

Easy[®] Line Real Time



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Easy® KRAS cat.no. RToo1 (24 test, CE IVD)

Main features	<p>Detection of the main mutations of exon 2 (codons 12, 13), of exon 3 (codons 59, 61) and of exon 4 (codons 117, 146) of the gene KRAS using 12 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> <p>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.</p>
Controls	<p>Control DNA positive for all the mutations detected by the kit.</p> <p>Reference standard DNA Horizon KRAS G12V 1% to monitor the analytical process and the performances of the system.</p> <p>The standard is characterized by a well defined allelic ratio wild-type/mutant.</p>
Sensitivity	<p>The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%)</p>
Starting material	<p>The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues.</p>
Execution time	<p>2 hours</p>

Easy® BRAF cat.no. RToo2 (24 test, CE IVD)

Main features	<p>Detection of the main mutations of codon 600 of the gene BRAF using 5 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> <p>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.</p> <p>Control DNA positive for all the mutations detected by the kit.</p>
Controls	<p>Reference standard DNA Horizon BRAF V600E 1% to monitor the analytical process and the performances of the system.</p> <p>The standard is characterized by a well defined allelic ratio wild-type/mutant.</p>
Sensitivity	<p>The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%).</p>
Starting material	<p>The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues.</p>
Execution time	<p>2 hours</p>

Easy® EGFR cat.no. RToo3 (24 test, CE IVD)

Main features	<p>Detection of the main mutations of exons 18, 19, 20, 21 of EGFR gene using 8 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p> <p>A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.</p>
Controls	<p>Control DNA positive for all the mutations detected by the kit.</p> <p>Reference standard DNA Horizon EGFR ΔE746-A750 1% to monitor the analytical process and the performances of the system.</p> <p>The standard is characterized by a well defined allelic ratio wild-type/mutant.</p>
Sensitivity	<p>The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%).</p>
Starting material	<p>The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues and of circulating tumor DNA extracted from plasma.</p>
Execution time	<p>2 hours</p>

Easy® NRAS cat.no. RToo4 (24 test, CE IVD)

Main features	Detection of the main mutations of exon 2 (codons 12, 13), of exon 3 (codons 59, 61) and of exon 4 (codons 117, 146) of NRAS gene of EGFR gene using 8 oligo mixes. Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene. A specific oligo control mix enables the evaluation of the quality and the quantity of the DNA in each sample.
Controls	Control DNA positive for all the mutations detected by the kit. Reference standard DNA Horizon NRAS Q61K 1% to monitor the analytical process and the performances of the system. The standard is characterized by a well defined allelic ratio wild-type/mutant.
Sensitivity	The kit allows the detection of low percentages of mutated allele in presence of high amounts of wild-type genomic DNA by real-time amplification with sequence-specific probes marked with FAM and HEX (LOD down to 0.5%)
Starting material	The kit allows the analysis of DNA extracted from fresh, frozen and formalin-fixed paraffin-embedded tissues.
Execution time	2 hours

Easy® ALK cat.no. RToo5 (24 test, CE IVD)

Main features	Qualitative detection of aberrant expression of the tyrosin-kinase domain of ALK associated to the gene fusion by retrotranscription and co-amplification of a region located at 3' terminus of ALK mRNA (detected by a FAM marked probe) and of an endogenous control gene (detected by a HEX marked probe).
Controls	Control RNA for the monitoring of the analytical process.
Starting material	The kit allows the analysis of RNA extracted from fresh, frozen or formalin-fixed paraffin-embedded tissues.
Execution time	2 hours

Kit linea Easy®

The Easy® kits allow the qualitative detection of the main somatic mutations of the genes EGFR, KRAS, NRAS and BRAF by Real-Time PCR in association with a system of enrichment of the mutated allele.

The kit Easy® ALK is designed for the qualitative detection of the aberrant expression of the tyrosin-kinase domain of ALK, which is caused by events of gene rearrangement, by One Step Real-Time RT-PCR.

Each kit includes all the reagents necessary for the test and the positive controls of reaction. The kits are validated on the following instruments:

- Rotor-Gene Q
- Rotor-Gene 6000
- ABI 7500
- Stratagene Mx3000P
- Stratagene Mx3005P
- ABI 7300
- Bio-Rad CFX96

All the kits (on each of the above listed instruments) share the same thermal profile for the detection of the somatic mutations.

*The registered names and trademarks indicated in this document have to be considered protected by law, even when not explicitly stated.

Helix® Circulating Nucleic Acid cat.no. H8040 (50 test, CE IVD)

The kit allows the manual extraction of circulating free DNA (cfDNA) from plasma. The kit Helix® Circulating Nucleic Acid, in association with the kit Easy® EGFR, enables the mutational analysis of EGFR gene in the circulating tumor DNA (liquid biopsy) when the tumor tissue is not evaluable, according to the EMA/129677/2014 recommendations of September 25th 2014.

Main features	DNA capture by silica membrane and vacuum-based system. System to concentrate final eluate up to 3 times included in the kit.
Starting material	1-5 ml of fresh or frozen plasma.
Execution time	3 hours

Easy® DPYD cat. no. RToo6 (24 test, CE IVD)

Main features	<p>Detection, by allelic discrimination, of the DPYD gene polymorphisms DPYD*2A (IVS14+1G>A, c.1905+1G>A, rs3918290), DPYD*13 (c.1679T>G, rs55886062), DPYD D949V (c.2846A>T, rs67376798) and DPYD IVS10 (c.1129-5923C>G, rs75017182), associated with the toxicity due to the treatment with fluoropyrimidines, using 4 oligo mixes.</p> <p>Each mix allows the co-amplification of the mutant sequence (FAM) as well as the wild-type sequence (HEX).</p>
Controls	<p>DPYD WT positive control: Positive control DNA containing a mixture of synthetic wild-type DNA sequences for DPYD polymorphisms analyzed.</p> <p>DPYD MT positive control: Positive control DNA containing a mixture of synthetic mutant DNA sequences for DPYD polymorphisms analyzed.</p>
Starting material	The kit allows the analysis of genomic DNA extracted from whole blood
Execution time	2 hours

Easy® UGT1A1 cat. no. RToo7 (24 test, CE IVD)

Main features	<p>Detection, by allelic discrimination, of the UGT1A1 gene polymorphisms UGT1A1*1 (TA)6, UGT1A1*28 (TA)7, UGT1A1*36 (TA)5 and UGT1A1*37 (TA)8, associated with the toxicity due to the treatment with irinotecan, using 1 oligo mix.</p> <p>UGT1A1 mix contains HEX labeled probes for UGT1A1*28 and UGT1A1*37 and FAM labeled probes for UGT1A1*1 and UGT1A1*36.</p>
Controls	<p>UGT1A1 WT positive control: Positive control DNA containing synthetic wild-type UGT1A1*1/*1 DNA sequence.</p> <p>UGT1A1 MT positive control: Positive control DNA containing synthetic mutant UGT1A1*28/*28 DNA sequence.</p>
Starting material	The kit allows the analysis of genomic DNA extracted from whole blood
Execution time	2 hours

Easy® THYROID cat. no. RToo8 (24 test, CE IVD)

Main features	<p>Detection of the main mutations of exon 2 (codons 12,13), of exon 3 (codons 61) of the genes KRAS, NRAS, HRAS and of the codons 600 and 601 of the gene BRAF using 8 oligo mixes.</p> <p>Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.</p>
Controls	Positive control DNA containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.
Starting material	<p>The kit allows the analysis of genomic DNA extracted from fresh, frozen or formalin fixed paraffin-embedded (FFPE) tumor tissue.</p> <p>The kit allows the analysis of genomic DNA extracted from cytological samples.</p>
Execution time	2 hours