



URGENT FIELD SAFETY NOTICE

Commercial name of the affected product: TCL1 Breakapart Probe

FSCA identifier: VC/2021/006

Type of action: Device Destruction

Date: 20th May 2021

Product name(s): TCL1 Breakapart Probe

Catalogue number(s): LPH046

Lot number(s): 074332 and 074190

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 LPH046 TCL1 Breakapart Probe, Lots 074332 and 074190 (Probe lots 200923-018 and 200928-009). 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 14q32. 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 14q32. 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 LPH046 TCL1 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 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 check that signal patterns were not misinterpreted as a result of any additional locus specific signal at 9q34.



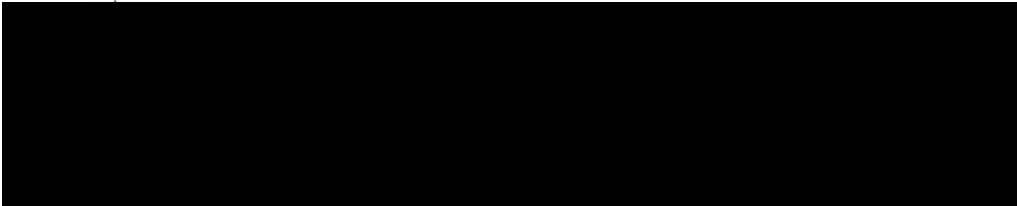
A Sysmex Group Company

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation.

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.

Yours sincerely,



CytoCell Ltd.



DECLARATION FORM

Commercial name of the affected product: TCL1 Breakapart Probe

FSCA identifier: VC/2021/006

Type of action: Device Destruction

Email: 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	Quantity destroyed	Quantity of replacements required
LPH046 TCL1 Breakapart Probe					

Declaration

I hereby confirm that we have read and understood the Urgent Field Safety Notice on LPH046 TCL1 Breakapart Probe. We confirm that all actions have been carried out and evidence of completion can be provided as requested.

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.