Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0682919	02/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ameripath Florida Llc	895 Sw 30 Ave Ste 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 2/21/2023 found the AMERIPATH FLORIDA LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor observation, record review, and interview, the mobile laboratory had an expired motor vehicle registration. The findings include: 1. The surveyor observed the motor vehicle registration JAAG86, decal 19559034, had expired at midnight on 12/31/22, during a tour of the mobile laboratory on 2/21/23 at 10:30am. 2. There was no valid vehicle registration, during a record review on 2/21/23 at 11am. 3. The general supervisor stated during an interview on 2/21/23 at 1:30pm, that the mobile laboratory motor vehicle registration had expired on 12/31/22.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on the surveyor observation, record review, a memo, and interview, the laboratory failed to store its records. The findings include: 1. The surveyor observed that the test records had been destroyed, during a record review on 2/21/23 at 9:30am.

	The destroyed records were for the analytic systems (refer to D3031), test system verifications (refer to D3033), and quality system assessments (refer to D3039). 2. A memo from the general supervisor and laboratory director (refer to D6079) dated 7/12 /22 stated that the test records were placed in a storage box, but during a mass cleaning were destroyed by an employee who shredded them. 3. The general supervisor stated during an interview on 2/21/23 at 1:15pm, that the test records of two Mohs' patients had been destroyed in June 2022.
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 the surveyor observation, record review, a memo, and interview, the laboratory failed to retain its analytic systems records for at least two years. The findings include: 1. The surveyor observed that all the analytic systems records had been destroyed, during a record review on 2/21/23 at 9:30am. 2. A memo from the general supervisor and laboratory director (refer to D6079) dated 7/12/22 stated that the test records were placed in a storage box, but during a mass cleaning were destroyed by an employee who shredded them. The destroyed records were the chemical inventory list, equipment maintenance, room temperature and humidity logs, refrigerator temperature logs, freezer temperature logs, histopathology stain logs, histopathology technical quality logs, reagent and chemical new and daily lot, verification logs, histopathology specimen tracking logs, glassware testing logs, bench decontamination logs, thermometer calibration logs, water quality logs, and annual vendor records. 3. The general supervisor stated during an interview on 2/21/23 at 1: 15pm, that the test records of two Mohs' patients had been destroyed in June 2022.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on the surveyor observation, record review, a memo, and interview, the laboratory failed to retain its records of test systems performance specifications, for no less than two years. The findings include: 1. The surveyor observed that all the test systems performance specifications records had been destroyed, during a record review on 2/21/23 at 9:30am. 2. A memo from the general supervisor and laboratory (refer to D6079) director dated 7/12/22 stated that the test records were placed in a storage box, but during a mass cleaning were destroyed by an employee who shredded them. The destroyed records were the equipment and instrument performance verification logs. 3. The general supervisor stated during an interview on 2/21/23 at 1: 15pm, that the test records of two Mohs' patients had been destroyed in June 2022.
D3039	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation, record review, a memo, and interview, the laboratory failed to retain its quality system assessment records for at least two years. The findings include: 1. The surveyor observed that all the quality system assessment records had been destroyed, during a record review on 2/21/23 at 9:30am. 2. A memo from the general supervisor and laboratory director (refer to D6079) dated 7/12/22 stated that the test records were placed in a storage box, but during a mass cleaning were destroyed by an employee who shredded them. The destroyed quality system assessment records were the quality control charts, and quality assurance records. 3. The general supervisor stated during an interview on 2/21/23 at 1:15pm, that the test records of two Mohs' patients had been destroyed in June 2022.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: A. Based on surveyor observation, a memo, and interview, the laboratory director failed to ensure the preservation of records. The findings include: 1. The surveyor observed that all the test records had been destroyed, during a record review on 2/21 /23 at 9:30am. The destroyed records were for the analytic systems (refer to D3031), test system verifications (refer to D3033), and quality system assessments (refer to D3039). 2. A memo from the general supervisor and laboratory director dated 7/12/22 stated that the test records were placed in a storage box, but during a mass cleaning were destroyed by an employee who shredded them (refer to D3013). 3. The general supervisor stated during an interview on 2/21/23 at 1:15pm, that the test records of two Mohs' patients had been destroyed in June 2022. B. Based on surveyor observation, record review, and interview, the laboratory director failed to ensure the mobile laboratory had a valid motor vehicle registration. The findings include: 1. The surveyor observed the motor vehicle registration JAAG86, decal 19559034, had expired at midnight on 12/31/22, during a tour of the mobile laboratory on 2/21/23 at 10:30am (refer to D3009). 2. There was no valid vehicle registration, during a record review on 2/21/23. 3. The general supervisor stated during an interview on 2/21/23 at 1:30pm, that the mobile laboratory motor vehicle registration had expired on 12/31 /22.