

【PRODUCT SPECIFICATION】

Product Name	IB-GW-RPSM1006
Specification	1 FFPE Section/tube DNA ≥ 200 ng/vial, RNA ≥ 100 ng/vial (DNA extracted by Maxwell® 16 FFPE plus LEV DNA Purification Kit (Promega), RNA extracted by RNeasy FFPE Kit (Qiagen))

【INTENDED USE】

The product is a full-process reference standard designed for use with targeted-Next Generation Sequencing (NGS) assays that detect somatic mutations in human cancer patient samples. The Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard is intended as a quality reference material in translational and disease research testing, aiding in monitoring DNA isolation, library preparation, sequencing, and detection of genetic mutations under specified bioinformatics pipeline parameters.

For Research Use Only. Not for diagnostic procedures.

【PRINCIPLES OF THE PROCEDURE】

The product must undergo extraction prior to input into NGS library preparation. The product consists of engineered cells cultivated from human immortalization cell lines. Cells are treated by formalin fixation and embedded in paraffin to create an FFPE block, which is then sectioned into 10 μm curls.

【APPEARANCE & COMPONENTS】

The product is one or two 10 μm FFPE sections in a vial. The product consists of engineered cells which have been formalin-treated and embedded in paraffin.

【STORAGE INSTRUCTIONS】

Shipped at ambient temperature, the product should be stored refrigerated at 2-8°C and is valid for 24 months. Adverse shipping and/or storage conditions or the use of outdated materials may produce erroneous results.

【PROCEDURE】

Process the product according to the test kits' instructions for unknown specimens or the laboratory's standard operating procedures.

Instructions for Use

Allow the product vial to equilibrate at room temperature for 5 minutes. The Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard must undergo DNA isolation, target selection and library preparation in parallel with testing specimens. Refer to routine assay procedures to determine the required amount of material.

Quality Control

The Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard is a qualitative material. It is extensively validated using digital PCR and is suitable for guiding genetic mutation assessment with NGS targeted panels or PCR. Variations in assay results may occur and may be significant. Therefore, it is recommended that each laboratory qualifies the use of each lot of the Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard with each assay system before routine use.

【EXPECTED RESULTS】

Detection of specific variants and variant allele frequencies may vary among different assays, procedures, lot numbers, and laboratories. Each laboratory should establish its own range of acceptable values. Table 1 lists the mutations presented in the product.

【INTERPRETATION OF RESULTS】

Detection of variants and variant allele frequencies may vary with different NGS targeted sequencing-based assays and different test reagent lots. As the reference material does not have assigned values, each laboratory must establish an acceptable range for each variant and each lot of the Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard. Results outside the established acceptance range may indicate unsatisfactory test performance, with potential sources of error including deterioration of test kit reagents, operator error, equipment malfunction, reagent contamination, or changes in bioinformatics pipeline parameters.

【LIMITATIONS OF THE PROCEDURE】

The GeneWell Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard MUST NOT BE SUBSTITUTED FOR CONTROL REAGENTS provided with manufactured test kits. It is imperative to closely follow the test procedures provided by manufacturers, as deviations may yield unreliable results. The reference standard is not a calibrator and should not be used for assay calibration. It also does not evaluate specimen extraction methods. Adverse shipping and storage conditions or the use of outdated products may produce erroneous results.

【WARNINGS AND PRECAUTIONS】

For Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle the GeneWell Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard and all materials derived from human blood products with care as if they can transmit infectious agents. The reference standard is manufactured using processed human genomic DNA.

Safety Precautions

Adhere to CDC-recommended universal precautions for handling reference standards and human specimens¹. Avoid pipetting by mouth; do not smoke, eat, or drink in areas where specimens are handled. Clean any spillage immediately with a 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as if they contain infectious agents.

Handling Precautions

Do not use the reference standard beyond its expiration date. Avoid contamination of the product when opening and closing the vials.

【SUMMARY】

A well-designed quality control program adds confidence to the reliability of results obtained for unknown specimens. The use of independent reference standards can provide valuable information concerning assay sensitivity, specificity and precision and bioinformatics pipeline analysis.

【REFERENCES】

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *Am J Infect Control*. 2007 Dec;35(10 Suppl 2): S65-164.

【MANUFACTURER】

GeneWell Biotechnology Co., Ltd.
Address: Room 802, Unit 3, Building 1, Dabaihui Life and Health Industrial Park, No. 2028, Shenyang Road, Tiandong Community, Haishan Street, Yantian District, Shenzhen, 518081 Guangdong, P.R. China
Phone: +86 (0)755 2516 7057.
Email: info@gene-well.com

Table 1. Onco Fusion Multiplex FFPE (DNA/RNA) Reference Standard mutations

Locus	COSMIC ID	Fusion/Mutation Information (GRCh38 · COSMICv94)	Expected Allele Frequency	RNA Expression
EML4(13)-ALK(20)	COSF408	ENST00000318522.9(EML4):r.1_1751::ENST00000389048.7(ALK):r.4080_6220	4%~7%	Yes
SLC34A2(4)-ROS1(32&34)	COSF1196	ENST00000382051.7(SLC34A2):r.1_429::ENST00000368508.7(ROS1):r.5448_7435	4%~7%	Yes
TPM3(7)-NTRK1(10)	COSF1329	ENST00000368533.7(TPM3):r.1_717::ENST00000392302.6(NTRK1):r.1262_2609	6%~10%	Yes
ETV6(5)-NTRK3(15)	COSF571	ENST00000396373.8(ETV6):r.1_1283::ENST00000394480.6(NTRK3):r.1908_19984	10%~40%	Yes
FGFR2(17)-COL14A1(34)	//	ENST00000358487.10(FGFR2):r.17_12148369_8_COL14A1_exon34:120289608	16%~24%	Yes
FGFR3(17)-TACC3(4)	COSF1350	ENST00000440486.8(FGFR3):r.17_1807033_11_TACC3:4:1727832	5%~9%	Yes
CCDC6(1)-RET(12)	COSF1271	ENST00000263102.6(CCDC6):r.1_535::ENST00000355710.7(RET):r.2369_5659	8%~13%	Yes
MET-exon14-skipping/c.3082+1G>T	COSM6108462	c.3082+1G>T	12%~20%	Yes