



## **URGENT FIELD SAFETY NOTICE**

**Commercial name of the affected product:** E2A (TCF3) Breakapart Probe

**FSCA identifier:** VC/2021/008

**Type of action:** Device Destruction

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**Date:** 28 May 2021

**Product name(s):** E2A (TCF3) Breakapart Probe

**Catalogue number(s):** LPH019 and LPH019-S

**Lot number(s):** 073521, 072967, 072835 and 074018

**Product expiry date(s):** 09/22

**Dear [Customer/Distributor Name],**

The purpose of this letter is to advise you that Cytocell Ltd is issuing a Field Safety Corrective Action (FSCA) on product LPH019 and LPH019-S E2A (TCF3) Breakapart Probe, Lots 073521, 072967 and 074018 (Probe lots 200918-006, 200918-006, 200918-006 and 200918-008). Our records show that you have received one or more units of the affected devices.

### **Technical details:**

This FSCA has been initiated due to a complaint investigation establishing that the device may show unexpected locus specific signals in addition to those at 19p13.3. Users may observe faint additional locus specific signals at 9q34. These additional signals have been observed at Cytocell under normal use conditions, but could be ignored as cross hybridisation as they are weaker than the main probe signal at 19p13.3. The device instructions for use indicates the probe has no known cross-reactivity and sequence homology checks have confirmed there is no known cross hybridization to 9q34.

Cytocell have not identified any health risks and do not expect any adverse health consequences associated with the use of this device. There is a low risk of a no result being obtained when using the LPH019 and LPH019-S E2A (TCF3) Breakapart Probe.

The internal investigation has shown the locus specific signals at 9q34 may be visible under normal use conditions. The presence of additional green signals in a single cell would alert an analyst that this is an unusual signal pattern.

### **Recommended actions for distributors and end users:**

Immediately examine your inventory and quarantine all product subject to recall. Cytocell requests that you destroy the remaining inventory. We also suggest that laboratories undertake a review of the results obtained with the affected devices and



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check that signal patterns were not misinterpreted as a result of any additional locus specific signal at 9q34.

**Transmission of this Field Safety Notice:**

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

We wish to sincerely apologise for any inconvenience caused as a result of this Urgent Field Safety Notice. If you have any questions or comments arising from this Urgent Field Safety Notice, please contact us at on +44(0) 1223 294048 or email us at [vigilance@ogt.com](mailto:vigilance@ogt.com).

Yours sincerely,

A handwritten signature in black ink, appearing to be 'S. Chatters', with a long horizontal flourish extending to the right.

Steve Chatters  
Executive Vice President of Regulatory, Medical, and Quality Affairs  
Cytocell Ltd.



# DECLARATION FORM

**Commercial name of the affected product:** E2A (TCF3) Breakapart Probe

**FSCA identifier:** VC/2021/008

**Type of action:** Device Destruction

**Email:** [vigilance@ogt.com](mailto:vigilance@ogt.com) **or Fax to:** +44 (0) 1223 294986

## Customer Information

Organisation: [Customer/Distributor Name]

Address: [Customer/Distributor Address]

Contact person: [Customer/Distributor Contact Name]

Our records show that you have received the following quantities of affected devices. Please complete the table below, sign the declaration and return to Cytocell as soon as possible.

Affected Product Reconciliation Table (from end users)					
Product / Description	Lot	Quantity Received	Quantity Used (by end users)	Quantity destroyed	Quantity of replacements required
LPH019 E2A (TCF3) Breakapart Probe	073521				
LPH019 E2A (TCF3) Breakapart Probe	072967				
LPH019 E2A (TCF3) Breakapart Probe	072835				
LPH019-S E2A (TCF3) Breakapart Probe	074018				

## Declaration

I hereby confirm that we have read and understood the Urgent Field Safety Notice LPH019 and LPH019-S E2A (TCF3) Breakapart Probe and we have communicated this to all our end users of the above stated device. We confirm that all actions have been carried out and evidence of completion can be provided as requested.



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**As declared by (name):**

**Job Title:**

**Signature and date:**

Please sign this form and return the completed document (by FAX or as a scanned PDF) to the address provided above within two weeks.