



ADVISORY NOTICE

REFERENCE: AN/02(OE)/05-06-OLMEI

**CRP
OSR6199 – All Lots**

For the Highly Sensitive Application on the AU400/600/640 system

Market Correction

Dear Olympus customer,

Olympus Life and Material Science Europa GmbH (Irish Branch) has confirmed that a sample with a CRP concentration above the upper limit of the measuring range of 160 mg/L returned a result within the measuring range without an alert for the user of this incorrect result.

Olympus will be revising the CRP reagent Instruction For Use to include the following statement:

"When using the Highly Sensitive Application on the AU400/600/640 systems, patients with CRP concentration above 400mg/L may return an inappropriately low CRP result, within the measuring range. Patients with inflammatory and/or infectious conditions should have their CRP measured using the Normal Application, particularly in patient monitoring."

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: 31st May 2006

Christine Fazentieux
(Regulatory Affairs Specialist)