

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0941531	(X3) Date Survey Completed 08/05/2021
Name of Provider or Supplier Gastroenterology Associates Pa	Street Address, City, State 415 North Center St Suite 300, Hickory, NC	
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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the equipment manufacturer's instructions and review of 2019, 2020, and 2021 temperature and humidity logs 8/5/21, the laboratory failed to document corrective actions when the humidity was outside the acceptable limits for the Tissue Tek DRS 2000 Stainer and the Tissue Tek Embedder. Findings: Review of the Tissue Tek DRS 2000 Automatic Slide stainer operating manual under specifications states, "Operating Conditions: ...Relative Humidity-30% to 85% (noncondensing)." The Tissue Tek TEC5 Tissue Embedding Console system operating manual under specifications states for the Embedding and Cryo module, "Relative Humidity range 30% - 85% RH(noncondensing)." Review of the 2019, 2020, and 2021 temperature and humidity logs revealed a 25-80% room humidity range which is inconsistent with the manufacturer's specifications. Review of the temperature and humidity logs also revealed the humidity was below the equipment manufacturer's limits of 30% with no corrective action documentation for the following: 1. 11 of 19 days in November 2019; 2. 5 of 22 days in January 2020; 3. 12 of 20 days in February 2020; 4. 8 of 16 days in March 2020; 5. 8 of 19 days in November 2020; 6. 11 of 21 days in December 2020; 7. 17 of 20 days in January 2021; 8. 16 of 20 days in February 2021; 9. 12 of 23 days in March 2021; 10. 6 of 8 days in April 2021.</p>