Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard

IVD

For In Vitro Diagnostic Use

REF HD784-IVD Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard

Intended Use

The Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard is a commutable control material comprising a formalin-fixed paraffin-embedded (FFPE) curl derived from human cancer cell lines, containing 3 RNA fusions. It is intended for qualitative monitoring of next-generation sequencing (NGS) or reverse transcription polymerase chain reaction (RT-PCR) assays designed to detect RNA fusion transcripts in RNA from human samples for *in vitro* diagnostic use.

The RNA obtained from Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard can be used in NGS or RT-PCR workflows, 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 analyze 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, RT-PCR workflows are commonly used to detect and confirm mRNA sequences, allowing accurate detection of the size by converting the target mRNA to complementary DNA (cDNA)[3].

The Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard enables direct analysis of patient-derived RNA samples against important cancer-related somatic mutations for fast and accurate results as part of diagnostic tests and scientific research. The product is designed to fit into NGS and RT-PCR workflows to help accurately analyze patient-derived samples.

Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard is a curl mimicking the patient tissue sections, sectioned from an FFPE block derived from well-established cell lines via cell pellet collection and blending followed by fixation in 10% paraformaldehyde (PFA) and paraffin embedding.

The standard contains fusion transcripts of 3 key cancer genes, with more than 100 ng of RNA recovery per section. This specificity allows for comprehensive assessment of assay performance and accuracy.

The Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard is a multiplex standard covering the fusion transcripts of the following genes: *EML4-ALK (Exon 13 - Exon 20), CCDC6-RET (Exon 1 – Exon 12), and SLC34A2-ROS1 (Exon 4 – Exon 32)*.

Principles of Operation

The Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard contains a single curl suitable for RNA extraction, derived directly from well-characterized cell lines to mimic patient samples. No synthetic genetic material is incorporated into this product. The FFPE curl is intended to be integrated into the customer's workflow for RNA extraction. Every batch of ALK-RET-ROS1 Fusion FFPE has 3 fusion transcripts confirmed by endpoint RT-PCR followed by agarose gel electrophoresis (Table 1 and Figure 1).

In addition, further quality control of this product was performed via fluorometric analysis to accurately determine the RNA content of each FFPE section.

Material Provided

Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard.

- Catalogue/Model number: HD784-IVD. One vial, 1x FFPE curl, 10 µm thickness.

⚠ **Precautions and Warning**

- This product is not classified as dangerous, however; users are advised to handle all materials as potentially biohazardous, following standard laboratory safety procedures.
- Dispose of all waste materials in accordance with local regulations.
- Avoid contamination of the product when opening and closing the vial by making sure that the curl is intact and sits at the bottom of the vial.
- Inspect the vial for any signs of melting before opening.

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Table 1: Verified fusions and the corresponding amplicon sizes confirmed by RT-PCR.

Gene	Variant	Amplicon Size
ALK	EML4-ALK	249 bp
RET	CCDC6-RET	336 bp
ROS1	SLC34A2-ROS1	193 bp

Storage and Handling

- Store unopened at 2 to 8 °C.
- Do not use this product beyond the expiration date printed on the product label.
- Please see the following instructions for handling:
  - Open the tube by twisting and lifting the lid.
  - If needed, please remove the curl carefully without destruction by using suitable forceps (e.g. anatomical forceps) and transfer the curl appropriately.
  - If the whole curl is to be removed from the vial, we recommend all handling takes place at temperatures below room temperature (~15-25°C).
  - If the curl does not need to be transferred, please keep it in the vial and perform your assay accordingly (e.g. RNA extraction).

Quality Control and Performance Characteristics

Variant detection when using the Mimix™ ALK-RET-ROS1 Fusion FFPE RNA Reference Standard 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 RT-PCR. The expected amplicon size list of the ALK-RET-ROS1 Fusion FFPE provided can be used to compare each subsequent run.

Following our QC procedure, the acceptance criteria are described in 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 RNA yield 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.

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

Test name	Test purpose	Acceptance criteria
Fluorometric analysis	Measure the quantity and quality of FFPE RNA	RNA ≥100ng
RT-PCR	Measure the size of fusion mRNA	At the accepted amplicon size. Refer to Table 1.

The RNA yield obtained from the ALK-RET-ROS1 Fusion FFPE RNA Reference standard is shown in Figure 1.

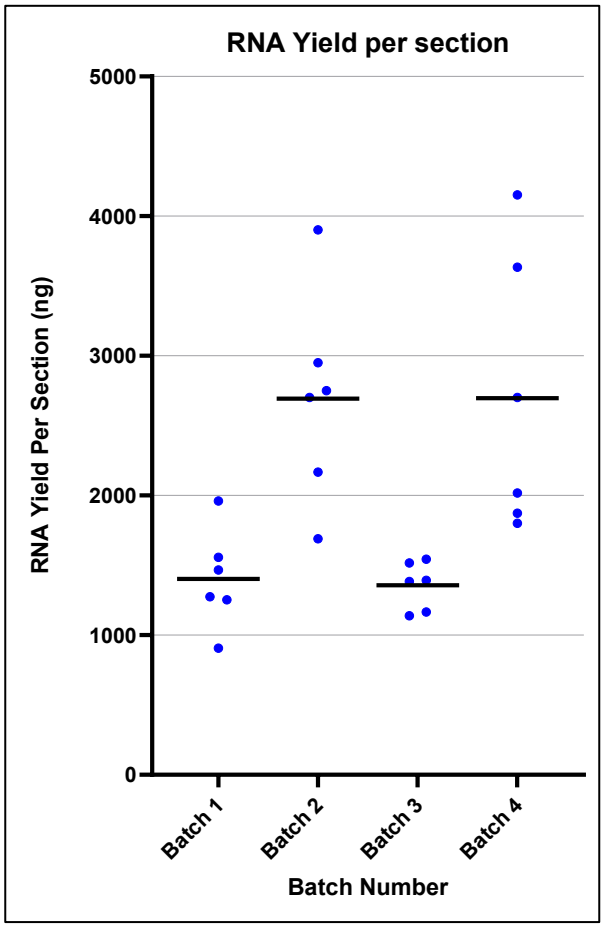


Figure 1. Batch-to-batch yield of RNA extracted from ALK-RET-ROS1 Fusion FFPE RNA Reference Standard.

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Figure 2 shows the gel electrophoresis analysis of RT-PCR. Amplicon sizes for all 3 fusions are confirmed.

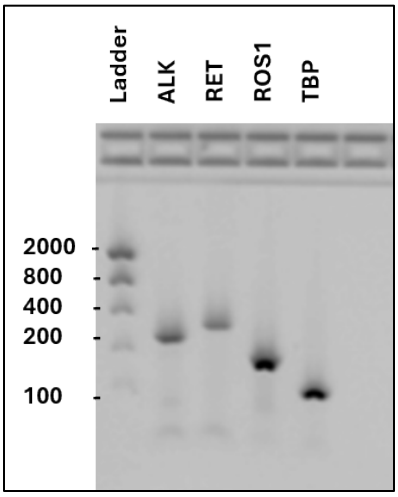


Figure 2. Gel electrophoresis image for one representative batch, showing amplicon sizes for all 3 fusion transcripts. TATA-binding protein (TBP) was used as a positive control.

Limitations

- The ALK-RET-ROS1 Fusion FFPE RNA Reference Standard is not to be used as a substitute for the internal controls provided by manufacturers within their IVD assay kits.

Technical Support

Scientific 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 Malewski T, Malewska A, Rutkowski R. RT-PCR technique and its applications. State-of the-art. *J Anim Feed Sci*. 2003;12(3):403–416. doi:10.22358/jafs/67719/2003

Glossary

IVD In Vitro Diagnostic Medical Device

REF Catalogue Number

Manufacturer

Temperature Limit

Caution

Consult instructions for use

Use-by date

UDI Unique device identifier

QTY Quantity

CONTROL + Positive control

Trademark and Patent information

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