

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2290136	(X3) Date Survey Completed 06/24/2026
Name of Provider or Supplier Ameripath Florida Llc	Street Address, City, State 1324 E Lake Cannon Drive Nw, Winter Haven, 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 Ameripath Florida LLC on 06242026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy twice annually for flow cytometry samples for one of one year reviewed, 2025, for the specialty Hematology and subspecialty Histopathology. Findings included: 1. Proficiency testing records for 2025 were reviewed for flow cytometry. The lab participated in an educational challenge dated 02/25/2025 with a proficiency testing company to verify the accuracy of testing reported for flow cytometry. No additional documentation was available. 2. An interview was conducted with the QA Specialist at 1:20 p.m. They stated, multiple time, they verify the accuracy by pulling 5% of the high complexity testing personnel's work but were unable to provide any further supporting evidence.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of

the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have all records and data accessible and retrievable during the survey conducted on 06/24/2026 for 11/2024 and 05/2026, for the subspecialty of Histopathology. Findings included: 1. The survey was announced via electronic communication on 05/24/2026 at 9 a.m., one month before the scheduled recertification survey. 2. An accession log was requested for 11/2024 on 06/24/2026 so a patient sample could be chosen to review the retention of analytic records. 2. An interview with the QA Specialist at 1 p.m. on 06/24/2026 revealed the lab had archived all the records from 2024. They stated it would take one week to retrieve any analytic records (stained slides) for that month. 3. Patient #4's Surgical Pathology Report dated 05/08/2026 was reviewed. The report had a comment "Immunohistochemical stains for CD138, kappa and lambda performed on block A." The surveyor requested the slides for review. 4. The QA Specialist was interviewed on 06/24/2026 at 2 p.m. They stated it would take 1 hour to retrieve the samples. It was agreed that the lab would communicate via encrypted electronic communication by 5 p.m. and provide the slides for patient #4. 5. Encrypted electronic communication was received on 06/24/2026 at 4:17 p.m. Patient #4's Hematoxylin and eosin stained slide was included however, the CD138, kappa, and lambda stained slides were not included.