DIACARTA®

For Lung Cancer

QFusion™ ROS1 Fusion Detection Kit

XNA technology helps increase assay sensitivity and specificity

Lung cancer is the most commonly occurring malignancy in both men and women worldwide. Genomic alterations, including structural rearrangements in lung cancer, have significant predictive value in the treatment of disease.

In lung cancer, two c-ROS oncogene-1 (ROS1) ROS1 fusion transcripts, SLC34A2-ROS1 and CD74-ROS1 were first reported as proto-oncogenes2. ROS1 rearrangement mostly occurs at the exon 32, 34, 35, or 36 or introns 31 or 333,4. Among the fusion partners, the most common partners are CD74 (38-54%), EZR (13-24%), SDC4 (9-13%), SLC34A2 (5-10%), and GOPC (2-3%) (Figure 1). ROS1 rearrangement test is now recommended for all metastatic lung carcinomas.

FISH is the gold standard to diagnose ROS1 fusion, but it has a relatively high cost, technical difficulties due to limited tumor cell availability, and is operator-dependent results7,8. RT-qPCR using primers specific to ROS1 fusion shows excellent performance with 100% sensitivity and 85.1% specificity.

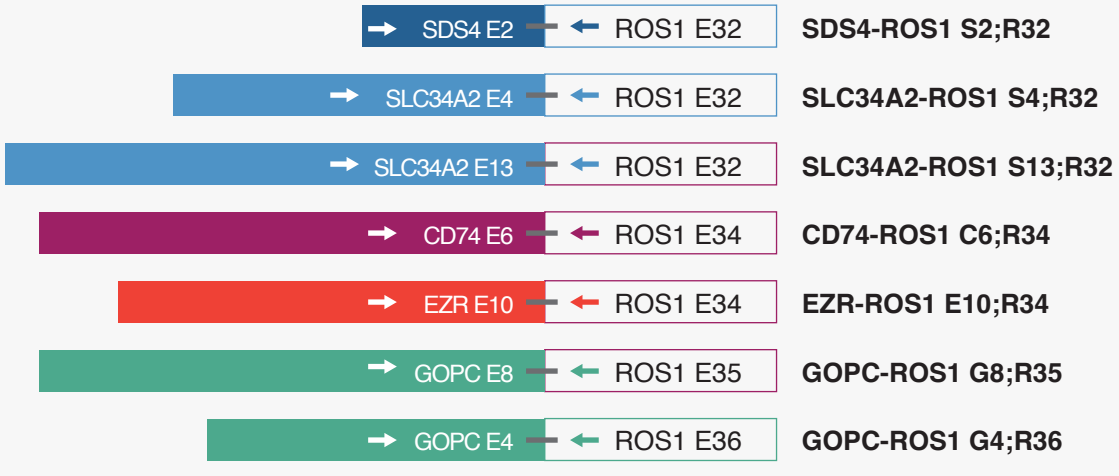


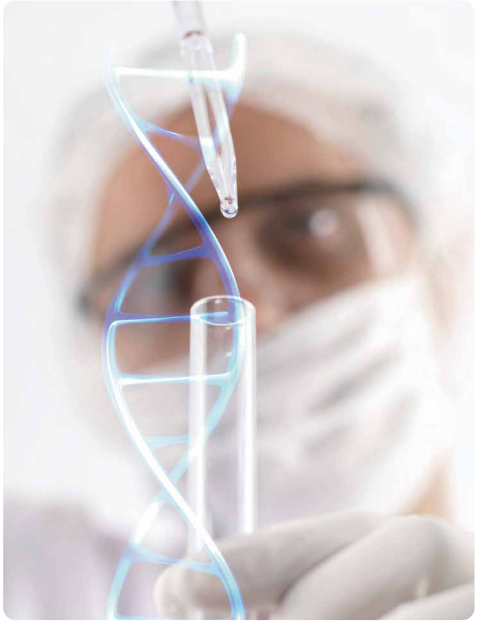
Figure 1. Schematic of ROS1 Fusions Detected by QFusion™ ROS1 Fusion Detection Kit

Two tyrosine kinase inhibitors, crizotinib and entrectinib, have been approved by FDA as first-line therapy. Therefore, the detection of ROS1 fusions is critical in therapeutic management.“

Although NGS is used now for ROS1 fusion detection, qPCR can be a cost-effective yet still accurate tool for detection since the ROS1 fusion partners are very limited.

QFusion™ ROS1 Fusion Detection Kit

The Qfusion™ ROS1 Fusion Gene Detection kit is a real-time RT-qPCR based in vitro diagnostic test intended for qualitative and indiscriminatory detection of seven ROS1 fusions in RNA extracted from cells, tissues, and formalin-fixed paraffin-embedded (FFPE) samples. The kit identifies the presence or absence of fusions but does not specify the exact nature of the fusion.



The assay has been validated on three instruments: Roche LightCycler 480II, AB QuantStudio5, and Bio-Rad CFX 384. The assay sensitivity: 50 copies and assay reproducibility: % CV is 0.7 to 3.2%, depending on the targets and instruments.

The QFusion™ ROS1 Fusion Detection kit is for Research Use Only (RUO), not for use in diagnostic procedures without clinical validation in a CLIA lab.

XNA technology helps increase assay sensitivity and specificity

The QFusion™ ROS1 Fusion Detection assay is based on xenonucleic acid (XNA) mediated PCR clamping technology. **XNA is a synthetic DNA analog in which the phosphodiester backbone has been replaced by a novel synthetic backbone chemistry.** XNAs hybridize tightly to complementary DNA target sequences only if the sequence is a complete match. Binding of XNA to its target sequence blocks strand elongation by DNA polymerase. When there is a fusion or a mutation in the target site, and therefore a mismatch such as ROS1 fusion sequence, the XNA: DNA duplex is unstable, allowing strand elongation by DNA polymerase. Addition of an XNA, whose sequence is a complete match to wild-type ROS1 DNA, into a PCR reaction blocks the amplification of wild-type DNA, allowing selective amplification of fusion DNA. XNA oligomers are not recognized by DNA polymerases and cannot be utilized as primers in subsequent real-time PCR reactions. Because XNA blocks the wildtype sequence amplification, both assay sensitivity and specificity have been

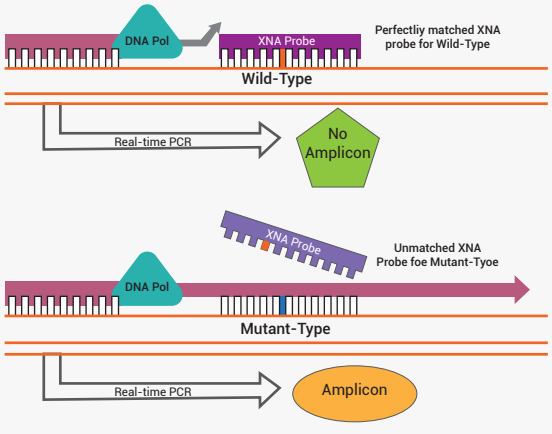


Figure 2. Principle of the QFusion ROS1 Fusion Gene Detection by XNA

Product Name: QFusion™ ROS1 Fusion Detection Kit

Catalog number	5 sample: DC-20-0004R	20 samples: DC-20-0005R