

April 2011

Update to letter dated March 2011

### IMPORTANT PRODUCT INFORMATION

This information is intended for the end user of this product  
If you are not the end user, please forward this information to the appropriate laboratory personnel

**Subject: Disinfecting swabs CON-ZELLIN included in individual test devices of OptiMAL-IT (Ref. 710024) and IT-Leish (Ref. 710124) kits.**

**OptiMAL batches affected: 0C0011M, 0J0024M, 0K0027M and 0K0030M**

Dear Customer

We have been informed by the MHRA (Medical and Healthcare products Regulatory Agency), Ref: MDA/2011/023, of a problem with potential bacterial contamination of some lots of the **disinfecting swabs CON-ZELLIN included in individual test devices of OptiMAL-IT (Ref. 710024) and IT-Leish (Ref. 710124) kits.**

MHRA advise that potential bacterial contamination of the alcohol swabs may lead to skin infection. Immunocompromised individuals are at greater risk of serious infection.

This problem is confined to the alcohol swabs and does not affect any other components of the kits.

On advice from MHRA we are implementing the following corrective actions:

- **CON-ZELLIN disinfecting swabs from lots starting with a # 7, 8, 9, or 0, which are included in individual packs of OptiMAL-IT and/or IT-Leish kits must not be used any more for skin preparation.**
- Replace with the sterile swab attached to the kit or use cotton with modified alcohol.
- Please ensure CON-ZELLIN disinfecting swabs that are removed from the kit are disposed of safely and securely.

**If you are not the final user of OptiMAL-IT and/or IT Leish kits, please take necessary actions to ensure this information is forwarded to the end user.**

We apologise for the inconvenience, and remain at your disposal for any further information.

Yours sincerely,

TCS BIOSCIENCES LTD

A handwritten signature in blue ink, appearing to read 'G. Williams', is written over the printed name and title.

Gareth Williams  
Sales and Marketing Director



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