

FFPE Reference Standards

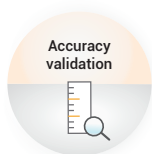
 Monitor the whole workflow of your assay



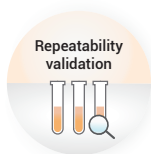
Product list

Product Code	Product Name	Specification	Shelf Life
IB-GW-RPSM1006	Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard	1 FFPE section/tube	24 months
IB-GW-OPSM002	Onco Structural Multiplex 5% FFPE Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSM003	Onco SNV 5% FFPE Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSM005	Onco Wild Type FFPE Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS204	5% EGFR T790M FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS206	5% EGFR E746_A750del (6223) FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS209	5% EGFR A767_V769dup FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS211	5% KRAS G12D FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS215	5% KRAS Q61H FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS216	5% KRAS G12A FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS229	5% PIK3CA E545K FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS230	5% PIK3CA H1047R FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS238	5% NRAS G12V FFPE DNA Reference Standard	1 FFPE section/tube	48 months
IB-GW-OPSS239	5% NRAS G13D FFPE DNA Reference Standard	1 FFPE section/tube	48 months

Evaluate workflow integrity from pre-analytical DNA extraction to post-analytical bioinformatics



Accuracy validation



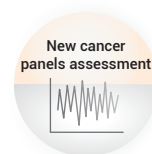
Repeatability validation



Robustness validation



DNA extraction efficiency



New cancer panels assessment

Key Features



Available in both block or sections formats, with DNA or RNA type



Covering pathogenic and hot-spot fusions and variants recommended by NCCN guidelines



Cell-derived reference standards, highly mimic clinical FFPE samples



Strictly quality control process for extraction amount and allelic frequency of variants

FFPE RNA & DNA: GW-RPSM1006 Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard

Variants	Variant Type	Expected Allelic Frequency, %
EML4(13)-ALK(20)	Fusion	4%~7%
SLC34A2(4)-ROS1(32&34)	Fusion	4%~7%
TPM3(7)-NTRK1(10)	Fusion	6%~10%
ETV6(5)-NTRK3(15)	Fusion	10%~40%
FGFR2(17)-COL14A1(34)	Fusion	16%~24%
FGFR3(17)-TACC3(4)	Fusion	5%~9%
CCDC6(1)-RET(12)	Fusion	8%~13%
MET Exon 14 Skipping	SNV	12%~20%

FFPE DNA:GW-OPSM002 Onco Structural Multiplex 5% FFPE Reference Standard

Variants	Variant Type	Expected Allelic Frequency, %
AKT1 E17K	SNV	5%
PIK3CA E545K	SNV	5%
EGFR A767_V769dup	Duplication	5%
EGFR E746_A750del	Deletion	5%
CD74(6)-ROS1(34)	Fusion	5%
EML4(6)-ALK(20)	Fusion	5%
MET Amplification	CNV	3.5 copies
ERBB2 Amplification	CNV	7.0 copies

FFPE DNA: GW-OPSM003 Onco SNV 5% FFPE Reference Standard

Variants	Variant Type	Expected Allelic Frequency, %
EGFR L858R	SNV	5%
EGFR T790M	SNV	5%
EGFR E746_A750del	Deletion	5%
PIK3CA E545K	SNV	5%
KRAS G12D	SNV	5%
KRAS G13D	SNV	5%
KRAS A146T	SNV	5%
NRAS Q61K	SNV	5%

Quality Control

Testing Items	Testing Method	Acceptance Criteria
Allelic Frequency and Copy Number	QX200 Droplet Digital™ PCR+ddPCR Supremix for Probes (No dUTP) (BIO-RAD)	1%≤AF≤5%, accepted range = ±30%, 5%<AF≤20%,accepted range = ±20%, AF>20%, accepted range = ±10%, Copy number<5, accepted range = ±40%, 5≤Copy number<10, accepted range = ±30%
Extraction Amount	Qubit 4.0 Fluorometer+Qubit dsDNA BR Assay Kit (Thermo Fisher Scientific)	Extraction amount>400ng/15µm section



GeneWell Biotechnology Co., Ltd

Technical support : +86 755 2516 7057

E-mail :global@gene-well.com

GW-MKT202406B0PSS-1.v2

Add : Room 802, Building 3A, Dabaihui Life Health Industrial Park, No. 2028, Shenyan Road, Yantian District, Shenzhen,Guangdong,China



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