

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0861976	(X3) Date Survey Completed 03/13/2018
Name of Provider or Supplier Raphael Reiss & Physicians Pc	Street Address, City, State 69-05 Yellowstone Blvd, Forest Hills, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of laboratory quality control (QC) records and an interview with the laboraoty testing person, the laboratory failed to test QC material when a new bottle of Siemens' Ketostix reagent strips was opened. Findings Include: It was confirmed with the laboratory testing person on March 19, 2018 that the laboratory failed to follow the manufacturer's instruction for the Siemens' Ketostix reagent and test a poitive/negative control when the bottle is first opened. Approximately 2000 patient tests were performed for urinalysis and results reported for year 2017.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of patient reports/records and an interview with the laboratory director, the laboratory failed to have a written or electronic request order for patient testing. Finding Include: It was confirmed by the laboratory director on March 13, 2018, at approximately 1:00 PM that during the review of patient charts /records the laboratory failed to have documentation of test orders for four of six patient tested for the BD Affirm VP III.</p>

D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory testing person, the director did not sign and date the laboratory's procedures. Finding Include: It was confirmed by the laboratory testing person on March 13, 2018, at approximately 1:15 pm, that the laboratory director failed to approve, sign and date the Individualized Quality Control Plan (IQCP) validation procedure and the accepted manufacturer's procedure test manual for the BD Affirm VPIII test kit.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures and records and an interview with the laboratory director and testing person, the laboratory director failed to sign the IQCP procedure and the accepted manufacturer's manual for the BD Affirm VP III. Refer to D5301, and D5407.</p>