Onco SNV Multiplex ctDNA Reference Standard Set

【PRODUCT SPECIFICATION】

Product Code	IB-GW-OCTM009
Specification	3 tubes*0.5μg/tube, 20ng/μL±15% (Measured by Qubit 4.0 Fluorometer)

【INTENDED USE】

The product is a full-process reference standard designed for use with PCR or targeted-Next Generation Sequencing (NGS) assays that detect cancer-relevant somatic mutations present in the bloodstream as circulating cell-free tumor DNA. The Onco SNV Multiplex ctDNA Reference Standard Set is intended as a quality reference material in translational and disease research testing, aiding in monitoring 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 is ready to use in NGS assays in steps that follow DNA isolation; no further purification or DNA isolation is needed. The product contains DNA purified from cell lines and fragmented to an average size of about 160 bp. The DNA is diluted in Tris-EDTA (10mM Tris-HCl, 1mM EDTA), pH 8.0, to a concentration of 20 ng/μL. 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 fragmented human genomic DNA in a 10 mM Tris / 1 mM EDTA, pH 8.0, aqueous buffer.

Item No.	Product Name
IB-GW-OCTM006	Onco SNV Multiplex 0% ctDNA Reference Standard
IB-GW-OCTM007	Onco SNV Multiplex 0.1% ctDNA Reference Standard
IB-GW-OCTM008	Onco SNV Multiplex 1% ctDNA Reference Standard

【STORAGE INSTRUCTIONS】

Shipped at ambient temperature, the product should be stored refrigerated at 2-8°C and is valid for 36 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 Adverse shipping and/or storage conditions or the use of outdated materials may produce erroneous results.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. Mix by vortexing to ensure a homogeneous solution and spin down briefly. The Onco SNV Multiplex ctDNA Reference Standard Set must undergo 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 SNV Multiplex ctDNA Reference Standard Set 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 SNV Multiplex ctDNA Reference Standard Set 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 or PCR-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 SNV Multiplex ctDNA Reference Standard Set. 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 SNV Multiplex ctDNA Reference Standard Set 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 SNV Multiplex ctDNA Reference Standard Set 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 specimens[1]. 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, 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】

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Table 1 Onco SNV Multiplex ctDNA Reference Standard Set mutations

No.	Locus	Mutation Type	Expected Allelic Frequency (%)
Onco SNV Multiplex 0% ctDNA Reference Standard			
1	EGFR L858R	SNV	0%
2	EGFR T790M	SNV	0%
3	EGFR E746_A750del	Deletion	0%
4	EGFR A767_V769dup	Insertion	0%
5	PIK3CA E545K	SNV	0%
6	KRAS G12D	SNV	0%
7	KRAS A146T	SNV	0%
8	NRAS Q61K	SNV	0%
Onco SNV Multiplex 0.1% ctDNA Reference Standard			
1	EGFR L858R	SNV	0.1%
2	EGFR T790M	SNV	0.1%
3	EGFR E746_A750del	Deletion	0.1%
4	EGFR A767_V769dup	Insertion	0.1%
5	PIK3CA E545K	SNV	0.1%
6	KRAS G12D	SNV	0.1%
7	KRAS A146T	SNV	0.1%
8	NRAS Q61K	SNV	0.1%
Onco SNV Multiplex 1% ctDNA Reference Standard			
1	EGFR L858R	SNV	1%
2	EGFR T790M	SNV	1%
3	EGFR E746_A750del	Deletion	1%
4	EGFR A767_V769dup	Insertion	1%
5	PIK3CA E545K	SNV	1%
6	KRAS G12D	SNV	1%
7	KRAS A146T	SNV	1%
8	NRAS Q61K	SNV	1%