

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0719483	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Rutgers Diagnostic Services	Street Address, City, State 110 Bergen Street, Newark, NJ	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from October 2017 to the date of survey. The LD confirmed on 1/25 /18 at 11:00 am that a BA procedure was not established.</p>
D5601	<p>HISTOPATHOLOGY 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: Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to record the reaction of a QC slide for</p>

Hematoxylin and Eosin stains used in Histology Testing from October 2017 to the date of survey. The LD confirmed on 1/25/18 at 11:10 am that a QC reaction was not documented.