
Urgent Field Safety Notice

Hemoglobin Denaturant, OSR0004 – All lots

FSN/02/01-08-OLRE

Market Correction.

Date: 25-Jan-08

Dear Olympus customer,

Olympus Life Science Research Europa GmbH wishes to inform you of a potential problem with the performance of the **Hemoglobin Denaturant, OSR0004**, which has been released to the market. The Olympus Hemoglobin Denaturant Reagent is intended for pre-treatment of whole blood samples prior to analysis with the Olympus HbA1c reagent OSR6192.

This Field Safety Corrective Action has been generated as a result of 3 isolated incidents in the USA where incorrect HbA1c values were reported. Extensive investigations were unable to reproduce this issue; however we are centering our investigations on the pre-treatment phase as we recognise this is a potentially variable event. As a precaution we wish to emphasise/reinforce our instructions concerning the pre-treatment step until our investigations identify the root cause of this issue.

These recommendations are in 2 parts; handling of the denaturant in order to minimise any contamination risk and additional QC management procedures.

(i) Handling the denaturant OSR0004:

- Never use discoloured or turbid denaturing solution and always store this reagent at 2-8°C.
- Pour off the amount of denaturant needed to pre-treat samples into a clean container - recap and return the opened denaturant bottle to storage at 2-8°C.
- Only pipette from this aliquot - Do not pipette directly from the opened bottle of denaturant.
- Discard any remaining unused aliquotted denaturant.

(ii) Additional pre-treatment/QC recommendations:

1. Strictly follow the pre-treatment directions in the Instructions for Use of HbA1c Control (ODC0022).
2. Incubate controls with the denaturant at room temperature for exactly 5 minutes before placing onto the system. It is imperative that this step is controlled as accurately as possible and that it reflects the process that all patient samples are subjected to.
3. Once a control has been assayed - discard it - never rerun pre-treated HbA1c controls; instead repeat the pre-treatment step. This will ensure that any issues with the pre-treatment process or denaturant solution are identified and the performance of the HbA1c assay (OSR6192) is effectively monitored.
4. If at any time HbA1c controls are out of range, discontinue the use of the current open bottle of OSR0004 Hemoglobin Denaturant and repeat steps 1-4.
5. Review any HbA1c results that have been generated prior to this QC material being assayed and repeat samples as necessary.
6. Contact your local support organization to return the affected vial for replacement product as required.

***This Field Safety Notice can be translated
however the legally binding version is the original English letter issued by OLRE***



While we are continuing our investigations of this issue, we advise all customers to closely follow the above recommendations. Further corrective measures will be implemented once the root cause is determined.

Please share this information with your laboratory staff and retain this notification in your Olympus Reagent Guide.

Olympus Life Science Research 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.

Contact reference person:

Catriona NEILAN
Regulatory Affairs Department

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency
Sincerely,

Catriona Neilan,
OLRE Regulatory Affairs Department

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FSN/02/01-08-OLRE
FQA105
CCF 08-0061

Version 9
Ref: SOP RA 010

Page 2 of 2
Effective date: 24 JAN 2008

