

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0725831	(X3) Date Survey Completed 06/14/2018
Name of Provider or Supplier Paul F Rockley Md	Street Address, City, State 17101 Ne 19th Ave Ste 101, North Miami Beach, 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
D5609	<p>HISTOPATHOLOGY 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 record review and interview, the laboratory failed to document the open dates for reagents used in their Hematoxylin & Eosin (H & E) stains. Findings include: Record review of the laboratory's logs titled "Reagent Log", "Tissue Processor Maintenance Log" and "Hematoxylin and Eosin Staining Maintenance Log" showed that the laboratory failed to record when the reagents were opened from 6/14/16 to 6/14/18. During an interview on 6/14/18 at 3:08 PM, Testing Personnel B stated she didn't know they needed to record the open date for their reagents.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment (QA) plan failed to monitor, access and correct problems identified to ensure the accuracy of patient reports. Findings include: Review of the laboratory's monthly QA checklist documentation showed that the laboratory did not do any random monthly review of patient requisitions to the final surgical reports to ensure accuracy from 6/14/16</p>

through 6/14/18. During an interview on 6/14/18 at 4:12 PM, Testing Personnel B stated they did not do monthly random checks of patient requisitions to the final surgical reports to ensure accuracy.