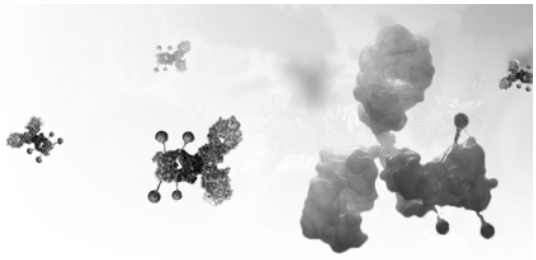

RET Fusion Detection Test for Lung Cancer (PCR-CT-009)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Sample	Cells, tissues, and formalin-fixed paraffin-embedded (FFPE) samples
Intended Use	The RET Fusion Gene Detection kit is an XNA-based real-time RT-qPCR based in vitro diagnostic test intended for qualitative and indiscriminatory detection of seven RET fusions (two CCDC6-RET, four KIF5B-RET, and one NCOA4-RET 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 fusion partner and truncation position of the fusion. XNA-based RET fusion detection can increase assay sensitivity (reducing false negatives) and specificity (reducing false positives)
Size	5 samples, 20 samples
Principle	The RET 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 XNA is a synthetic DNA analog in which the phosphodiester backbone has been replaced by a novel synthetic backbone chemistry.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 RET 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 RET 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 increased.
Performance Characteristics	1. **Analytical sensitivity:** as low as 50 copies of fusions can be detected with 100% 2. **Reproducibility:** inter-reproducibility: 0.8 to 3.3% depending on the targets; intra-reproducibility: 0.7 to 3.3% depending on the targets

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