A Sysmex Group Company

URGENT FIELD SAFETY NOTICE

Commercial name of the affected product: *FAST* FISH Prenatal Enumeration Probe kit
FSCA identifier: VC/2022/006
Type of action: Device Destruction

Date: 25 February 2022

Product name: *FAST* FISH Prenatal Enumeration Probe kit

Catalogue number: LPF001-50

Lot numbers: 078495, 078572

Product expiry date: 2023-04

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 LPF001-50, lots 078495 and 078572 (probe lot: 211222-033). 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, during manufacture of this probe, the Y centromere (DYZ3) has been labelled with an incorrect fluorophore. As a consequence the Y centromere is labelled in Red rather than Orange as indicated in the device labelling. This means that users will see the Y chromosome with the DAPI/FITC/Texas Red filter but may not see it with DAPI/FITC/TRITC as described within the instructions for use.

Cytocell have identified a risk that an incorrect result for Turner syndrome (false positive) or Klinefelter syndrome (false negative) may be reported out due to this issue.

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 no results were misinterpreted due to the incorrect fluorophore labelling.

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.

Cytocell Limited, OGT
418 Cambridge Science Park, Milton Road, Cambridge CB4 0PZ
T: +44 (0)1223 294048 F: +44 (0)1223 294986 E: probes@cytocell.com W: ogt.com

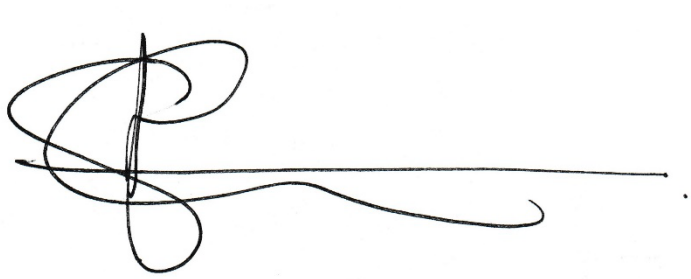
CytoCell

Please transfer this notice to other organisations on which this action has an impact.

Please follow up on this notice and resulting action for an appropriate period to ensure required actions have been carried out.

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,



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

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DECLARATION FORM

Commercial name of the affected product: *FAST* FISH Prenatal Enumeration Probe kit
FSCA identifier: VC/2022/006
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 Reconcilliation Table				
Product / Description: LPF001-50 *FAST* FISH Prenatal Enumeration Probe kit				
Lot	Quantity Received	Quantity Used	Quantity destroyed	Quantity of replacements required
078495				
078572				

Declaration
I hereby confirm that we have read and understood the Urgent Field Safety Notice on LPF001-50 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.

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.

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