Mimix™ Structural Multiplex gDNA Reference Standard

IVD

For In Vitro Diagnostic Use

REF HD753-IVD Mimix™ Structural Multiplex gDNA Reference Standard

Intended Use

The Mimix™ Structural Multiplex gDNA Reference Standard is a commutable control material comprising a mixture of genomic DNA (gDNA) derived from human cancer cell lines, containing 9 variants across 8 cancer genes. It is intended for qualitative and/or quantitative monitoring of next-generation sequencing (NGS) and droplet digital polymerase chain reaction (ddPCR) assays designed to detect structural variants in human gDNA samples for *in vitro* diagnostic use.

This control can be used to monitor NGS and ddPCR workflow, test performance, assay variation and helps identify increases in random or systematic errors. This product is for professional laboratory use only.

Summary and Explanation

NGS assays are widely adopted by researchers as well as clinical and diagnostic laboratories to analyse the genetic make-up of patient-derived samples, making it useful to gain insightful data on common or rare diseases[1]. Providing high-throughput data, NGS helps identify genetic differences in patients or any genetic changes introduced as certain diseases progress[2]. Similarly, digital PCR workflows, including ddPCR, are commonly used to enhance traditional PCR performance by allowing a significantly increased number of reactions to be performed and analysed real time[3].

The Mimix™ Structural Multiplex gDNA Reference Standard enables direct analysis of patient-derived DNA samples against a wide range of cancer-related structural variants for fast and accurate results as part of diagnostic tests and scientific research. The product is designed to fit into NGS and ddPCR workflows to help accurately analyse patient-derived samples.

Structural Multiplex gDNA is a gDNA reference standard derived from well-characterized cell lines, mimicking patient-derived gDNA samples. It contains 9 variants across 8 key cancer genes, with variant allele frequencies represented at approximately %5 for limit of detection determination of your assay. In addition, the Structural Multiplex gDNA Reference Standard also represents copy number variation (CNV) of MET and MYC-N genes at 4.5 and 9.5 copies, respectively. This diversity allows for comprehensive assessment of assay performance and quantitative accuracy.

The Mimix™ Structural Multiplex gDNA Reference Standard is a multiplex standard covering the mutations in the following genes: *GNA11, AKT1, PIK3CA, EGFR, ROS1, RET, MET, MYC-N*.

Principles of Operation

The Mimix™ Structural Multiplex gDNA Reference Standard contains genomic DNA stored in Tris-EDTA, isolated from well-characterized cell lines to mimic patient samples. No synthetic DNA is incorporated into this product. The gDNA is intended to be integrated into the customer's workflow for DNA extraction. Every batch of Structural Multiplex DNA has 9 variants confirmed by ddPCR (Table 1), in addition to being fully exome sequenced. This provides an accurate and reliable set for comparison to any NGS assay's performance.

In addition to ddPCR and NGS, further quality control of this product was performed via spectrophotometry.

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Table 1: Verified variants and the corresponding allelic frequencies (AF) or copy number variants (CNV) confirmed by ddPCR.

Gene	Variant	Chromosome	Expected Allelic Frequency % or CNV	Acceptance Criteria
GNA11	Q209L	chr19	5.60%	4.45-6.67%
AKT1	E17K	chr14	5.00%	4.00-6.00%
PIK3CA	E545K	chr3	5.60%	4.45-6.67%
EGFR	A767_V769dup	chr7	5.60%	4.48-6.72%
EGFR	ΔE746 - A750	chr7	5.30%	4.21-6.31%
ROS1	SLC34A2/ROS1 fusion	N/A	5.60%	4.48-6.72%
RET	CCDC6/RET fusion	N/A	5.00%	4.00-6.00%
MET	Amplification	N/A	4.5 copies	3.60-5.40 copies
MYC-N	Amplification	N/A	9.5 copies	7.60-11.40 copies

Material Provided: Reagents

Mimix™ Sturctural Multiplex gDNA Reference Standard

- Catalogue/Model number: HD753-IVD
  One vial, 1x 20µL
  Material provided in Tris-EDTA (10 mM Tris-HCl, 1 mM EDTA), pH 8.0.

⚠ Precautions and Warning

- Although this product is not classified as dangerous, handle all materials as potentially biohazardous, following standard laboratory safety procedures.
- Dispose of all waste materials in accordance with local regulations.
- Inspect the vial for any signs of damage or leakage.

Storage and Handling

- Store unopened at 2 to 8 °C.
- Do not use this product beyond the expiration date printed on the product label.
- Centrifuge briefly before opening and make sure all contents are at the bottom of the tube.

Interpretation of Results

Variant detection results for the Mimix™ Structural Multiplex gDNA may vary depending on the library preparation method, sequencing platform, and bioinformatics pipeline used for NGS assays, as well as primer/probe set, analysis type/platform, and assay conditions for ddPCR. The expected variant list of the Structural Multiplex gDNA provided can be used to compare each subsequent run.

Quality Control and Performance Characteristics

Following our QC procedure, the acceptance criteria are described below (Table 2). Users should note that results will vary depending on the equipment and workflow used. Users are expected to perform their own validation to determine AFs within the workflow to be monitored. The below reported data were obtained using the validated equipment and workflow as specified for each quality control test. Spectrophotometry and ddPCR data are provided in Figures 1 and 2, respectively.

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Table 2. List of quality control tests applied and the corresponding acceptance criteria.

Test name	Test purpose	Acceptance criteria
Spectrophotometry	Measure quantity and purity of gDNA	Concentration: 48-52 ng/µL 260nm/280nm ratio: 1.75-2.00
ddPCR	Measure stability of AF	Within the accepted target range. Refer to Table 1.

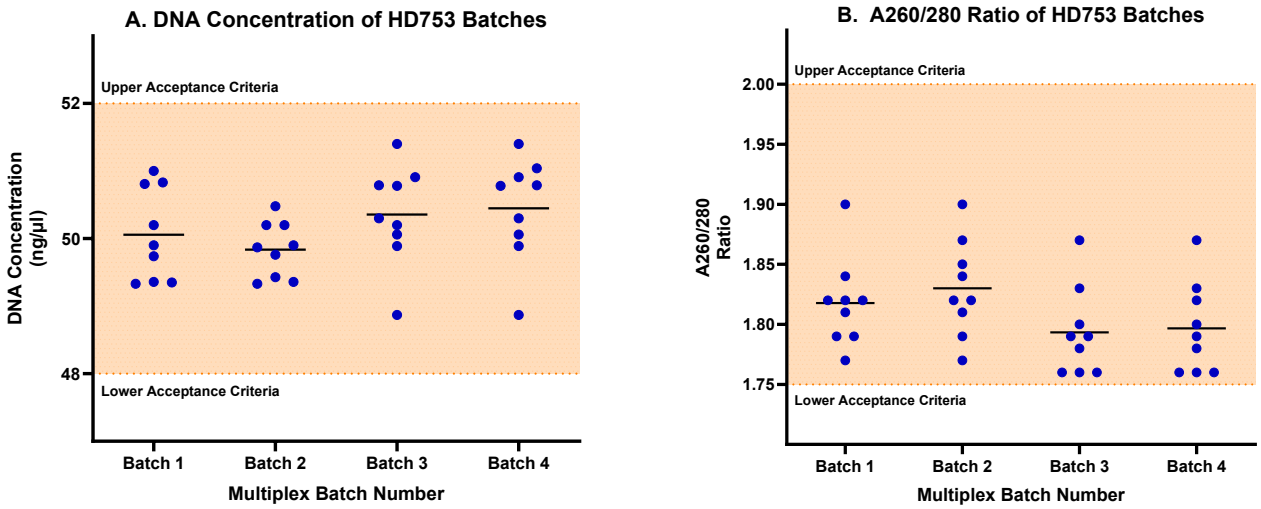


Figure 1. A. Concentration of Structural Multiplex gDNA measured by spectrophotometry. B. A260/280 ratio of Structural Multiplex gDNA measured by spectrophotometry. The graphs display the upper and lower limits of the acceptance range (red dotted lines and shaded area in A and B).

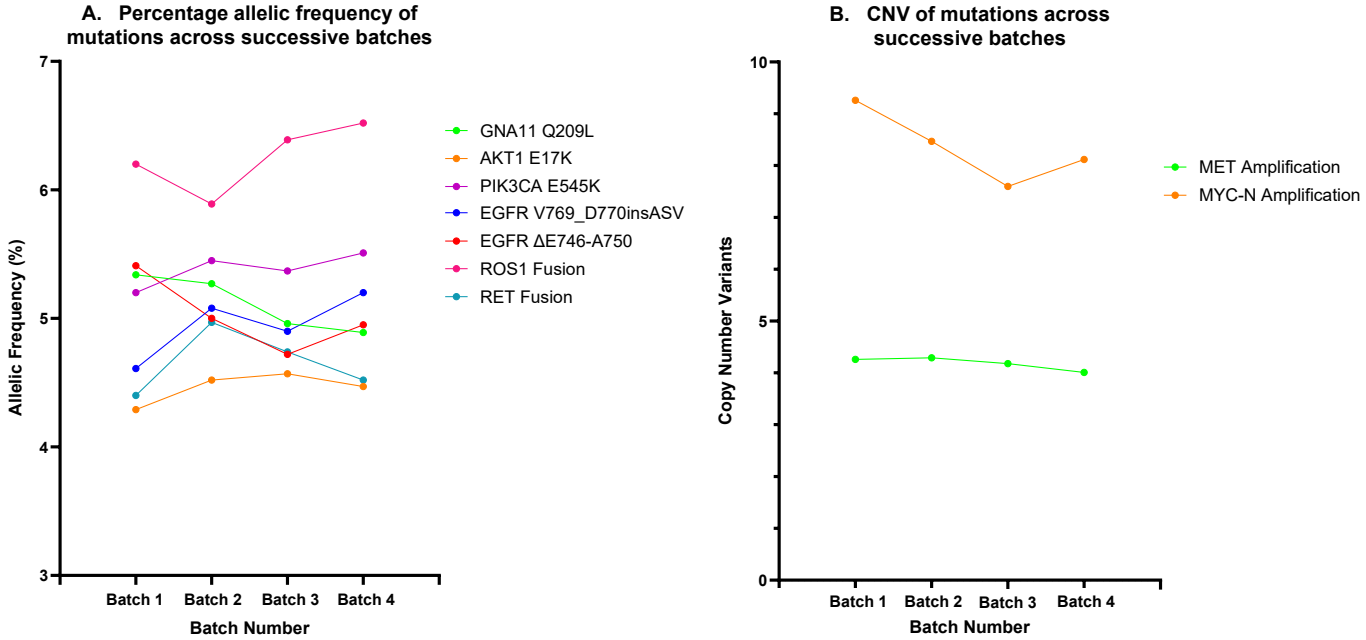


Figure 2. Percentage allelic frequencies (A) and CNV (B) measured by ddPCR.

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Limitations

- The Mimix™ Structural Multiplex gDNA Reference Standard is not to be used as a substitute for the internal controls provided by manufacturers within their IVD assay kits.

Technical Support

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References

1 Vinkšel, M., Writzl, K., Maver, A. *et al.* Improving diagnostics of rare genetic diseases with NGS approaches. *J Community Genet* 12, 247–256 (2021). https://doi.org/10.1007/s12687-020-00500-5

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3 Mirabile A, Sangiorgio G, Bonacci PG, et al. Advancing Pathogen Identification: The Role of Digital PCR in Enhancing Diagnostic Power in Different Settings. *Diagnostics (Basel)*. 2024;14(15):1598. Published 2024 Jul 25. doi:10.3390/diagnostics14151598

Glossary

IVD In Vitro Diagnostic Medical Device

REF Catalogue Number

Legal Manufacturer

Temperature Limit

Caution

NON STERILE Non-sterile

Consult Instructions for Use

Use-by date

UDI Unique device identifier

QTY Quantity

CONTROL + Positive control

Trademark and Patent information

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