

## **Urgent Field Safety Notice**

### **T-Cell *Select*™ Reagent Kit (Cat. No. TSK.910)**

**06 March 2021**

### **Device Modification – Change in the stated shelf life**

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**Date:** 06 March 2021

**Attention:** Laboratory Manager and Users of T-Cell *Select* reagent kit

#### **Details on affected devices:**

**Product:** T-Cell *Select* kit

**Kit Catalogue number:** TSK.910

**Kit Lot Numbers:** 016

#### **Description of the problem:**

We have recently noticed an error on the labelling of the T-Cell *Select* reagent kit, lot number 016, which indicates a shelf life longer than the validated shelf life for the product. The aforementioned device has been labelled with an incorrect expiration date of 20 August 2021 (2021-08-20).

**The correct expiration date for T-Cell *Select* lot 016 is 06 July 2021 (2021-07-06).**

If the device is used after 06 July 2021, there is a risk of malfunction affecting performance when used in association with a cell-mediated immune assay, such as the T-SPOT.*TB* test. This variation in performance carries a potential risk of false negative or false positive results. There is no risk associated to devices used before 06 July 2021.

**Advice on action to be taken by the user:**

Due to this incident, we ask that you take the following measures:

1. Identify any T-Cell *Select* lot 016 remaining in stock.
2. Ensure T-Cell *Select* lot 016 remaining in stock is used before the modified expiration date of 06 July 2021
3. Confirm that you have received this information by signing the attached *Customer Information Form*.
4. Please inform us about both the number of kits you have in your stock in the attached *Customer Information Form*.

**Transmission of this Field Safety Notice:**

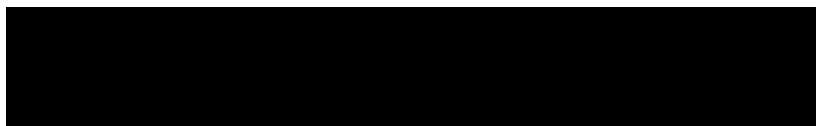
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred, if appropriate.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact reference person:**

Dr. Jon Hughes  
VP, Regulatory Affairs & Quality Assurance  
Oxford Immunotec Ltd.  
143 Park Drive East, Milton Park,  
Abingdon, OX14 4SE, UK  
Tel: +44 (0)1235 442 780  
Email: [regulatory@oxfordimmunotec.com](mailto:regulatory@oxfordimmunotec.com)

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

**Important Note:**

This Field Safety Notice has no impact on the performance of the T-SPOT.*TB* test kit, and customers can continue to use other cell separation methods, as described in the T-SPOT.*TB* package insert.

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## **Customer Information Form**

Please complete and send this form by e-mail to [regulatory@oxfordimmunotec.com](mailto:regulatory@oxfordimmunotec.com) immediately after receiving the Urgent Field Safety Notice for the following:

**Product:** T-Cell *Select* reagent kit

**Kit Catalogue number:** TSK.910

**Kit Lot Numbers:** 016

We understand that we should immediately:

1. Identify any T-Cell *Select* lot 016 remaining in stock and record below
2. Ensure T-Cell *Select* lot 016 remaining in stock is used before the modified expiration date of 06 July 2021.

Number of kits remaining in stock:

Name:

Title:

Customer Name:

Country:

Signature:

Date: