



(In accordance with BS EN ISO/IEC 17050-1:2010)

EC Declaration of Conformity

to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 October 1998

on *in vitro* diagnostic medical devices

According to Annex III of Directive 98/79/EC



CYTOCELL LIMITED, Oxford Gene Technology, 418 Cambridge Science Park, Milton Road,
CAMBRIDGE, Cambridgeshire, CB4 0PZ, UNITED KINGDOM



SYSMEX EUROPE GMBH, Bornbarch 1, 22848 Norderstedt, GERMANY



See attached Cytocell Limited Master Product Schedule v021.0 unique ID 101925440 for details of the IVD medical devices that are the objects of this declaration.

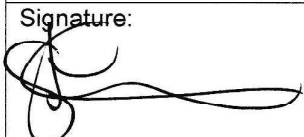
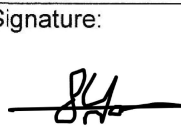
CYTOCELL LIMITED, as the manufacturer, hereby declares that:

- It takes sole responsibility for this EC Declaration of Conformity.
- The above-referenced IVD medical devices are in conformity with Directive 98/79/EC.

CLASSIFICATION: "General IVDs" under Article 9 of Directive 98/79/EC (not devices covered by Annex II, not devices for performance evaluation, not devices for self-testing).

ADDITIONAL INFORMATION: CYTOCELL LIMITED operates a Quality Management System that has been approved to ISO 13485:2016, ISO 9001:2015, and MDSAP / ISO 13485.

APPLIED STANDARDS: EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015, EN 13612:2002, EN 13975:2003.

Signed for and on behalf of CYTOCELL LIMITED, the Legal Manufacturer, by the following duly authorised person:		Signed for and on behalf of SYSMEX EUROPE GMBH, the Authorised Representative, by the following duly authorised person:	
Signature: 	Date: 11 DEC 20	Signature: 	Date: 16/12/2020
Steve Chatters, DipRCPATH Executive VP of Regulatory, Medical, and Quality Affairs CYTOCELL LIMITED Oxford Gene Technology 418 Cambridge Science Park Milton Road CAMBRIDGE CB4 0PZ UNITED KINGDOM		Sinem Yaman Vice President of Regulatory Affairs, Quality Assurance and Quality Control EMEA SYSMEX EUROPE GMBH Bornbarch 1 22848 Norderstedt GERMANY	

This EC Declaration of Conformity is valid until 2022-05-25, or until a revised EC Declaration of Conformity is issued due to, e.g., updates to the Master Product Schedule.



Cytocell Limited Master Product Schedule 2021 (v021.0)

IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Prenatal and FAST FISH Prenatal FISH Probes	
Prenatal Enumeration Probe kit (10 / 5 / 30 / 50 tests)	LPA 001 / LPA 001-S / LPA 001-30 / LPA 001-50
Prenatal X, Y and 18 Enumeration Probe kit (10 / 5 tests)	LPA 002 / LPA 002-S
Prenatal 13 and 21 Enumeration Probe kit (10 / 5 tests)	LPA 003 / LPA 003-S
Prenatal 18 Enumeration Probe kit (10 / 5 tests)	LPA 004 / LPA 004-S
Prenatal 13, 18 and 21 Enumeration Probe kit (10 / 5 tests)	LPA 005 / LPA 005-S
<i>FAST FISH</i> Prenatal Enumeration Probe kit (10 / 5 / 30 / 50 tests)	LPF 001 / LPF 001-S / LPF 001-30 / LPF 001-50
<i>FAST FISH</i> Prenatal X, Y and 18 Enumeration Probe kit (10 / 5 tests)	LPF 002 / LPF 002-S
<i>FAST FISH</i> Prenatal 13 and 21 Enumeration Probe kit (10 / 5 tests)	LPF 003 / LPF 003-S
Satellite Enumeration FISH Probes	
Chromosome 1 Classical Satellite Probe (Green, 5 tests)	LPE 001G
Chromosome 1 Classical Satellite Probe (Red, 5 tests)	LPE 001R
Chromosome 2 Alpha Satellite Probe (Green, 5 tests)	LPE 002G
Chromosome 2 Alpha Satellite Probe (Red, 5 tests)	LPE 002R
Chromosome 3 Alpha Satellite Probe (Green, 5 tests)	LPE 003G
Chromosome 3 Alpha Satellite Probe (Red, 5 tests)	LPE 003R
Chromosome 4 Alpha Satellite Probe (Green, 5 tests)	LPE 004G
Chromosome 4 Alpha Satellite Probe (Red, 5 tests)	LPE 004R
Chromosome 5 Alpha Satellite Probe (Green, 5 tests)	LPE 005G
Chromosome 5 Alpha Satellite Probe (Red, 5 tests)	LPE 005R
Chromosome 6 Alpha Satellite Probe (Green, 5 tests)	LPE 006G
Chromosome 6 Alpha Satellite Probe (Red, 5 tests)	LPE 006R
Chromosome 7 Alpha Satellite Probe (Green, 5 tests)	LPE 007G
Chromosome 7 Alpha Satellite Probe (Red, 5 tests)	LPE 007R
Chromosome 8 Alpha Satellite Probe (Green, 5 tests)	LPE 008G
Chromosome 8 Alpha Satellite Probe (Red, 5 tests)	LPE 008R
Chromosome 9 Classical Satellite Probe (Green, 5 tests)	LPE 009G
Chromosome 9 Classical Satellite Probe (Red, 5 tests)	LPE 009R
Chromosome 10 Alpha Satellite Probe (Green, 5 tests)	LPE 010G
Chromosome 10 Alpha Satellite Probe (Red, 5 tests)	LPE 010R
Chromosome 11 Alpha Satellite Probe (Green, 5 tests)	LPE 011G
Chromosome 11 Alpha Satellite Probe (Red, 5 tests)	LPE 011R
Chromosome 12 Alpha Satellite Probe (Green, 5 tests)	LPE 012G
Chromosome 12 Alpha Satellite Probe (Red, 5 tests)	LPE 012R
Chromosomes 13/21 Alpha Satellite Probe (Green, 5 tests)	LPE 013G



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Satellite Enumeration FISH Probes (continued)	
Chromosomes 13/21 Alpha Satellite Probe (Red, 5 tests)	LPE 013R
Chromosomes 14/22 Alpha Satellite Probe (Green, 5 tests)	LPE 014G
Chromosomes 14/22 Alpha Satellite Probe (Red, 5 tests)	LPE 014R
Chromosome 15 Alpha Satellite Probe (Green, 5 tests)	LPE 015G
Chromosome 15 Alpha Satellite Probe (Red, 5 tests)	LPE 015R
Chromosome 16 Alpha Satellite Probe (Green, 5 tests)	LPE 016G
Chromosome 16 Alpha Satellite Probe (Red, 5 tests)	LPE 016R
Chromosome 17 Alpha Satellite Probe (Green, 5 tests)	LPE 017G
Chromosome 17 Alpha Satellite Probe (Red, 5 tests)	LPE 017R
Chromosome 18 Alpha Satellite Probe (Green, 5 tests)	LPE 018G
Chromosome 18 Alpha Satellite Probe (Red, 5 tests)	LPE 018R
Chromosome 20 Alpha Satellite Probe (Green, 5 tests)	LPE 020G
Chromosome 20 Alpha Satellite Probe (Red, 5 tests)	LPE 020R
Chromosome X Alpha Satellite Probe (Green, 5 tests)	LPE 0XG
Chromosome X Alpha Satellite Probe (Red, 5 tests)	LPE 0XR
Chromosome Y Alpha Satellite Probe (Green, 5 tests)	LPE 0YcG
Chromosome Y Alpha Satellite Probe (Red, 5 tests)	LPE 0YcR
Chromosome Y Classical Satellite Probe (Green, 5 tests)	LPE 0YqG
Chromosome Y Classical Satellite Probe (Red, 5 tests)	LPE 0YqR
Chromosome X Alpha and Y Classical Satellite Probes (10 tests)	LPE 0XYq
Chromosome X Alpha and Y Alpha Satellite Probes (10 tests)	LPE 0XYc
Acro-P-Arm Probe (10 / 5 tests)	LPE NOR / LPE NOR-S
Chromosome 8 Alpha Satellite Probe (Blue, 10 tests)	LPE 008B
Chromosome 12 Alpha Satellite Probe (Blue, 10 tests)	LPE 012B
Chromosome 17 Alpha Satellite Probe (Blue, 10 tests)	LPE 017B
Haematology FISH Probes	
13q14.3 Deletion Probe (10 / 5 tests)	LPH 006 / LPH 006-S
BCR/ABL Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 007 / LPH 007-S
P16 Deletion Probe (10 / 5 tests)	LPH 009 / LPH 009-S
c-MYC Breakapart Probe (10 / 5 tests)	LPH 010 / LPH 010-S
ATM Deletion Probe (10 / 5 tests)	LPH 011 / LPH 011-S
TEL/AML1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 012 / LPH 012-S
MLL Breakapart Probe (10 / 5 tests)	LPH 013 / LPH 013-S
IGH Breakapart Probe (10 / 5 tests)	LPH 014 / LPH 014-S
MYB Deletion Probe (10 / 5 tests)	LPH 016 / LPH 016-S
P53 Deletion Probe (10 / 5 tests)	LPH 017 / LPH 017-S
IGH/BCL2 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 018 / LPH 018-S



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Haematology FISH Probes (continued)	
E2A Breakapart Probe (10 / 5 tests)	LPH 019 / LPH 019-S
Del (20q) Deletion Probe (10 / 5 tests)	LPH 020 / LPH 020-S
IGH/CCND1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 021 / LPH 021-S
CBFβ/MYH11 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 022 / LPH 022-S
PML/RARα Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 023 / LPH 023-S
Del (5q) Deletion Probe (10 / 5 tests)	LPH 024 / LPH 024-S
Del (7q) Deletion Probe (10 / 5 tests)	LPH 025 / LPH 025-S
AML1/ETO Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 026 / LPH 026-S
AML1 Breakapart Probe (10 / 5 tests)	LPH 027 / LPH 027-S
IGH/MAF Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 029 / LPH 029-S ³
IGH/FGFR3 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 030 / LPH 030-S
PDGFRB Breakapart Probe (10 / 5 tests)	LPH 031 / LPH 031-S
FIP1L1/CHIC2/PDGFRα Deletion/Fusion Probe (10 / 5 tests)	LPH 032 / LPH 032-S
IGL Breakapart Probe (10 / 5 tests)	LPH 033 / LPH 033-S
IGK Breakapart Probe (10 / 5 tests)	LPH 034 / LPH 034-S
BCL6 Breakapart Probe (10 / 5 tests)	LPH 035 / LPH 035-S
EVI1 Breakapart Probe (10 / 5 tests)	LPH 036 / LPH 036-S
BCR/ABL Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 038 / LPH 038-S
CKS1B/CDKN2C (P18) Amplification/Deletion Probe (10 / 5 tests)	LPH 039 / LPH 039-S
IGH/CCND3 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 040 / LPH 040-S
IGH/c-MYC Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 041 / LPH 041-S
D13S25 Deletion Probe (10 / 5 tests)	LPH 043 / LPH 043-S
IGH/MAFB Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 044 / LPH 044-S
IGH/MYEOV Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 045 / LPH 045-S
TCL1 Breakapart Probe (10 / 5 tests)	LPH 046 / LPH 046-S
TCRAD Breakapart Probe (10 / 5 tests)	LPH 047 / LPH 047-S
TCRB Breakapart Probe (10 / 5 tests)	LPH 048 / LPH 048-S
TLX1 Breakapart Probe (10 / 5 tests)	LPH 049 / LPH 049-S
TLX3 Breakapart Probe (10 / 5 tests)	LPH 050 / LPH 050-S
P53/ATM Probe Combination (10 / 5 tests)	LPH 052 / LPH 052-S
FAST PML/RARα Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 064 / LPH 064-S
RARα Breakapart Probe (10 / 5 tests)	LPH 065 / LPH 065-S
D13S319/13qter/12cen Deletion, Enumeration Probe (10 / 5 tests)	LPH 066 / LPH 066-S
CLL <i>PROFILER</i> (10 / 5 tests)	LPH 067 / LPH 067-S
D13S319 Plus Deletion Probe (10 / 5 tests)	LPH 068 / LPH 068-S
Alpha Satellite 12 Plus for CLL (10 / 5 tests)	LPH 069 / LPH 069-S
IGH Plus Breakapart Probe (10 / 5 tests)	LPH 070 / LPH 070-S

³ LPH 029 / LPH 029-S devices have been withdrawn from sale as of 18 May 2020.



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Haematology FISH Probes (continued)	
IGH/BCL2 Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 071 / LPH 071-S
IGH/CCND1 Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 072 / LPH 072-S
IGH/MAF Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 073 / LPH 073-S ⁴
IGH/FGFR3 Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 074 / LPH 074-S
IGH/CCND3 Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 075 / LPH 075-S
IGH/c-MYC Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 076 / LPH 076-S
IGH/MAFB Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 077 / LPH 077-S
IGH/MYEOV Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 078 / LPH 078-S
E2A/PBX1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 079 / LPH 079-S
E2A/PBX1 Plus Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 080 / LPH 080-S
MLL/AFF1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 081 / LPH 081-S
CLL Plus Screening Panel (10 / 5 tests)	LPH 087 / LPH 087-S
IGH/MAF v2 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 101 / LPH 101-S
IGH/MAF Plus v2 Translocation, Dual Fusion Probe (10 / 5 tests)	LPH 108 / LPH 108-S
Whole Chromosome Paint FISH Probes ¹	
Chromosome 1 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 01G
Chromosome 1 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 01R
Chromosome 2 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 02G
Chromosome 2 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 02R
Chromosome 3 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 03G
Chromosome 3 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 03R
Chromosome 4 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 04G
Chromosome 4 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 04R
Chromosome 5 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 05G
Chromosome 5 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 05R
Chromosome 6 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 06G
Chromosome 6 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 06R
Chromosome 7 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 07G
Chromosome 7 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 07R
Chromosome 8 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 08G
Chromosome 8 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 08R
Chromosome 9 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 09G
Chromosome 9 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 09R
Chromosome X Whole Chromosome Painting Probe (Green, 5 tests)	LPP 0XG
Chromosome X Whole Chromosome Painting Probe (Red, 5 tests)	LPP 0XR
Chromosome Y Whole Chromosome Painting Probe (Green, 5 tests)	LPP 0YG
Chromosome Y Whole Chromosome Painting Probe (Red, 5 tests)	LPP 0YR
Chromosome 10 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 10G
Chromosome 10 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 10R

¹ **All LPP ### devices have been withdrawn from sale as of 31st December 2019.**

⁴ **LPH 073 / LPH 073-S devices have been withdrawn from sale as of 18 May 2020.**



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Whole Chromosome Paint FISH Probes (continued) ¹	
Chromosome 11 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 11G
Chromosome 11 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 11R
Chromosome 12 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 12G
Chromosome 12 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 12R
Chromosome 13 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 13G
Chromosome 13 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 13R
Chromosome 14 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 14G
Chromosome 14 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 14R
Chromosome 15 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 15G
Chromosome 15 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 15R
Chromosome 16 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 16G
Chromosome 16 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 16R
Chromosome 17 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 17G
Chromosome 17 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 17R
Chromosome 18 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 18G
Chromosome 18 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 18R
Chromosome 19 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 19G
Chromosome 19 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 19R
Chromosome 20 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 20G
Chromosome 20 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 20R
Chromosome 21 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 21G
Chromosome 21 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 21R
Chromosome 22 Whole Chromosome Painting Probe (Green, 5 tests)	LPP 22G
Chromosome 22 Whole Chromosome Painting Probe (Red, 5 tests)	LPP 22R
Whole Chromosome Painting Probes for Chromosomes 1, 2 and 4 (10 tests)	LPP 124
Pathology FISH Probes	
HER2 Amplification Probe (10 / 5 / 50 tests)	LPS 001 / LPS 001-S / LPS 001-50
TOP2A Amplification/Deletion Probe (10 / 5 tests)	LPS 002 / LPS 002-S
EGFR Amplification Probe (10 / 5 tests)	LPS 003 / LPS 003-S
c-MET Amplification Probe (10 / 5 tests)	LPS 004 / LPS 004-S
ZNF217 Amplification Probe (10 / 5 tests)	LPS 005 / LPS 005-S
EWSR1 Breakapart Probe (10 / 5 tests)	LPS 006 / LPS 006-S
FLI1/EWSR1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPS 007 / LPS 007-S
EWSR1/ERG Translocation, Dual Fusion Probe (10 / 5 tests)	LPS 008 / LPS 008-S
N-MYC Amplification Probe (10 / 5 tests)	LPS 009 / LPS 009-S
SRD (CHD5) Deletion Probe (10 / 5 tests)	LPS 010 / LPS 010-S
RB1 Deletion Probe (10 / 5 tests)	LPS 011 / LPS 011-S

¹ **All LPP ### devices have been withdrawn from sale as of 31st December 2019.**



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Pathology FISH Probes (continued)	
PAX3 Breakapart Probe (10 / 5 tests)	LPS 012 / LPS 012-S
PAX7 Breakapart Probe (10 / 5 tests)	LPS 013 / LPS 013-S
SYT Breakapart Probe (10 / 5 tests)	LPS 014 / LPS 014-S
CHOP Breakapart Probe (10 / 5 tests)	LPS 015 / LPS 015-S
MDM2 Amplification Probe (10 / 5 tests)	LPS 016 / LPS 016-S
MALT1 Breakapart Probe (10 / 5 tests)	LPS 017 / LPS 017-S
FGFR1 Breakapart/Amplification Probe (10 / 5 tests)	LPS 018 / LPS 018-S
ALK Breakapart Probe (10 / 5 tests)	LPS 019 / LPS 019-S
EML4 Breakapart Probe (10 / 5 tests)	LPS 020 / LPS 020-S
TMPRSS2/ERG Deletion/Breakapart Probe (10 / 5 tests)	LPS 021 / LPS 021-S
ROS1 Breakapart Probe (10 / 5 tests)	LPS 022 / LPS 022-S
MYC Breakapart Probe (10 / 5 tests)	LPS 027 / LPS 027-S
BCL2 Breakapart Probe (10 / 5 tests)	LPS 028 / LPS 028-S
BCL6 Breakapart Probe (10 / 5 tests)	LPS 029 / LPS 029-S
CCND1 Breakapart Probe (10 / 5 tests)	LPS 030 / LPS 030-S
IGH/CCND1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPS 031 / LPS 031-S
IGH Breakapart Probe (10 / 5 tests)	LPS 032 / LPS 032-S
IGH/BCL2 Translocation, Dual Fusion Probe (10 / 5 tests)	LPS 033 / LPS 033-S
IGH/MALT1 Translocation, Dual Fusion Probe (10 / 5 tests)	LPS 034 / LPS 034-S
IGH/MYC Translocation, Dual Fusion Probe (10 / 5 tests)	LPS 035 / LPS 035-S
P16 Deletion Probe (10 / 5 tests)	LPS 036 / LPS 036-S
P53 Deletion Probe (10 / 5 tests)	LPS 037 / LPS 037-S
IGK Breakapart Probe (10 / 5 tests)	LPS 038 / LPS 038-S
IGL Breakapart Probe (10 / 5 tests)	LPS 039 / LPS 039-S
RET Breakapart Probe (10 / 5 tests)	LPS 045 / LPS 045-S
ROS1 Plus Breakapart Probe (10 / 5 tests)	LPS 046 / LPS 046-S
1p36/1q25 and 19q13/19p13 Deletion Probe Kit (10 / 5 tests)	LPS 047 / LPS 047-S
FOXO1 Breakapart Probe (10 / 5 tests)	LPS 049 / LPS 049-S
FUS Breakapart Probe (10 / 5 tests)	LPS 050 / LPS 050-S
Telomere FISH Probes	
1pter Subtelomere Specific Probe (Green, 5 tests)	LPT 01PG
1pter Subtelomere Specific Probe (Red, 5 tests)	LPT 01PR
1qter Subtelomere Specific Probe (Green, 5 tests)	LPT 01QG
1qter Subtelomere Specific Probe (Red, 5 tests)	LPT 01QR
2pter Subtelomere Specific Probe (Green, 5 tests)	LPT 02PG
2pter Subtelomere Specific Probe (Red, 5 tests)	LPT 02PR
2qter Subtelomere Specific Probe (Green, 5 tests)	LPT 02QG



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Telomere FISH Probes (continued)	
2qter Subtelomere Specific Probe non-polymorphic clone (Green, 5 tests)	LPT 02QNPG
2qter Subtelomere Specific Probe non-polymorphic clone (Red, 5 tests)	LPT 02QNPR
2qter Subtelomere Specific Probe (Red, 5 tests)	LPT 02QR
3pter Subtelomere Specific Probe (Green, 5 tests)	LPT 03PG
3pter Subtelomere Specific Probe (Red, 5 tests)	LPT 03PR
3qter Subtelomere Specific Probe (Green, 5 tests)	LPT 03QG
3qter Subtelomere Specific Probe (Red, 5 tests)	LPT 03QR
4pter Subtelomere Specific Probe (Green, 5 tests)	LPT 04PG
4pter Subtelomere Specific Probe (Red, 5 tests)	LPT 04PR
4qter Subtelomere Specific Probe (Green, 5 tests)	LPT 04QG
4qter Subtelomere Specific Probe (Red, 5 tests)	LPT 04QR
5pter Subtelomere Specific Probe (Green, 5 tests)	LPT 05PG
5pter Subtelomere Specific Probe (Red, 5 tests)	LPT 05PR
5qter Subtelomere Specific Probe (Green, 5 tests)	LPT 05QG
5qter Subtelomere Specific Probe (Red, 5 tests)	LPT 05QR
6pter Subtelomere Specific Probe (Green, 5 tests)	LPT 06PG
6pter Subtelomere Specific Probe (Red, 5 tests)	LPT 06PR
6qter Subtelomere Specific Probe (Green, 5 tests)	LPT 06QG
6qter Subtelomere Specific Probe (Red, 5 tests)	LPT 06QR
7pter Subtelomere Specific Probe (Green, 5 tests)	LPT 07PG
7pter Subtelomere Specific Probe (Red, 5 tests)	LPT 07PR
7qter Subtelomere Specific Probe (Green, 5 tests)	LPT 07QG
7qter Subtelomere Specific Probe (Red, 5 tests)	LPT 07QR
8pter Subtelomere Specific Probe (Green, 5 tests)	LPT 08PG
8pter Subtelomere Specific Probe (Red, 5 tests)	LPT 08PR
8qter Subtelomere Specific Probe (Green, 5 tests)	LPT 08QG
8qter Subtelomere Specific Probe (Red, 5 tests)	LPT 08QR
9pter Subtelomere Specific Probe (Green, 5 tests)	LPT 09PG
9pter Subtelomere Specific Probe (Red, 5 tests)	LPT 09PR
9qter Subtelomere Specific Probe (Green, 5 tests)	LPT 09QG
9qter Subtelomere Specific Probe (Red, 5 tests)	LPT 09QR
10pter Subtelomere Specific Probe (Green, 5 tests)	LPT 10PG
10pter Subtelomere Specific Probe (Red, 5 tests)	LPT 10PR
10qter Subtelomere Specific Probe (Green, 5 tests)	LPT 10QG
10qter Subtelomere Specific Probe (Red, 5 tests)	LPT 10QR
11pter Subtelomere Specific Probe (Green, 5 tests)	LPT 11PG
11pter Subtelomere Specific Probe (Red, 5 tests)	LPT 11PR



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Telomere FISH Probes (continued)	
11qter Subtelomere Specific Probe (Green, 5 tests)	LPT 11QG
11qter Subtelomere Specific Probe (Red, 5 tests)	LPT 11QR
12pter Subtelomere Specific Probe (Green, 5 tests)	LPT 12PG
12pter Subtelomere Specific Probe (Red, 5 tests)	LPT 12PR
12qter Subtelomere Specific Probe (Green, 5 tests)	LPT 12QG
12qter Subtelomere Specific Probe (Red, 5 tests)	LPT 12QR
13qter Subtelomere Specific Probe (Green, 5 tests)	LPT 13QG
13qter Subtelomere Specific Probe (Red, 5 tests)	LPT 13QR
14qter Subtelomere Specific Probe (Green, 5 tests)	LPT 14QG
14qter Subtelomere Specific Probe (Red, 5 tests)	LPT 14QR
15qter Subtelomere Specific Probe (Green, 5 tests)	LPT 15QG
15qter Subtelomere Specific Probe (Red, 5 tests)	LPT 15QR
16pter Subtelomere Specific Probe (Green, 5 tests)	LPT 16PG
16pter Subtelomere Specific Probe (Red, 5 tests)	LPT 16PR
16qter Subtelomere Specific Probe (Green, 5 tests)	LPT 16QG
16qter Subtelomere Specific Probe (Red, 5 tests)	LPT 16QR
17pter Subtelomere Specific Probe (Green, 5 tests)	LPT 17PG
17pter Subtelomere Specific Probe (Red, 5 tests)	LPT 17PR
17qter Subtelomere Specific Probe (Green, 5 tests)	LPT 17QG
17qter Subtelomere Specific Probe (Red, 5 tests)	LPT 17QR
18pter Subtelomere Specific Probe (Green, 5 tests)	LPT 18PG
18pter Subtelomere Specific Probe (Red, 5 tests)	LPT 18PR
18qter Subtelomere Specific Probe (Green, 5 tests)	LPT 18QG
18qter Subtelomere Specific Probe (Red, 5 tests)	LPT 18QR
19pter Subtelomere Specific Probe (Green, 5 tests)	LPT 19PG
19pter Subtelomere Specific Probe (Red, 5 tests)	LPT 19PR
19qter Subtelomere Specific Probe (Green, 5 tests)	LPT 19QG
19qter Subtelomere Specific Probe (Red, 5 tests)	LPT 19QR
20pter Subtelomere Specific Probe (Green, 5 tests)	LPT 20PG
20pter Subtelomere Specific Probe (Red, 5 tests)	LPT 20PR
20qter Subtelomere Specific Probe (Green, 5 tests)	LPT 20QG
20qter Subtelomere Specific Probe (Red, 5 tests)	LPT 20QR
21qter Subtelomere Specific Probe (Green, 5 tests)	LPT 21QG
21qter Subtelomere Specific Probe (Red, 5 tests)	LPT 21QR
22qter Subtelomere Specific Probe (Green, 5 tests)	LPT 22QG
22qter Subtelomere Specific Probe (Red, 5 tests)	LPT 22QR
XYpter Subtelomere Specific Probe (Green, 5 tests)	LPT XYPG



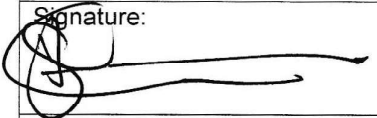
IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Telomere FISH Probes (continued)	
XYpter Subtelomere Specific Probe (Red, 5 tests)	LPT XYPR
XYqter Subtelomere Specific Probe (Green, 5 tests)	LPT XYQG
XYqter Subtelomere Specific Probe (Red, 5 tests)	LPT XYQR
TeloMark FISH Probes	
TeloMark Mix 01 (10 / 5 tests)	LPT MRK01 / LPT MRK01-S
TeloMark Mix 02 (10 / 5 tests)	LPT MRK02 / LPT MRK02-S
TeloMark Mix 03 (10 / 5 tests)	LPT MRK03 / LPT MRK03-S
TeloMark Mix 04 (10 / 5 tests)	LPT MRK04 / LPT MRK04-S
TeloMark Mix 05 (10 / 5 tests)	LPT MRK05 / LPT MRK05-S
TeloMark Mix 06 (10 / 5 tests)	LPT MRK06 / LPT MRK06-S
TeloMark Mix 07 (10 / 5 tests)	LPT MRK07 / LPT MRK07-S
TeloMark Mix 08 (10 / 5 tests)	LPT MRK08 / LPT MRK08-S
TeloMark Mix 09 (10 / 5 tests)	LPT MRK09 / LPT MRK09-S
TeloMark Mix 10 (10 / 5 tests)	LPT MRK10 / LPT MRK10-S
TeloMark Mix 11 (10 / 5 tests)	LPT MRK11 / LPT MRK11-S
TeloMark Mix 12 (10 / 5 tests)	LPT MRK12 / LPT MRK12-S
TeloMark Mix 13 (10 / 5 tests)	LPT MRK13 / LPT MRK13-S
TeloMark Mix 14 (10 / 5 tests)	LPT MRK14 / LPT MRK14-S
TeloMark Mix 15 (10 / 5 tests)	LPT MRK15 / LPT MRK15-S
TeloMark Kit (10 / 5 tests)	LPT MRK / LPT MRK-S
Microdeletion FISH Probes	
DiGeorge/VCFS TUPLE1 + 22q13.3 Deletion Probe Combination (10 / 5 tests)	LPU 004 / LPU 004-S
Prader-Willi/Angelman (SNRPN) Probe (10 / 5 tests)	LPU 005 / LPU 005-S
Angelman (UBE3A/D15S10) Probe (10 / 5 tests)	LPU 006 / LPU 006-S
Smith-Magenis (FLII)/Miller-Dieker Probe Combination (10 / 5 tests)	LPU 007 / LPU 007-S ²
Wolf-Hirschhorn (WHSCR) Probe (10 / 5 tests)	LPU 009 / LPU 009-S
DiGeorge/VCFS N25 + 22q13.3 Deletion Probe Combination (10 / 5 tests)	LPU 010 / LPU 010-S
Williams-Beuren Probe (10 / 5 tests)	LPU 011 / LPU 011-S
Alagille (JAG1) Probe (10 / 5 tests)	LPU 012 / LPU 012-S ²
Cri-Du-Chat/SOTOS Probe Combination (10 / 5 tests)	LPU 013 / LPU 013-S
DiGeorge TBX1 + 22q13.3 Deletion Probe Combination (10 / 5 tests)	LPU 014 / LPU 014-S
DiGeorge II (10p14) Probe (10 / 5 tests)	LPU 015 / LPU 015-S
Kallmann (KAL1)/STS Probe Combination (10 / 5 tests)	LPU 016 / LPU 016-S
Neurofibromatosis Type 1 Probe (10 / 5 tests)	LPU 017 / LPU 017-S ²
XIST Probe (10 / 5 tests)	LPU 018 / LPU 018-S ²
Smith-Magenis (RAI1)/Miller-Dieker Probe Combination (10 / 5 tests)	LPU 019 / LPU 019-S

² **Select LPU ### devices have been withdrawn from sale as of 31st December 2019.**



IVD Medical Device Name (additional description)	IVD Medical Device Catalogue Number(s)
Microdeletion FISH Probes	
Monosomy 1p36 Probe (10 / 5 tests)	LPU 020 / LPU 020-S ²
CHARGE Probe (10 / 5 tests)	LPU 021 / LPU 021-S ²
Langer-Giedion Probe (10 / 5 tests)	LPU 022 / LPU 022-S ²
Rubinstein-Taybi Probe (10 / 5 tests)	LPU 023 / LPU 023-S ²
Saethre-Chotzen/Williams-Beuren Probe Combination (10 / 5 tests)	LPU 024 / LPU 024-S
SHOX Probe (10 / 5 tests)	LPU 025 / LPU 025-S
SRY Probe (10 / 5 tests)	LPU 026 / LPU 026-S
Ancillary Reagents and Accessories	
DAPI Antifade ES (0.125µg/ml, 500µl / 1000µl vial)	DES500L / DES1000L
Hybridisation Solution B (500µl / 1000µl vial)	HB500L / HB1000L
Tissue Pretreatment Kit	LPS 100

² Select LPU ### devices have been withdrawn from sale as of 31st December 2019.

Signed for and on behalf of CYTOCELL LIMITED, the Legal Manufacturer, by the following duly authorised person:		Signed for and on behalf of SYSMEX EUROPE GMBH, the EU Authorised Representative, by the following duly authorised person:	
Signature:	Date:	Signature:	Date:
	11 DEC 20		16/12/2020
Steve Chatters, DipRCPATH EVP of Regulatory, Medical, and Quality Affairs Cytocell Limited, Oxford Gene Technology 418 Cambridge Science Park Milton Road CAMBRIDGE CB4 0PZ UNITED KINGDOM		Sinem Yaman Vice President of Regulatory Affairs, Quality Assurance and Quality Control EMEA Sysmex Europe GmbH Bornbarch 1 22848 Norderstedt GERMANY	

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