



Standard Operating Procedure Form  
F-40 EC Declaration of Conformity Template

Rev Date: 05/17/2022

Revision: 3

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Authorized By: Amy Intini

Approved By: Michael Bianchi

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EDMA# 16-02-01-90-00

ANALYTE	PRODUCT NAME
11q23 & 13q14	11q23/13q14 Dual Color FISH Probe
CDKN2C (1p) & CKS1B (1q)	1p1q FISH Probe
1q21 & 8p21	1q21/8p21 Dual Color FISH Probe
6q21 & MYB	6q21/MYB FISH Probe
ABL1	ABL1 Break Apart FISH Probe
ABL2	ABL2 FISH Probe
ABL2	ABL2 Break Apart FISH Probe
ACP5	ACP5 FISH Probe
ADCK5	ADCK5 Break Apart FISH Probe
ALK	ALK Break Apart FISH Probe
ALK & EML4	ALK Break Apart/ROS1 Break Apart FISH Probe
ALK & ROS1	ALK/EML4 FISH Probe
ATM	ATM FISH Probe
ATM & Chromosome 11 Control (11p11.11-q11)	ATM/CON11 FISH Probe
ATM/TP53	ATM/TP53 FISH Probe
ATRIP	ATRIP FISH Probe
BAP1	BAP1 FISH Probe
BCL10	BCL10 Break Apart FISH Probe
BCL11A	BCL11A FISH Probe
BCL2	BCL2 Break Apart FISH Probe
BCL2 & BCL6	BCL2 Break Apart/BCL6 Break Apart FISH Probe
BCL2L1	BCL2L1 FISH Probe
BCL3	BCL3 Break Apart FISH Probe
BCL6	BCL6 Break Apart FISH Probe
BCOR	BCOR Break Apart FISH Probe
BCR	BCR Break Apart FISH Probe
BLVRB	BLVRB FISH Probe
BPTF	BPTF FISH Probe
BRAF	BRAF Break Apart FISH Probe
BRCA2	BRCA2 FISH Probe
BRD4 & Chromosome 19 Control (19p13.11)	BRD4/CON19 FISH Probe
BRD9	BRD9 FISH Probe
C11orf95	C11orf95 Break Apart FISH Probe
CAMTA1	CAMTA1 Break Apart FISH Probe

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CAMTA1 & WWTR1	CAMTA1/WWTR1 FISH Probe
CBFA2T3	CBFA2T3 Break Apart FISH Probe
CCND1	CCND1 FISH Probe
CCND1	CCND1 Break Apart FISH Probe
CCND1 & Chromosome 11 Control (11p11.11-q11)	CCND1/CON11 FISH Probe
CCND1 & IGH	CCND1/IGH Full FISH Probe
CCND1 & IGH	CCND1/IGH Split FISH Probe
CCND2	CCND2 Break Apart FISH Probe
CCR5	CCR5 FISH Probe
CDH1	CDH1 FISH Probe
CDK4 & Chromosome 12 Control (12p11-q11)	CDK4/CON12 FISH Probe
CDK6	CDK6 FISH Probe
CEBPD	CEBPD Break Apart FISH Probe
CEP19	CEP19 FISH Probe
CHIC2	delCHIC2 FISH Probe
CIC	CIC Break Apart FISH Probe
CIITA	CIITA Break Apart FISH Probe
COLEC10	COLEC10 FISH Probe
Chromosome 1 Control (1p11-q11)	CON1 FISH Probe
Chromosome 2 Control (2q11.1)	CON2 FISH Probe
Chromosome 3 Control (3p11.1)	CON3 FISH Probe
Chromosome 4 Control (4p11)	CON4 FISH Probe
Chromosome 6 Control (6p11-q11)	CON6 FISH Probe
Chromosome 7 Control (7q11.21)	CON7 FISH Probe
Chromosome 7 Control (7q11.21) and 7q31.2	CON7/7Q31 FISH Probe
Chromosome 7 (7q11.21) & 8 (8p11-q11)	CON7/CON8 FISH Probe
Controls	
Chromosome 8 Control (8p11-q11)	CON8 FISH Probe
Chromosome 9 Control (9q21.33)	CON9 FISH Probe
Chromosome 10 Control (10p11-q11)	CON10 FISH Probe
Chromosome 11 Control (11p11.11-q11)	CON11 FISH Probe
Chromosome 12 Control (12p11-q11)	CON12 FISH Probe
Chromosome 13 Control (13q21.31)	CON13 FISH Probe
Chromosome 13 (13q21.31) & 21 (21q21.1)	CON13/21 FISH Probe
Controls	
Chromosome 14 Control (14q11.2)	CON14 FISH Probe
Chromosome 16 Control (16p11.1)	CON16 FISH Probe
Chromosome 17 Control (17p11.1)	CON17 FISH Probe
Chromosome 18 Control (18p11.1-q11.1)	CON18 FISH Probe
Chromosome 19 Control (19p13.11)	CON19 FISH Probe
Chromosome 20 Control (20p11.21)	CON20 FISH Probe
Chromosome 21 Control (21q21.1)	CON21 FISH Probe
Chromosome X (Xq11.1)	CONX FISH Probe
Chromosome X (Xq11.1) & Y (Yp11.1-q11.1)	CONXY FISH Probe
Controls	
Chromosome Y Control (Yp11.1-q11.1)	CONY FISH Probe
COL1A1 & PDGFB	COL1A1/PDGFB Dual Color FISH Probe

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	CRLF2	CRLF2 FISH Probe
	CRLF2	CRLF2 Break Apart FISH Probe
	CRYBA1	CRYBA1 FISH Probe
	CSF1	CSF1 Break Apart FISH Probe
	CSF1R	CSF1R Break Apart FISH Probe
	CUX1 & CUL1	CUX1/CUL1 FISH Probe
	CUX1 & CUL1 & Chromosome 7 Control (7q11.21)	CUX1/CUL1/CON7 FISH Probe
	D13S319 & Chromosome 12 Control (12p11-q11)	D13S319/CON12 FISH Probe
	D13S319 & LAMP1	D13S319/LAMP1 FISH Probe
	DDIT3	DDIT3 Break Apart FISH Probe
	20q & 20p	Del20q/20p FISH Probe
	DENND3	DENND3 FISH Probe
	DUSP22	DUSP22 Break Apart FISH Probe
	DUSP22 & IRF4	DUSP22/IRF4 Break Apart FISH Probe
	EGFR	EGFR FISH Probe
	EGR1 & CSF1R	EGR1/CSF1R FISH Probe
	EPOR	EPOR Break Apart FISH Probe
	ERG	ERG Break Apart FISH Probe
	ERG & TMPRSS2	ERG/TMPRSS2 Break Apart FISH Probe
	ESR1	ESR1 FISH Probe
	ETV3 & NCOA2	ETV3/NCOA2 FISH Probe
	ETV6	ETV6 FISH Probe
	ETV6	ETV6 Break Apart FISH Probe
	ETV6	ETV6/RUNX1 FISH Probe
	ETV6 & RUNX1	EWSR1 Break Apart FISH Probe
	EWSR1	FAM84B FISH Probe
	FAM84B	FAM96B FISH Probe
	FAM96B	FAM135B FISH Probe
	FAM135B	FGFR1 Break Apart FISH Probe
	FGFR1	FGFR2 FISH Probe
	FGFR2	FGFR2 Break Apart FISH Probe
	FGFR2	FGFR2/CON10 FISH Probe
	FGFR2 & Chromosome 10 Control (10p11.1-q11.1)	
	FGFR3	FGFR3 FISH Probe
	FGFR3	FGFR3 Break Apart FISH Probe
	FGFR3 & IGH	FGFR3/IGH Full FISH Probe
	FGFR3 & IGH	FGFR3/IGH Split FISH Probe
	FGFR4	FGFR4 FISH Probe
	FHIT	FHIT FISH Probe
	FN1	FN1 Break Apart FISH Probe
	FOS	FOS Break Apart FISH Probe
	FOXC1	FOXC1 FISH Probe
	FOXE1	FOXE1 FISH Probe
	FOXO1	FOXO1 Break Apart FISH Probe
	GATA6	GATA6 FISH Probe
	GLI1	GLI1 Break Apart FISH Probe
	GLI1 & Chromosome 12 Control (12p11-q11)	GLI1/CON12 FISH Probe

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HK2	HK2 FISH Probe
HLF	HLF Break Apart FISH Probe
HMGA2	HMGA2 Break Apart FISH Probe
ID2	ID2 FISH Probe
IGH	IGH FISH Probe
IGH	IGH Break Apart FISH Probe
IGH & MAF	IGH/MAF Full FISH Probe
IGH & MAF	IGH/MAF Split FISH Probe
IGH & MAFB	IGH/MAFB Split FISH Probe
IKZF1	IKZF1 FISH Probe
IKZF1 & CUX1	IKZF1/CUX1 FISH Probe
IL-3 & IGH	IL-3/IGH Split FISH Probe
IL33 & Chromosome 9 Control (9q21.33)	IL33/CON9 FISH Probe
JAK2	JAK2 Break Apart FISH Probe
KIAA1549 & BRAF	KIAA1549/BRAF FISH Probe
KIT & Chromosome 4 Control (4p11)	KIT/CON4 FISH Probe
MAF	MAF FISH Probe
MAFB	MAFB FISH Probe
MAFB	MAFB Break Apart FISH Probe
MAML2	MAML2 Break Apart FISH Probe
MAP3K8	MAP3K8 Break Apart FISH Probe
MDM2 & Chromosome 12 Control (12p11-q11)	MDM2/CON12 Dual Color FISH Probe
MDM2 & Chromosome 12 Control (12p11.1-q11)	MDM2/CON12 CSTM Dual Color FISH Probe
MECOM	MECOM Break Apart FISH Probe
MET	MET FISH Probe
MLH1	MLH1 Break Apart FISH Probe
MLL	MLL Break Apart FISH Probe
MLLT10	MLLT10 Break Apart FISH Probe
MYB	MYB Break Apart FISH Probe
MYCN & AFF3	MYCN/AFF3 FISH Probe
NCOA2	NCOA2 Break Apart FISH Probe
NR4A3	NR4A3 Break Apart FISH Probe
NRAS	NRAS FISH Probe
NTRK1	NTRK1 FISH Probe
NTRK1	NTRK1 Break Apart FISH Probe
NTRK2	NTRK2 Break Apart FISH Probe
NTRK3	NTRK3 FISH Probe
NTRK3	NTRK3 Break Apart FISH Probe
NUP98	NUP98 Break Apart FISH Probe
NUTM1	NUTM1 Break Apart FISH Probe
NUTM1 & BRD4	NUTM1/BRD4 FISH Probe
P16	P16 FISH Probe
P16 & Chromosome 9 Control (9q21.33)	P16/CON9 FISH Probe
PAX3	PAX3 Break Apart FISH Probe
PAX5	PAX5 FISH Probe
PAX5	PAX5 Break Apart FISH Probe
PBX1 & TCF3	PBX1/TCF3 FISH Probe
PCM1 & JAK2	PCM1/JAK2 FISH Probe

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PDGFRA	PDGFRA Break Apart FISH Probe
PDGFRB	PDGFRB Break Apart FISH Probe
PD-L1 (CD274)	PD-L1 (CD274) FISH Probe
PD-L1 (CD274)	PD-L1 (CD274) Break Apart FISH Probe
PD-L1 (CD274) & Chromosome 9 Control (9q21.33)	PD-L1 (CD274)/CON9 FISH Probe
PD-L1 (CD274), PD-L2 (PDCD1LG2) & Chromosome 9 Control (9q21.33)	PD-L1 (CD274)/ PD-L2 (PDCD1LG2) /CON9 FISH Probe
PD-L2 (PDCD1LG2)	PD-L2 (PDCD1LG2) FISH Probe
PICALM	PICALM Break Apart FISH Probe
PLAG1	PLAG1 Break Apart FISH Probe
PMP22 & Chromosome 17 Control (17p11.1)	PMP22/CON17 FISH Probe
PRDM16	PRDM16 Break Apart FISH Probe
PRKCA	PRKCA Break Apart FISH Probe
PRKCB	PRKCB Break Apart FISH Probe
PTCH1	PTCH1 FISH Probe
PTEN & Chromosome 10 Control (10p11.1-q11.1)	PTEN/CON10 FISH Probe
PTPRT & MYBL2	PTPRT/MYBL2 FISH Probe
PVT1	PVT1 FISH Probe
RARB	RARB Break Apart FISH Probe
RB1	RB1 FISH Probe
RB1 & LAMP1	RB1/LAMP1 FISH Probe
REL	REL Dual Color FISH Probe
RELA	RELA Break Apart FISH Probe
RICTOR	RICTOR FISH Probe
ROS1	ROS1 Break Apart FISH Probe
SHOX	SHOX FISH Probe
SHOX & Chromosome X Control (Xq11.1)	SHOX/CONX FISH Probe
SPI1	SPI1 Break Apart FISH Probe
SRF	SRF Break Apart FISH Probe
SS18	SS18 Break Apart FISH Probe
SS18 & SSX1	SS18 Break Apart/SSX1 FISH Probe
TCF3	TCF3 Break Apart FISH Probe
TERT	TERT FISH Probe
TERT	TERT Break Apart FISH Probe
TERT & EGR1 & CSF1R	TERT/EGR1/CSF1R FISH Probe
TERT & NSD1	TERT/NSD1 FISH Probe
TFE3	TFE3 Break Apart FISH Probe
TFEB	TFEB Break Apart FISH Probe
TLX3	TLX3 FISH Probe
TMPRSS2	TMPRSS2 Break Apart FISH Probe
TP63	TP63 Break Apart FISH Probe
TRIM11	TRIM11 Break Apart FISH Probe
P16, Chromosome 3 Control (3q11.1-q11.2), Chromosome 7 Control (7q11.21) & Chromosome 17 Control (17p11.1)	UroFocus FISH Probe
USP6	USP6 Break Apart FISH Probe
VGLL3 & Chromosome 3 Control (3p11.1)	VGLL3/CON3 FISH Probe

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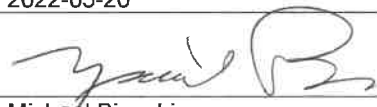
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VHL	VHL FISH Probe
WT1 & EWSR1	WT1/EWSR1 FISH Probe
XIST	XIST FISH Probe
YAP1	YAP1 FISH Probe
YWHAE	YWHAE Break Apart FISH Probe
ZNF217	ZNF217 FISH Probe
ZNF384	ZNF384 Break Apart FISH Probe

We, Empire Genomics Corp., hereby declare, under our sole responsibility, that the above-mentioned product(s) meets the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Devices, which apply to it.

<b>CLASSIFICATION:</b>	Other device
<b>CONFORMITY ASSESSMENT ROUTE:</b>	Self-Certification per Annex III IVDD 98/79/EC
<b>STANDARDS APPLIED:</b>	ISO 13485:2016
<b>NOTIFIED BODY:</b>	N/A
<b>START OF CE-MARKING:</b>	November 2015

This declaration is valid for the above-mentioned products bearing the CE mark and manufactured by Empire Genomics Corp.

<b>PLACE OF ISSUE:</b>	Empire Genomics Corp. 1000 Youngs Road, Suite 207 Williamsville, NY, USA 14221
<b>DATE OF ISSUE:</b>	2022-05-20
<b>SIGNATURE:</b>	
<b>NAME OF ABOVE SIGNED:</b>	Michael Bianchi
<b>POSITION:</b>	Director of Operations

Note: EDMA # 16-02-01-90-00 falls under Acquired Gene or Chromosome Alterations product group.

**Change History**

Revision	Description of Change	Effective Date	CO#
1	Reformatting of form.	08/03/2021	CO-74
2	Company name change for EU Authorized Representative.	01/03/2022	CO-187
3	Change Empire Genomics Inc. to Empire Genomics Corp.	5/17/2022	CO-880

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