CytoCell

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A Sysmex Group Company

IVDR-Certified FISH Probes

June 2023

Our IVDR-certified FISH probes are here!

- Proven safe, reliable and effective probes
- Essential for haematological malignancies and aneuploidy testing
- Clinical labs will be required to use an IVDR-certified probe if one is available on the market
- No revalidation needed for existing users of an IVDD equivalent probe

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IVDR-certified probes

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IVDR-Certified FISH probes

Why choose OGT's CytoCell probes?

In 1991, we became the first provider of FISH probes in the world. Over 30 years later, we're the first-to-market with our In Vitro Diagnostic Regulation (IVDR) certified FISH Probes important for the management of haematological malignancies and aneuploidy testing!

IVDR is a priority for OGT as it ensures safe, reliable and effective products for you and your patients.

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.

Clinical expertise

OGT has more than 100 years of clinical experience within the company, helping to develop FISH probes that are IVDR compliant.

"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 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

Introducing our IVDR-Certified FISH Probes

Regulation (EU) 2017/746 (IVDR) is a new regulatory framework for IVD medical devices. It sets higher standards for quality and safety for in vitro diagnostic medical devices to ensure the highest level of public health protection.

All CytoCell® IVD FISH probes are affected by the IVDR and need to be compliant by May 2026. Critically, clinical labs will be required to use an IVDR-certified probe if one is available on the market by this date.

OGT will continue to pursue additional certification for our CytoCell FISH probe portfolio.

	Probe Name	Supported disease	Chromosome Region	Cat. No.
Haematological malignancies	AML1 (RUNX1) Breakapart Probe	AML, ALL	21q22.1	CE-LPH 027
	AML1/ETO (RUNX1/RUNX1T1) Translocation, Dual Fusion Probe	AML	8q21.3 21q22.1	CE-LPH 026
	BCR/ABL (ABL1) Translocation, Dual Fusion Probe	CML, AML, ALL	9q34.1 22q11.2	CE-LPH 007
	New BCR/ABL (ABL1) *Plus* Translocation, Dual Fusion Probe	CML, AML, ALL	9q34.1 22q11.2	CE-LPH 038
	New CBFB Breakapart Probe	AML	16q22	CE-LPH 089
	CKS1B/CDKN2C (P18) Amplification/ Deletion Probe	MM	1q21-q22 / 1p32.3	CE-LPH 039
	FAST PML/RARα (RARA) Translocation, Dual Fusion Probe	AML	15q24 17q21.1-q21.2	CE-LPH 064
	IGH/MAF *Plus* v2 Translocation, Dual Fusion Probe	MM	14q32.3 16q23	CE-LPH 108
	MLL (KMT2A) Breakapart Probe	ALL, AML, MDS	11q23.3	CE-LPH 013
Aneuploidy testing	Prenatal 13 and 21 Enumeration Probe Kit	Down and Patau syndrome	13q14.2 21q22.1	CE-LPA 003

Probe of interest not on our list yet?

More IVDR-certified probes are on their way.

Keep your finger on the IVDR pulse.
Sign up and be the first to know when we receive further certifications!

Ordering information

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What binds us, makes us.

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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.

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