PancancerLight® 800 gDNA Reference Standard

【PRODUCT SPECIFICATION】

Product Code	IB-GW-OGTM800
Specification	1μg/tube, 30 ng/μL±15% (Measured by Qubit DNA BR Assay)

【INTENDED USE】

The product is a full-process reference standard designed for use with PCR or targeted-Next Generation Sequencing (NGS) assays that detect somatic mutations in human cancer patient samples. The PancancerLight® 800 gDNA Reference Standard 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 consists of genomic DNA from human immortalization cell lines at a concentration of 30ng/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】

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 Adverse shipping and/or storage conditions or the use of outdated materials may produce erroneous results.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 PancancerLight® 800 gDNA Reference Standard 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 PancancerLight® 800 gDNA 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 PancancerLight® 800 gDNA 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 verified by digital PCR.

【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 PancancerLight® 800 gDNA 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 PancancerLight® 800 gDNA 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 PancancerLight® 800 gDNA 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 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 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】

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Table 1 PancancerLight 800 gDNA Reference Standard mutations

No.	Locus	Mutation Type	Expected Allelic Frequency (%)
1	EGFR L858R	SNV	1%
2	KRAS A146T	SNV	1%
3	NRAS Q61K	SNV	1%
4	EGFR T790M	SNV	2%
5	EGFR E746_A750del	Deletion	2%
6	FLT3 I836del	Deletion	2%
7	KIT D816V	SNV	2%
8	KRAS G12D	SNV	2%
9	EGFR A767_V769dup	Insertion	3%
10	EGFR G719S	SNV	4%
11	KRAS G13D	SNV	4%
12	ALK EML4(6)-ALK(20)	Fusion	5%
13	ROS1 CD74(6)-ROS1(34)	Fusion	6%
14	BRAF V600E	SNV	7%
15	PIK3CA H1047R	SNV	7%
16	ERBB2 Amplification	CNV	5copies