Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0879840	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ronald G Frank Md	1500 Pleasant Valley Way, West Orange, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. 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 have a procedure to verify new lots of controls before they were put in use for Prostate Specific Antigen (PSA) tests performed on the Qualigen Fast Pack from 11/08/18 to the date of the survey. The LD confirmed 6/8/21 at 1:30 pm that laboratory did not have the above procedure.