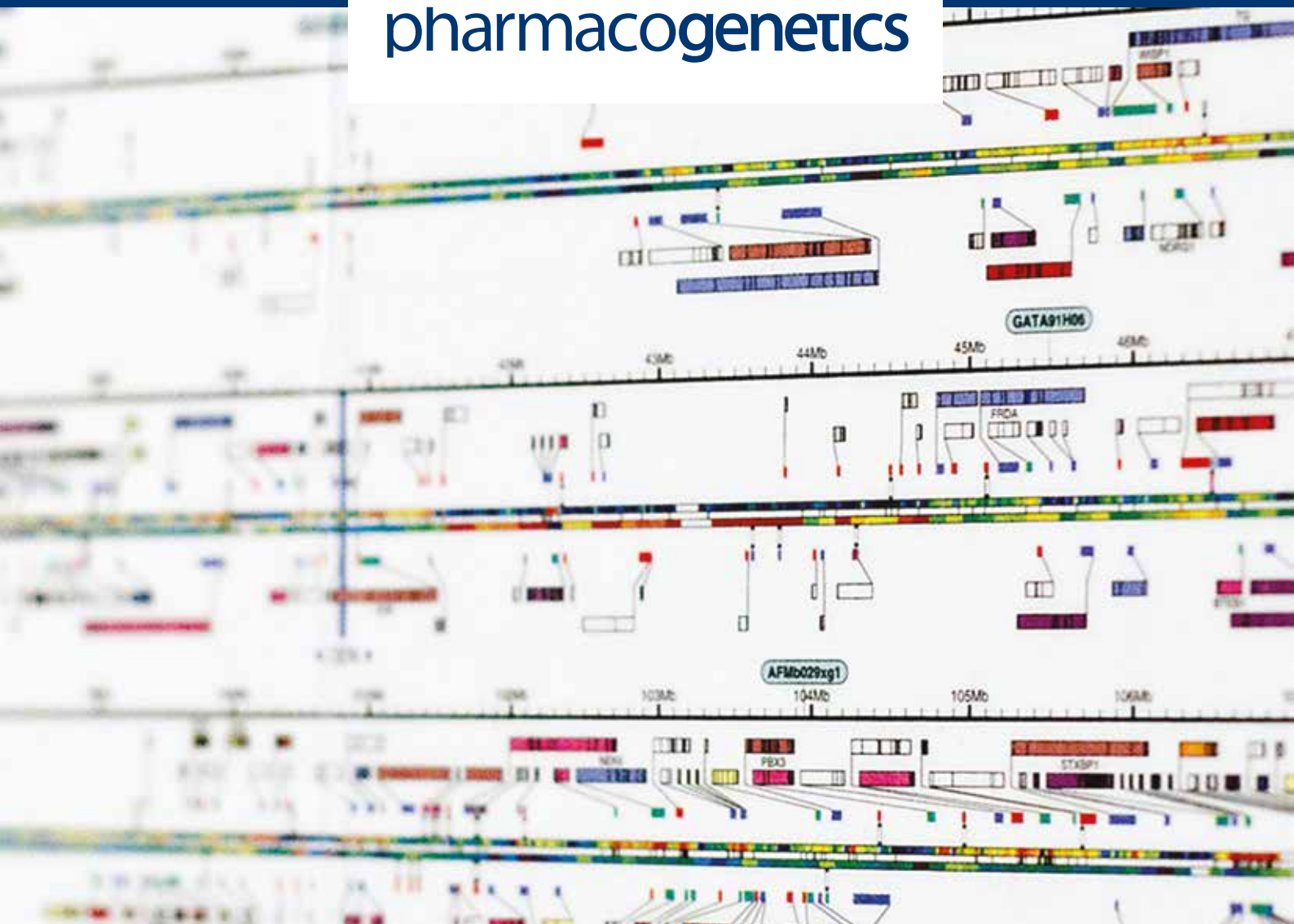
easyPGX®

Ready to youuse

diatech pharmacogenetics

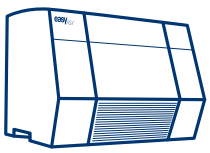


easy PGX® Ready to youse

Easy PGX® product line - key features

- **Ready to use**: reagents are delivered in 8-well strips preloaded with a complete master mix in a dry, room temperature and stable format
- **Easy to use**: no need for freezing, thawing or pipetting on ice and the few remaining pipetting steps minimize the risk of errors or contaminations
- **High sensitivity**: limit of detection as low as 0.5%
- **Flexible sample requirement**: low DNA input from a variety of sources, including FFPE and plasma
- **Turnaround time**: from tissue to result in less than 3 hours with only 10 minutes of hands-on time
- **Quality assurance**: manufactured under ISO 13485
- **Regulatory**: kits have been designed, developed and validated in accordance with the Directive 98/79/EC on in vitro diagnostic medical devices

From tissue to result in less than 3 hours

Workflow	One step tissue lysis	PCR setup	PCR run	Data analysis
Total time	**60** min	< **5** min	**90** min	< **1** min
				
	Add the Easy PGX Dep solution and extraction reagents to the sample	Add extracted samples to ready-to-use 8-well strip	Load the 8-well strip onto the thermal-cycler and start the run	Import raw data into the Easy PGX Analysis software
Hands-on time	< **5** min	< **5** min	< **1** min	< **1** min

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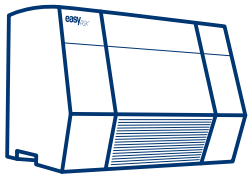
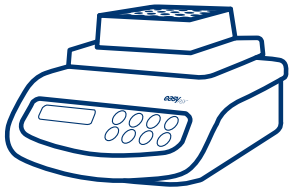
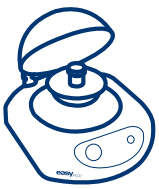
System ordering information

Catalog number	Product description	Picture
RT800 CE IVD	Easy$_{PGX}$ qPCR instrument	
RT800-96 CE IVD	Easy$_{PGX}$ qPCR instrument 96	
RT800-SW CE IVD	Easy$_{PGX}$ analysis software	
RT801 CE IVD	Easy$_{PGX}$ dry block	
RT802 CE IVD	Easy$_{PGX}$ centrifuge/vortex 1.5 ml	
RT803 CE IVD	Easy$_{PGX}$ centrifuge/vortex 8-well strips	

easy PGX® Ready to youse

Easy PGX® ready KRAS cat. no. RT021 (48 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 the gene KRAS 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
The kit is provided with the following controls:
- Positive control sample containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.
- Negative control.

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, formalin-fixed paraffin-embedded (FFPE) tissues and plasma*.

Easy PGX® ready BRAF cat. no. RT022 (48 test, CE IVD)

Main features
Detection of the main mutations of codon 600 of the gene BRAF using 4 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
The kit is provided with the following controls:
- Positive control sample containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.
- Negative control.

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, formalin-fixed paraffin-embedded (FFPE) tissues and plasma*.

Easy$_{PGX}$® ready EGFR cat. no. RT023 (48 test, CE IVD)

Main features
Detection of the main mutations of exons 18, 19, 20, 21 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
The kit is provided with the following controls:
- Positive control sample containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.
- Negative control.

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, formalin-fixed paraffin-embedded (FFPE) tissues and plasma*.

Easy$_{PGX}$® ready NRAS cat. no. RT024 (48 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 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
The kit is provided with the following controls:
- Positive control sample containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.
- Negative control.

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, formalin-fixed paraffin-embedded (FFPE) tissues and plasma*.

Easy$_{PGX}$® ready DPYD cat. no. RT026 (48 test, CE IVD)

Main features
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.
Each mix allows the co-amplification of the mutant sequence (FAM) as well as the wild-type sequence (HEX).

Controls
The kit is provided with the following controls:
- DPYD WT positive control: Positive control DNA containing a mixture of synthetic wild-type DNA sequences for the DPYD polymorphisms analyzed.
- DPYD MT positive control: Positive control DNA containing a mixture of synthetic mutant DNA sequences for the DPYD polymorphisms analyzed.
- Negative control.

Starting material
The kit allows the analysis of genomic DNA extracted from whole blood.

Easy$_{PGX}$® ready UGT1A1 cat. no. RT027 (48 test, CE IVD)

Main features
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. UGT1A1 mix contains HEX labeled probes for UGT1A1*28 and UGT1A1*37 and FAM labeled probes for UGT1A1*1 and UGT1A1*36.

Controls
The kit is provided with the following controls:
- UGT1A1 WT positive control: Positive control DNA containing synthetic wild-type UGT1A1*1/*1 DNA sequence.
- UGT1A1 MT positive control: Positive control DNA containing a synthetic mutant UGT1A1*28/*28 DNA sequence.
- Negative control.

Starting material
The kit allows the analysis of genomic DNA extracted from whole blood.

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Easy$_{PGX}$® ready Thyroid cat. no. RT028 (48 test, CE IVD)

Main features
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. Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.

Controls
The kit is provided with the following controls:
- Positive control sample containing a mixture of synthetic DNA sequences that correspond to each mutation detected by this kit in a background of wild-type genomic DNA.
- Negative control.

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%**.

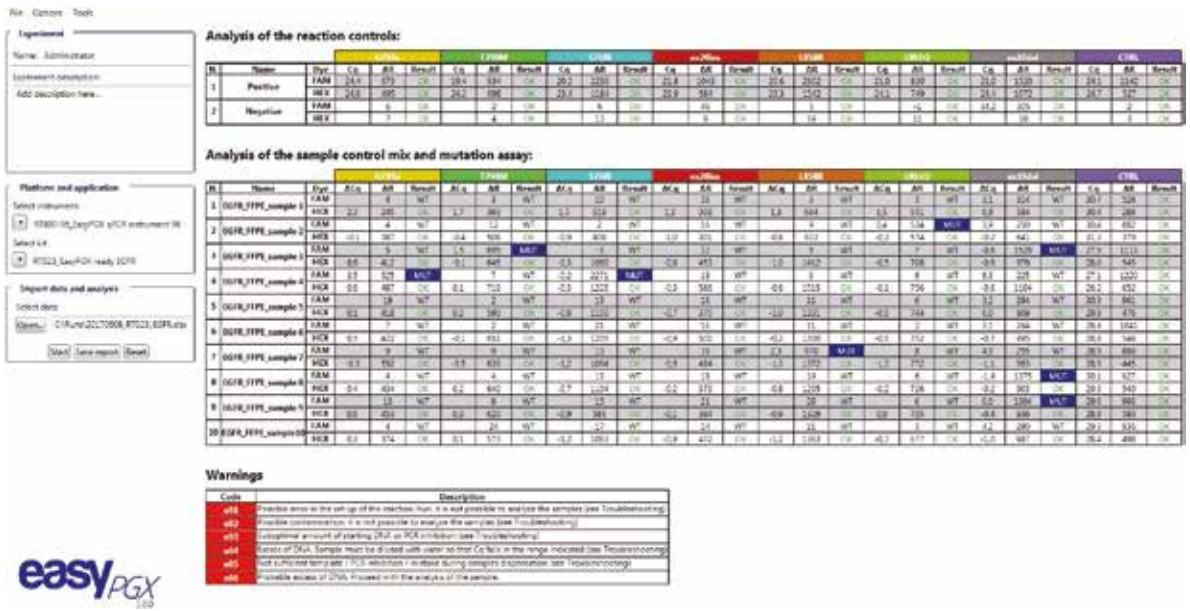
Starting material
The kit allows the analysis of DNA extracted from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues, plasma*, and cytological samples.

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

Main features
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$_{PGX}$® ready 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.
DNA capture by silica membrane and vacuum-based system. The system to concentrate the final eluate up to 3 times is included in the kit.

Starting material
1-5 ml of fresh or frozen plasma.

Turn around time
3 hours



* Please note that extraction from plasma is sold separately (cat.n. H8040)

For information please contact:

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