Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0719483	11/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rutgers Diagnostic Services	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Histopathology testing from 8/1021 to the date of survey. The LD confirmed on 11/14 /23 at 1:30 pm that the laboratory did not perform BA for Histopathology.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (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. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing on the date of survey. The findings include: 1. The laboratory did not document H&E stain QC reactions. 2. The

	laboratory read and reported approximately 200 patients annually,. 3. The OM confirmed on 11/14/23 at 1:30 pm that the laboratory did not document H&E QC stain reactions.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the TR included all the required information on the date of survey. The finding includes: 1. The TR did not have the name and address of where the Techincal Component for histopathology was performed. 2. The LD confirmed on 11/14/23 at 1:30 pm that the TR failed to include all the required information.