sysmex | Together for a better healthcare journey

# CytoCell

Be ready for the future, today!

## First to market IVDR-certified FISH probes

*'IVDR is all about patient safety and effectiveness, and at OGT, we're really committed to compliance with changing worldwide regulations and providing products that meet these needs, for clinicians and patients alike. We are 100 % IVDR-ready gaining certification for our first set of CytoCell® FISH probes. Our IVDR FISH probes are still the same trusted products that we've always had – the certification has further validated our quality, safety and effectiveness. These are products and a company you can depend on.'*

**Steve Chatters**
**Executive Vice President of**
**Regulatory, Medical and Quality Affairs at OGT**

Learn more about IVDR
**www.sysmex-europe.com/cytocell**

CytoCell
IVDR-certified probes

# Why should you move to IVDR-certified FISH probes today?

In 1991, CytoCell® became the first provider of FISH probes in the world. Over 30 years later, they are still pioneering the FISH frontiers and are the first to market with In Vitro Diagnostic Regulation (IVDR) certified FISH probes!

**Switching to IVDR-certified FISH probes means you can be confident that your laboratory is using safe, reliable and effective tools for diagnosing patients.**

CytoCell® IVDR FISH probes remain the same trusted products with the extra IVDR seal — the unquestionable testament to our commitment to provide innovative, class-leading products under this substantially more stringent regulation.

## Quality and confidence

IVDR certification demonstrates our continued commitment to provide safe, reliable and effective products.

## No revalidation needed

Our IVDR probes are the same robust, reliable designs, so existing users do not have to revalidate, saving you time in the lab.

## Support

Our experienced Field Applications Scientists are dedicated to supporting you to optimise our products, on-site or remotely.

# Introducing our first IVDR-certified FISH probes, more are to follow!

| | Probe name | Supported disease | Cat. No. |
|---|---|---|---|
| **Haematological malignancies** | AML1 (RUNX1) Breakapart Probe | AML, ALL | CE-LPH 027 |
| | AML1/ETO (RUNX1/RUNX1T1) Translocation, Dual Fusion Probe | AML | CE-LPH 026 |
| | BCR/ABL (ABL1) Translocation, Dual Fusion Probe | ALL, CML, AML | CE-LPH 007 |
| | CKS1B/CDKN2C (P18) Amplification/ Deletion Probe | MM | CE-LPH 039 |
| | *FAST* PML/RARα (RARA) Translocation, Dual Fusion Probe | AML | CE-LPH 064 |
| | IGH/MAF *Plus* v2 Translocation, Dual Fusion Probe | MM | CE-LPH 108 |
| | BCR/ABL (ABL1) *Plus* Translocation, Dual Fusion Probe | ALL, CML, AML | CE-LPH 038 |
| | CBFB Breakapart Probe | AML | CE-LPH 089 |
| | MLL (KMT2A) Breakapart Probe | ALL, AML, MDS | CE-LPH 013 |
| **Aneuploidy testing** | Prenatal 13 and 21 Enumeration Probe Kit | Down and Patau syndrome | CE-LPA 003 |

Check our IVDR certification first-hand from the accredited notified body website

OGT's CytoCell® IVDR-certified range of fluorescence *in situ* hybridisation (FISH) probe kits are *in vitro* diagnostic (IVD) medical devices for the detection of prenatal trisomy 13 & 21 and acquired cancer-related chromosome alterations. They have been CE-marked under Regulation (EU) 2017/746 (IVDR) as Class C IVD medical devices for laboratory professional use only and are not intended for use as a standalone diagnostic or companion diagnostic. Refer to each individual FISH probe kit's Instructions for Use for their specific Intended Purpose, Indications, and Limitations.
CytoCell®: Product availability may vary from country to country and is subject to varying regulatory requirements. Contact your local representatives for availability.
CytoCell® is a registered trade mark of Cytocell Limited.

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**Manufacturer CytoCell®: Cytocell Limited · www.ogt.com**
You will find your local Sysmex representative's address under www.sysmex-europe.com/contacts

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