Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2004353	02/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Regional Women's Lab	221 Laurel Road, Suite 155, Voorhees, 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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the General Supervisor (GS), the laboratory failed to ensure that test requisition included relevant and necessary information for accurate and reliable testing and reporting from 1/21/16 to the date of survey. The finding includes: 1. Review of five out of five TR revealed that there was no source of specimen information on TR. 2. The GS confirmed on 2/8/18 at 10:40 am that source of specimen information was not on TR.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the General Supervisor (GS), the laboratory failed to establish a procedure for verifying manual entry of test performed on Gen Probe from work log to the laboratory information system from 1/21/16 to the date of survey. The GS confirmed on 2/8/18 at 11:00 am that the laboratory have manual entry verification procedure.