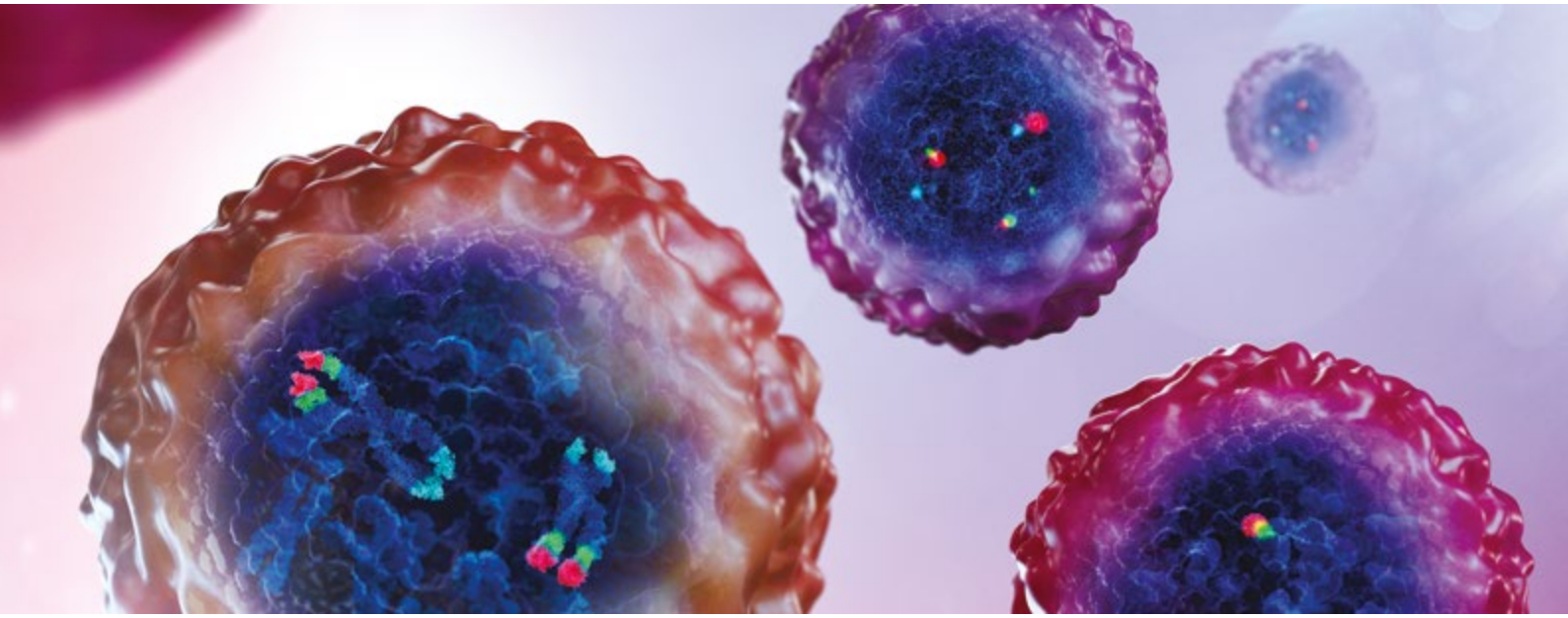
sysmex | Together for a better healthcare journey

CytoCell

Be ready for the future, today!

First to market IVDR-certified FISH probes



"We are committed to providing our customers with products that meet their needs, their patients' needs, and the highest standards of regulatory compliance.

At OGT, we were the first FISH manufacturer to introduce IVDR-certified CytoCell® FISH probes and these probes are designed and manufactured with the same level of excellence our customers expect from CytoCell. The IVDR certification formally recognises their quality, safety and performance, giving laboratories confidence in both their results and their regulatory readiness.

Our priority is to ensure customers have robust, reliable products—and a FISH partner—they can depend on."

Faidra Partheniou
Vice President, Regulatory and Medical 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 testing 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
	CBFß (CBFB)/MYH11 Translocation, Dual Fusion Probe	AML	CE-LPH 022
	Del(5q) Deletion Probe	AML, MDS	CE-LPH 024
	Del(7q) Deletion Probe	AML, MDS	CE-LPH 025
	Del(20q) Deletion Probe	MDS	CE-LPH 020
	EVI1 (MECOM) Breakapart Probe	AML, MDS	CE-LPH 036
	P53 (TP53)/ATM Combination Deletion Probe	CLL	CE-LPH 052
Prenatal conditions	Prenatal 13 and 21 Enumeration Probe Kit	Down and Patau syndrome	CE-LPA 003
	Prenatal X, Y, 13, 18 and 21 FISH Probe Kit	Down, Patau, Edwards and Turner syndromes	CE-LPA 001
	FAST FISH Prenatal X, Y, 13, 18 and 21 FISH Probe Kit		CE-LPF 001

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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