of 09/2021. Also, a bottle of Richard-Allen Scientific Mounting Media with an expiration date of 09/2021 was observed in the flammable cabinet. -While reviewing paperwork in the Lab Manager's office on 03/26/24 at 11:00 a.m., an expired bottle of EDM3 KOH (used for fungus detection) expired 09/30/2022 and mineral oil (used for scabies testing) expired 05/2023 were brought into the office by the QA Manager for observation. -Interview with the Mohs Technician on 03/26/24 at 10:21 a.m., confirmed that the reagent in the TBS Mounting Media bottle was poured

	off from the bottle of Richard-Allen Scientific Mounting Media with the expiration date of 09/2021. -Interview with the QA Manager on 03/26/24 at 11:05 a.m., confirmed that both the KOH and mineral oil used for testing were both expired.