Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0286049	05/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ross D Nochimson Md Pa	4994 N University Dr, Lauderhill, 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 on 05/28/2024 found the ROSS D NOCHINSOM MD PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the NOVA-ONE Diagnostics (NOD) FREND Immunoassay Control Kits (controls Level 1 and Level 2) for 22 out of 22 months reviewed. Findings included: Review of the manufacturer instructions revealed the following statement in the section "STORAGE AND STABILITY" "Unopened NODFREND Immunoassay Controls Kits are stable until the expiration date when stored frozen at -20C." Level 1 Lot 631A23002 and Level 2 6362A23002. -Review of the Freezer temperature log revealed an acceptable temperature range of -10 to -30 C. This range does not meet the storage requirement for controls which were below -20 C. -Review of documented temperature logs from 08/01/2022 to 05/28/2024 (22 months) revealed that the temperature had not reached the requirement of -20C or colder for all the 81 days that the temperature was recorded. During an interview on 05

	/28/2024 at 12:30 PM, the Testing Person confirmed that temperature records of the freezer used for the storage of the controls were outside of the acceptable temperature ranges in the period reviewed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform at least two levels of quality control (QC) each day of patient testing for the last 22 months for Vitamin D, Thyroid Stimulating Hormone (TSH) and Free Thyroxine (FT4). Findings included: -Review of QC records from August 2022 to May 2024 for Vitamin D, TSH and FT4 using the FREND Immunoassay, revealed that the laboratory tested two levels of external QC every thirty days. Review of patient charts and QC records revealed the following: a)Patient #1 (10/02/2022), tested for TSH, FT4 and Vitamin D. No controls tested that day. b)Patient #2 (07/30/2023) tested for TSH, FT4 and Vitamin D. No controls tested that day. c)Patient #3 (12/31/2023) tested for TSH, FT4 and Vitamin D. No controls tested that day. d)Patient #4 (01/21/2024) tested for TSH, FT4 and Vitamin D. No controls tested that day. -Based on review of FORM CMS-116, the annual testing volume for Vitamin D was 420 tests and the annual volume for TSH and FT4 was 720 tests. During an interview on 05/28/2024 at 11:30 AM, the Testin Personnel stated that they followed manufacturer instructions of doing QC every thirty days and confirmed that the laboratory did not have an Individualized Quality Control Plan.