HRD gDNA Reference Standard

【PRODUCT SPECIFICATION】

Product Code	IB-GW-FGTMXXX-T/N
Specification	30 ng/μL, 1 μg/tube (Measured by Qubit 4.0 Fluorometer)

【INTENDED USE】.

The Genewell HRD 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 variants under specified bioinformatics pipeline parameters.
For Research Use Only. Not for diagnostic procedures.

【PRINCIPLES OF THE PROCEDURE】

The product is ready for use in NGS assays post-DNA isolation and requires no further purification. It contains human genomic DNA at a concentration of 30 ng/μL, in 1 mM Tris, 0.1 mM EDTA, pH 8.0 aqueous buffer, compatible with PCR-based target amplification and hybridization-based target selection methods.

【APPEARANCE & COMPONENTS】

The product is a clear liquid, comprising human genomic DNA in 1 mM Tris, 0.1 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 Adverse shipping and/or storage conditions or the use of outdated materials may produce erroneous results.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. Vortex to ensure a homogeneous solution is achieved and spin down briefly. The Genewell HRD gDNA Reference Standard should be integrated into the library preparation following the DNA isolation step. It 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 Genewell HRD Reference Standard has been extensively validated using WGS and can be used to guide HRD score assessment using 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 Genewell HRD Reference Standard with each assay system before routine use.

【EXPECTED RESULTS】

HRD score will vary among different assays, procedures, lot numbers, and laboratories. Each laboratory should establish its own range of acceptable values. Table 1 lists the HRD score present in the catalogue product.

【INTERPRETATION OF RESULTS】

HRD score may vary with different NGS targeted sequencing-based assays and different test reagent lots. Each laboratory must establish an acceptable range and each lot of Genewell HRD 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 HRD 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 HRD 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 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】

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Table 1 HRD Score of Genewell Catalogue HRD gDNA Reference Standard

No.	Product Code	Product Name	LOH	TAI	LST	HRD score
1	IB-GW-FGTM002-T	HRD-2-T gDNA Reference Standard	24	32	7	63
2	IB-GW-FGTM002-N	HRD-2-N gDNA Reference Standard				
3	IB-GW-FGTM003-T	HRD-3-T gDNA Reference Standard	18	6	10	34
4	IB-GW-FGTM003-N	HRD-3-N gDNA Reference Standard				
5	IB-GW-FGTM005-T	HRD-5-T gDNA Reference Standard	25	12	6	43
6	IB-GW-FGTM005-N	HRD-5-N gDNA Reference Standard				
7	IB-GW-FGTM009-T	HRD-9-T gDNA Reference Standard	6	26	20	52
8	iB-GW-FGTM009-N	HRD-9-N gDNA Reference Standard				
9	IB-GW-FGTM012-T	HRD-12-T gDNA Reference Standard	35	35	24	94
10	IB-GW-FGTM012-N	HRD-12-N gDNA Reference Standard				

LOH: measure the number of 15 Mb exceeding loss of heterozygosity regions which do not cover the whole chromosome.
TAI: the unequal contribution of parental allele sequences with or without changes in the overall copy number of the region, which were extending towards the telomeric ends.
LST: defined as a chromosomal break between adjacent regions of at least 10 Mb, with a distance between them not larger than 3Mb.
HRDscore = LOH + TAI + LST.