Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0957961	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Edward A Gross Md Pa D/B/A	333 Arthur Godfrey Rd Ste 302, Miami Beach, 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 was conducted on November 20, 2024. EDWARD A GROSS MD D/B/A clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and staff interview, the laboratory failed to stop using expired reagent. Findings included: 1-During the laboratory tour on 11/20/2024 at 8:45 AM the surveyor found in use one 4 oz bottle of Optic Mount 1 with Lot number 45034, this bottle had an expiration date of 01/31/2024. No other bottle of this reagent was found. 2-Review of the procedure manual signed by the Laboratory Director on 03/08 /20219 revealed that on section "Reagent Storage, Use and Handling" stated: "Do not use reagents after expiration." On 11/20/2024 at 9:30 AM, the office Nurse confirmed that the expired reagent was in use.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for 1 out of 4 testing dates January 2024. Findings included: The laboratory uses the "HEMATOXYLIN & EOSIN STAINING QUALITY CONTROL WORKSHEET" to record the acceptability of the H&E stain. Review of the testing date column revealed that the laboratory recorded the evaluation of the QC slide for three testing dates In January: 01/04/2024, 01/11/2024 and 01/25/2024. Review of the QC slides for January 2024 revealed that the laboratory had QC slides for 01/04/2024, 01/11/2024, 01/18/2024 and 01/25/2024. During an interview on 11/20/2024 at 09:30 AM the office Nurse confirmed that the laboratory failed to document the acceptability of the Daily QC slide for H& E Stain for the day listed above.