

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2031758	<b>(X3) Date Survey Completed</b>  09/13/2022
<b>Name of Provider or Supplier</b>  Patricia McCormack, Md	<b>Street Address, City, State</b>  515 North Wood Avenue, Linden, NJ	
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>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 surveyor review of the Histopathology Slides (HS) and interview with the Office Manager (OM), the laboratory failed to retain HS for 10 years from the date of examination at the time of the survey. The finding includes: 1. Five patient records were reviewed from May 2022 to June 2022. Three of the five patients slides were not available at the time of the survey. 2. The OM confirmed on 9/13/22 at 11:00 am the HS were not retained.</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 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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from 6/6/22 to the date of survey. The findings include:

1. The laboratory did not document H&E QC reaction for reading of Histopathology slides.
2. The laboratory read and reported approximately 912 patient slides.
3. The OM confirmed on 9/13/22 at 10:40 am that the laboratory did not document H&E QC stain reaction.