CytoCell

ogt

A Sysmex Group Company

IVDR-Certified FISH Probes

Our IVDR-certified FISH probes are here!

- Proven safe, reliable and effective probes
- Essential for haematological malignancies and prenatal conditions
- 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

CytoCell

IVDR-certified probes

Why choose 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 that play a critical role in the management of patients with haematological cancers and prenatal conditions.

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, having gained certification for sixteen (16) 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 will 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. Switching to an IVDR-certified FISH probe now means you can be confident that your laboratory is using safe, reliable and effective tools for diagnosing patients.

Further IVDR-certified FISH probes will become available as we continue to pursue certifications for our CytoCell products.

	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
	BCR/ABL (ABL1) *Plus* Translocation, Dual Fusion Probe	CML, AML, ALL	9q34.1 22q11.2	CE-LPH 038
	CBFB Breakapart Probe	AML	16q22	CE-LPH 089
	New CBFß (CBFB)/MYH11 Translocation, Dual Fusion Probe	AML	16q22 / 16p13.1	CE-LPH 022
	CKS1B/CDKN2C (P18) Amplification/ Deletion Probe	MM	1q21-q22 / 1p32.3	CE-LPH 039
	Del(5q) Deletion Probe	AML, MDS	5q31.2 / 5p15.3	CE-LPH 024
	Del(7q) Deletion Probe	AML, MDS	7q22 / 7q31.2	CE-LPH 025
	Del(20q) Deletion Probe	MDS	20q12 / 20q13.1	CE-LPH 020
	New EVI1 (MECOM) Breakapart Probe	AML, MDS	3q26.2	CE-LPH 036
	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
	New P53 (TP53)/ATM Combination Deletion Probe	CLL	17p13 / 11q22.3	CE-LPH 052
Prenatal conditions	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

UK +44 (0) 1223 294048
contact@ogt.com
ogt.com

A Sysmex Group Company

What binds us, makes us.

Cytocell Ltd., Oxford Gene Technology, 418 Cambridge Science Park, Milton Road, Cambridge, CB4 0PZ, UK

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.

990351 03/24 v4