

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0872089	<b>(X3) Date Survey Completed</b>  11/18/2022
<b>Name of Provider or Supplier</b>  Boca Raton Gastroenterology Center Pa	<b>Street Address, City, State</b>  1000 Nw 9th Ct Ste 204, Boca Raton, 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>	A recertification survey conducted from 11/16/2022 to 11/18/2022 found the BOCA RATON GASTROENTEROLOGY CENTER PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain histopathology slides for at least 10 years for 53 cases in 2021. Findings include: -Review of stored slides revealed that the laboratory was missing the slides for 53 cases that were processed from January to April in 2021. During an interview on 11/16/2022 at 2:30 PM, the Laboratory Director confirmed that the laboratory failed to have on site the stained slides for the cases of reference, he explained that he was going to contact the reading pathologist to check if he had the slides of reference. On 11/18/2022, the laboratory confirmed that could not located the slides and they were going to request that new slides were processed.</p>
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(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</p>

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 observation, record review and staff interview, the laboratory failed to have and record the reactivity of negative control for immunohistochemical (IHC) stains for four (#1, #2, #3 and #4) of four (#1-#4) patients' slides and Pathology Reports reviewed in 2021 and 2022. Findings include: -The laboratory performs only the microscopic examination of the slides. Four of four patients' slides and Pathology Reports reviewed had IHC stained slides. The laboratory evaluated the following IHC stains: (Cluster Differentiation 3 T cell Lymphocytic (CD 3), Helicobacter pylori (H. pylori) IHC stain and protein CDX 2 (CDX2) IHC stain. No documentation of the IHC controls reactivity in the reports -Review of Stain control log for 2021 and 2022 revealed that the laboratory failed to document the negative control reactivity for the IHC of reference and failed to have negative control slides. During an Interview on 11/16/2022 at 02.30 PM, the laboratory director confirmed that the laboratory failed to have and document the negative control reactivity for the IHC stains for the cases of reference.