



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

Rev Date: 05/17/2022

Revision: 3

1 of 6

Authorized By: Amy Intini

Approved By: Michael Bianchi

| | |
|--|---|
| MANUFACTURER: | Empire Genomics Corp. 1000 Youngs Road, Suite 207 Williamsville, NY, USA 14221 Tel: +1 716 856 3873 Fax: +1 716 431 3440 |
| EUROPEAN AUTHORIZED REPRESENTATIVE: | MedNet EC-REP GmbH Borkstrasse 10 Muenster, Germany 48163 Tel: +49 251 32266-0 Fax: +49 251 32266-22 |

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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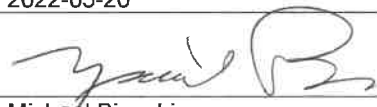
Approved By: Michael Bianchi

| | |
|-------------|-------------------------------|
| 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.

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

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

| | |
|------------------------------|---|
| PLACE OF ISSUE: | Empire Genomics Corp. 1000 Youngs Road, Suite 207 Williamsville, NY, USA 14221 |
| DATE OF ISSUE: | 2022-05-20 |
| SIGNATURE: |  |
| NAME OF ABOVE SIGNED: | Michael Bianchi |
| POSITION: | 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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