



ADVISORY NOTICE

REFERENCE: AN/01/05-06-OLMEI

**IgM
OSR6146 – All Lots**

Market Correction

Dear Olympus customer,

Olympus Life and Material Science Europa GmbH (Irish Branch) has determined that in very rare circumstances an excessively elevated IgM may give inappropriately low IgM results without any flags.

We have confirmed that a sample with a monoclonal IgM of around 120 g/L failed the IgM prozone check and was reported as being within the measuring range without any flagging to alert the operator to this abnormal condition. Although this sample failed the prozone check we are confident that the prozone check is appropriately configured and functions correctly for IgM concentrations up to 70g/L (7000 mg/dl).

A Corrective Action is being implemented to further optimise the prozone settings for this parameter, and you will receive this information in the form of a User Update as soon as we have completed this optimisation process.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

Olympus Life and Material Science Europa GmbH apologises for the inconvenience this issue may cause. If you require further information please contact your local Olympus representative. Thank you for your continued support of Olympus products.

Sincerely,

Dated: 04 May 2006

Christine Fazentieux
(Regulatory Affairs Specialist)