

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2032238	(X3) Date Survey Completed 02/14/2022
Name of Provider or Supplier Daniel D Cohen Md Pa	Street Address, City, State 315 N Lakemont, Winter Park, 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
D0000	A recertification survey was conducted on February 14, 2022. Daniel D Cohen MD PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	<p>RETENTION REQUIREMENTS 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 Quality Control (QC) records that documented the stain quality for the Hematoxylin and Eosin Stain (H&E), Papanicolaou stain (PAP), Acid Hem stain, and Immunohistochemical Stains (IHC) for five (#3, #4, #5, #6, #7) of seven patients (#1, #2, #3, #4, #5, #6, #7). Findings: The laboratory's "Stain QC Log" reported the quality of the H&E, PAP, Acid Hem, and IHC stains. Review of the laboratory's "Stains QC Log" showed the Previous Laboratory Director recorded the stain quality for January 2020, February 2020, March 2020, October 2020, December 2020 and January 2, 2021. Review of the patient's "Uro pathology Report" showed stain results were reported on the following patients: Patient #3 reported on 07/17/2020 Patient #4 reported on 06/30/2020 Patient #5 reported on 03/17/2020 Patient #6 reported on 02/03/2021 Patient #7 reported on 02/16/2021 The stain QC logs for the above mentioned dates were not available for review. On 02/14/2022 at 3:30 PM, Histology Support Technician stated the Previous Laboratory Director came in a limited number of times during the pandemic. She said she did not know where the stain QC logs were located.</p>