Onco Wildtype gDNA Reference Standard

【REF & SPEC】

REF	IB-GW-OGTM005
SPEC	5μg，30 ng/μl±15% (Measured by Qubit 4.0 Fluorometer)

【INTENDED USE】

The product is formulated for use with targeted Next Generation Sequencing (NGS) assays that detect mutations in key oncogenes and tumor suppressor genes. The *Onco* Wildtype gDNA Reference Standard is intended as a quality reference material for translational and disease research testing to monitor library preparation, sequencing, and variant allele detection under a given set of bioinformatics pipeline parameters. For Research Use only. Not for use in diagnostic procedures.

【PRINCIPLES OF THE PROCEDURE】

The product is ready to use in NGS assays in steps that follow DNA isolation; no further purification or DNA isolation is needed. The product contains human genomic DNA at a concentration of 30 ng/μL. The reference material is formulated in a diluted 10 mM Tris / 1 mM EDTA, pH 8.0, aqueous buffer that is compatible with both PCR-based target amplification and hybridization-based target selection methods.

【APPEARANCE & COMPONENTS】

The product is a clear liquid.
The product is human genomic DNA in a 10 mM Tris / 1 mM EDTA, pH 8.0, aqueous buffer.

【STORAGE INSTRUCTIONS】

Ambient shipping, store refrigerated at 2-8°C, valid for 36 months.
Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

【PROCEDURE】

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

Instructions for Use

Allow the product vial to equilibrate at room temperature for 5 minutes. Mix by vortexing to ensure a homogeneous solution and spin down briefly. *Onco* Wildtype gDNA Reference Standard should be integrated into library preparation after the DNA isolation step. *Onco* Wildtype gDNA Reference Standard must go through target selection and library preparation in parallel with the test specimens. Refer to your routine assay procedures in order to determine the amount of material to use.

Quality Control

Onco Wildtype gDNA Reference Standard does not have assigned values for the variant allele frequencies. However, the product is formulated using digital PCR quantitation to target all the variants listed in Table 1 to be present at expected allele frequency. There are many reasons why assay results may deviate from this target, which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of each lot of *Onco* Wildtype gDNA Reference Standard with each assay system prior to its routine use.

【EXPECTED RESULTS】

Specific detection of cancer variants and variant allele frequencies will vary among different assays, different procedures, different lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values. Table 1 lists mutations that are present in the product.

【INTERPRETATION OF RESULTS】

Detection of variants and the variant allele frequency may vary with different NGS targeted sequencing-based cancer panels and different test reagent lots. Since the reference material does not have an assigned value, the laboratory must establish an acceptable range for each variant and each lot of *Onco* Wildtype gDNA Reference Standard. When results for the product are outside of the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, or change in bioinformatics pipeline parameters.

【LIMITATIONS OF THE PROCEDURE】

Onco Wildtype gDNA Reference Standard MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.
TEST PROCEDURES provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. *Onco* Wildtype gDNA Reference Standard is not a calibrator and should not be used for assay calibration. These materials are also not whole process controls and do not evaluate the methods used for specimen extraction.
Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

【WARNINGS AND PRECAUTIONS】

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

CAUTION: Handle *Onco* Wildtype gDNA Reference Standard and all materials derived from human blood products as though they are capable of transmitting infectious agents. *Onco* Wildtype gDNA Reference Standard is manufactured using processed human genomic DNA.

Safety Precautions

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens[1]. Do not pipette by mouth; do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use *Onco* Wildtype gDNA Reference Standard beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

【SUMMARY】

A well-designed quality control program provides added confidence in the reliability of results obtained for unknown specimens. The use of independent reference materials may 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.

【MANUFACTURER】

Genewell Biotechnology Co., Ltd.
Address: F8, Building 3A, DBH Life Science Industry Park, No.2028 Shenyan Road, Yantian District, Shenzhen 518083 CHINA.
Phone: +86 (0)755 2516 7057.
Email: info@gene-well.com

Table 1: *Onco* Wildtype gDNA Reference Standard mutations

Locus	Expected Allele Frequency (%)	Locus	Expected Allele Frequency (%)	Locus	Expected Allele Frequency (%)	Locus	Expected Allele Frequency (%)
AKT1 E17K	0%	EGFR V769_D770insASV	0%	KRAS G12R	0%	ERBB2 A775_G776insYVMA	0%
BRAF V600E	0%	EGFR ΔE746_A750	0%	KRAS G12A	0%	FGFR3 Y375C	0%
EGFR G719S	0%	KRAS A146T	0%	NRAS Q61K	0%	MET Exon 14 Skipping	0%
EGFR L858R	0%	KRAS G12D	0%	NRAS Q61R	0%	CD74-ROS1 Fusion	0%
EGFR T790M	0%	KRAS G13D	0%	FLT3 ΔI836	0%	EML4-ALK Fusion V1	0%
EGFR L861Q	0%	KRAS G12C	0%	KIT D816V	0%	EML4-ALK Fusion V3	0%
EGFR S768I	0%	KRAS G12V	0%	PIK3CA E545K	0%	ERBB2 Amplification	2 copies
EGFR G719A	0%	KRAS G12S	0%	PIK3CA H1047R	0%	MET Amplification	2 copies