
10 January 2019

Urgent Field Safety Notice

Product removal from the market

Product: T-Cell *Select*[™] (Cat. No. TSK.910)

Dear Customer,

Oxford Immunotec Ltd. has made a decision to recall the following kit lots from the market:

Product: T-Cell *Select* kit

Kit Catalogue number: TSK.910

Kit Lot Numbers: 001, 002, 003, 006, 009

We have recently noticed variation in the performance of the kit lots mentioned above, effecting the performance of the device in its associated use with the T-SPOT[®].*TB* test. The variation in performance has led to a potential risk of a small number of false positive results. According to our investigations so far, the anomalies seem to be related to deterioration in the performance characteristics of a reagent component in the affected lots, but the root cause is still to be confirmed.

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

- Identify and quarantine any affected device lots remaining in stock. Immediately discontinue T-Cell *Select* use with the T-SPOT.*TB in vitro* diagnostic test.
- Evaluate the need for patient follow up for any positive results observed using the affected lots and, based on the opinion of the patient's clinician and any concurrent clinical assessments, consider re-testing patients with a positive result. [Please note that the T-SPOT.*TB* test is intended for use as an aid in the diagnosis of tuberculosis infection and, as such, a positive result should always be interpreted only in the context of the overall clinical picture and, therefore, in the light of additional clinical signs and symptoms of disease. Clinicians should use their judgement when reviewing the results.]
- Confirm that you have received this information by signing the attached *Customer Information Form*.

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- Please inform us about both the number of kits you have in your stock in the attached *Customer Information Form*.
 - All remaining kits should be returned to Oxford Immunotec Ltd.

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.

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

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.

Jon Hughes Ph.D., FTOPRA
VP, Regulatory Affairs & Quality Assurance

Customer Information Form

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

Product: T-Cell *Select* kit

Kit Catalogue number: TSK.910

Kit Lot Numbers: 001, 002, 006, 009

We understand that we should immediately:

1. Quarantine and discontinue the use of the above mentioned kit lots
2. Follow-up any patient with a positive result
3. Collect and return remaining kit lots to Oxford Immunotec Ltd.

Number of kits received:

Number of kits remaining in stock:

Name:

Title:

Customer Name:

Country:

Signature:

Date: