

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2141169	<b>(X3) Date Survey Completed</b>  07/15/2021
<b>Name of Provider or Supplier</b>  Ameripath Florida Llc	<b>Street Address, City, State</b>  8300 Collier Boulevard, Naples, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced recertification survey was conducted on 7/15/21 at Ameripath Florida LLC, a clinical laboratory in Fort Myers, Florida. Ameripath Florida LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance. .
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on CMS 209, competency records and procedure manual record review, and interview by electronic correspondence (email) with the Laboratory Manager, the laboratory failed to have documentation of competency assessment for the subspecialties of histopathology for 2 out of 2 years reviewed (2019-2021) for Testing Personnel B. The findings included: Review of the "Policy for Performance Assessment of Delegated Duties" procedure on page 5 of 13 revealed that, "In addition to assessment of delegated duties, Clinical Consultants, Technical Consultants, Technical Supervisors, and General Supervisors who perform testing on patient specimens must also have competency assessment on each test system and it must include all six required elements." Review of the CMS 209 signed by the Laboratory Director on 7/13/21 revealed the laboratory had two Testing Personnel: Testing Person #A (who is also the Laboratory Director) and Testing Person #B. Review of Testing Person #B's personnel file revealed that competency assessments had not been performed for 2 out of 2 years (2019-2021). Interview by email on 7/15 /21 at 1:31 p.m., the Laboratory Manager stated in the past the peer review had been acceptable to demonstrate competency.</p>