



NOTICE

Date: March 2, 2009

Dear Valued Clients:

Please be advised that Foundation Laboratory has altered the methodology for Rubella IgG from latex spot test to ELISA. Rubella ELISA II Test System is designed for the qualitative and/or quantitative detection of IgG antibodies to rubella virus in human serum. The test system is intended to be used to evaluate single sera for immune status or paired sera to demonstrate seroconversion, and is for *in vitro* diagnostic use. The results will be in numerical form with optical density ratio and IU/mL, replacing “immune”, “non-Immune” verbiage.

Index Values or OD ratios are interpreted as follows:

	<u>Index Value or OD Ratio</u>
Negative Specimens	≤ 0.90
Equivocal Specimens	0.91 to 1.09
Positive Specimens	≥ 1.10
	<u>IU/mL</u>
Negative Specimens	≤ 8.18
Positive Specimens	≥ 10.0
Equivocal Specimens	8.19 to 9.99

Linearity of the test system is 0-20 IU/mL. Values greater than 20 IU/mL will be reported as >20 IU/ml

Sincerely;

J. Kermani, MSMT (ASCP, NCA), Ph.D.
Director of Technical Operations