



March 2009

Dear Valued Customer,

bioMérieux, Inc is pleased to announce the FDA 510(k) clearance for our new second-generation **VIDAS® Rubella IgG** assay, product **#30226**. This new assay is intended as an aid in the determination of Rubella patient immune status.

The new **VIDAS Rubella IgG** assay, **product #30226** includes the following enhancements compared to the previous VIDAS Rubella IgG assay, product #30200:

- Quantitative versus Qualitative results
- World Health Organization (WHO) standardized **International Units (IU/mL)** versus **assay unique units**
- Stated traceability to the 1st WHO International Standard for anti-Rubella serum (Anti Rubella Immunoglobulin, Human NIBSC code: RUBI-1-94)
- Use of the Clinical Laboratory and Standards Institute (CLSI) recommended 10 IU/mL threshold for positive immune status

You will be contacted by your bioMérieux Sales Specialist in the near future to discuss your transition to the new second-generation **VIDAS Rubella IgG** assay, product **#30226**. Be sure to inquire about bioMérieux's other VIDAS assays for determining immune status.

Product	Product #	Product Description	Tests/Kit
Mumps	30218	For the qualitative detection of Mumps Virus IgG antibodies in serum	60
Measles	30219	For the qualitative detection of Measles (Rubeola) Virus IgG antibodies in serum	60
Varicella-Zoster	30217	For the qualitative detection of Varicella Zoster Virus IgG antibodies in serum	60
Toxoplasmosis IgM	30202-01	For the qualitative detection of Toxoplasma gondii IgM antibodies in serum	60
Toxoplasmosis IgG	30210-01	For the qualitative detection of Toxoplasma gondii IgG antibodies in serum	60
Toxoplasmosis IgM/IgG	30211-01	For the qualitative detection of Toxoplasma gondii IgG and IgM antibodies in serum or plasma	60
CMV IgG	30204-01	For the semi-quantitative detection of Cytomegalovirus IgG antibodies in serum	60
CMV IgM	30205-01	For the qualitative detection of Cytomegalovirus IgM antibodies in serum	30

Regards,

Beth Cosey
U.S. Clinical Marketing, VIDAS

P/N 60-00468-0



For More Information Contact:

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