Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1104670	03/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Associates Of Osceola Pa	710 Oak Commons Blvd, Kissimmee, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to define the criteria for the conditions essential for the accurate and reliable test system operations. Findings: Review of the laboratory's procedure manual revealed that it did not include the ranges and the instructions for the recording of the oven, waterbath, room temperatures, and the room humidity. During an interview on 3/6/19 at 2:45 PM, Testing Personnel A acknowledged that the procedure manuals did not include the ranges and instructions to document the temperatures and humidity.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the negative reactivity for immunohistochemical (IHC) stains performed from 3/6/17 to 3/6/19, and the positive reactivity for IHC stains performed from 1/1/18 to 7/10/18 on all patients. This is a repeat deficiency from the recertification survey conducted on 3/2 /17. Review of the procedure "Batch Controls" noted that "the reading pathologist will keep a log (see attached) where he/she marks the quality and degree of the slide (positive vs negative)." The laboratory performs CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain) and H. pylori (Helicobacter pylori - bacteria) IHC stains. Review of the "Stain/Processing Quality Control Log Sheet" from 3/6/17 to 12/31/17 showed a single check marked under the columns for CD3 and H. pylori. The "Stain /Processing Quality Control Log Sheet" failed to indicate whether the positive, negative, or both controls were acceptable. On 1/1/18 the laboratory started using "Daily Slide and Stain Quality Control" to record stain reactivity. Review of the "Daily Slide and Stain Quality Control" showed that the laboratory failed to record the positive and negative reactivity of IHC slides from 1/1/18 to 7/10/18. Review of the "Daily Slide and Stain Quality Control" from 7/11/18 to 3/6/19 showed that the column for negative reactivity of the IHC stains was blank. Review of patient slides showed that 6 (#2, #3, #5, #7, #8, and #9) out of 10 patients slides examined had a slide for H. pylori. During an interview on 3/6/19 at 2:25 PM, Testing Personnel A stated that they did not record the reactivity of the positive and negative control for their IHC stains from 1/1/18 to 7/10/18. During an interview on 3/6/19 at 2:40 PM, Testing Personnel A stated they ran a negative control for the IHC stains, but failed to record the negative reactivity.