

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0719483	(X3) Date Survey Completed 09/24/2019
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, interview with the Laboratory Director (LD), the laboratory failed to establish acceptable written procedures for Biannual Assessment (BA) calendar years 2018 and 2019. The findings include; 1) The BA did not have the current licence for the Physician reviewing the slides. 2) The BA did not state that slides were being sent to the reviewing physician without the diagnosis. 3) The LD confirmed on 8/6/19 at 10:30 am that the LD failed to establish acceptable written procedures for BA.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Test Report (TR) and interview with the Laboratory Director (LD), the laboratory failed to include the name and address of the laboratory where the Technical Component (TC) for Histopathology tests were performed from 1/25/2018 to the date of survey. The LD confirmed on 9/24/19 at 10:00 am that the TC laboratory name and address was not on the TR.