

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0989523	<b>(X3) Date Survey Completed</b>  01/08/2024
<b>Name of Provider or Supplier</b>  Steven M Hacker Md Pa	<b>Street Address, City, State</b>  230 George Bush Blvd Ste B, Delray Beach, 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 was conducted on January 8, 2024. Steven M Hacker MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5609</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control documents and interview, the laboratory failed to document quality control information including the lot numbers, expiration dates, and open dates for all reagents used in the staining of the Hematoxylin &amp; Eosin (H&amp;E) slides from 09/23/2021 to 01/08/2024. Findings: Review of the Regular H&amp;E and Mohs Stain procedure showed the lab used the following reagents: Xylene Substitute, 100% Alcohol, 95% Alcohol, Hematoxylin, Define, Bluing, and Eosin. Review of the laboratory's quality control records revealed there was no type of reagent log with the quality control information. On 01/08/2022 at 3:30 PM, the Histology Technologist stated they did not have a reagent log.</p>