Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2186593	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ameripath Florida Llc	895 Sw 30th Avenue Suite 101, Pompano 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 conducted on 08/19/2022 to 08/25/2022 found the AMERIPATH FLORIDA LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain stain process records for year 2021. Findings include: Review of laboratory's quality control documents revealed the laboratory failed to have the following records for year 2021: -Min/Max Humidity Monitoring Log. -Room temperature log. -Cryostat temperature. -Patient log. -Reagent Acceptability Worksheet. -Stain/Technical Quality. -Equipment maintenance. During an interview on 08/19/2022 at 12:30 PM, the General Supervisor confirmed that the laboratory failed to keep the documents of reference for year 2021.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to follow manufacturer instruction for the aceptable humidity range to ensure optimal operation for the Leica CM 1860 UV cryostat and the laboratory performed testing while humidity was out of the acceptable range for 8 out of 71 testing dates from 01/01 /2022 to 08/15/2022. The findings include: Review of Leica CM 1860 UV cryostat manual revealed a requirement for optimal operation that the Humidity must not exceed 60%. A review of Humidity log for 2022, revealed the following: -The aceptable Humidity range defined in the Humidity log was 30% to 70%. -The laboratory failed to follow manufacturer's instructions to operate the cryostat in humidity conditions below 60% for 8 testing dates in 2022: 01/03/2022, 02/23/2022, 02/28/2022, 03/14/2022, 05/25/2022, 05/26/2022, 06/29/2022 and 07/27/2022. During an interview on at 12:35 pm on 08/19/2022, the General Supervisor confirmed that the humidity was outside of the instrument requirement for the days listed above.