Onco Structural Multiplex 5% FFPE Reference Standard

【PRODUCT SPECIFICATION】

Product Code	IB-GW-OPSM002
Specification	1 FFPE Section/tube, ≥400ng/tube (Extracted by Maxwell® 16 FFPE plus LEV DNA Purification Kit (Promega))

【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 Structural Multiplex 5% FFPE Reference Standard is intended as a quality reference material in translational and disease research testing, aiding in monitoring DNA extraction, 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 that have been formalin treated and embedded in paraffin to create an FFPE block, which is then sectioned into 15 µm sections. One 15 µm FFPE section is provided per tube.

【APPEARANCE & COMPONENTS】

The product is a wax roll.

The product consists of engineered cells that 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 48 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 Adverse shipping and/or storage conditions or the use of outdated materials may produce erroneous results.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 Structural Multiplex 5% FFPE Reference Standard must undergo an extraction process, 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 Structural Multiplex 5% FFPE 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. 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 Structural Multiplex 5% FFPE 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 Structural Multiplex 5% FFPE 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 Onco Structural Multiplex 5% FFPE 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 Structural Multiplex 5% FFPE 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 cells.

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, Shenyan 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 Structural Multiplex 5% FFPE Reference Standard mutations

No.	Locus	Mutation Type	Expected Allele Frequency (%)
1	AKT1 E17K	SNV	5%
2	PIK3CA E545K	SNV	5%
3	EGFR A767_V769dup/COSM12376	Insertion	5%
4	EGFR E746_A750del	Deletion	5%
5	CD74(6)-ROS1(34)	Fusion	5%
6	EML4(6)-ALK(20)	Fusion	5%
7	MET Amplification	CNV	3.5 copies
8	ERBB2 Amplification	CNV	7.0 copies