

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2026857	<b>(X3) Date Survey Completed</b>  10/11/2021
<b>Name of Provider or Supplier</b>  West Florida Medical Specialists Pa D/B/A	<b>Street Address, City, State</b>  10820 State Road 54, #201, New Port Richey, 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 CLIA recertification survey was conducted at West Florida Medical Specialists PA DBA Gastroenterology Associates of West Florida on 10/11/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to retain the daily Embedding Center logs for 1 (September 2020) out of 4 (May 2019, January 2020, September 2020, and June 2021) months reviewed. Findings Included: Review of the policy and procedure (dated as reviewed by the Laboratory Director on 04/26/2021) revealed that "On a DAILY basis check and sign all appropriate aspects of the Embedding Quality Control Sheet." The log documented the cold plate temperature, paraffin temperature, clean forcep wells, remove paraffin debris, and clean wax reservoir. Review of the Embedding Center logs revealed no log for September 2020. Review of the slide Quality Control log revealed that patient testing occurred in September of 2020 on the 3, 7, 9, 15, 17, 22, and 26. On 10/11/2021 at 11:25 AM, Testing Person #B confirmed that the September 2020 Embedding Center log was not retained.</p>