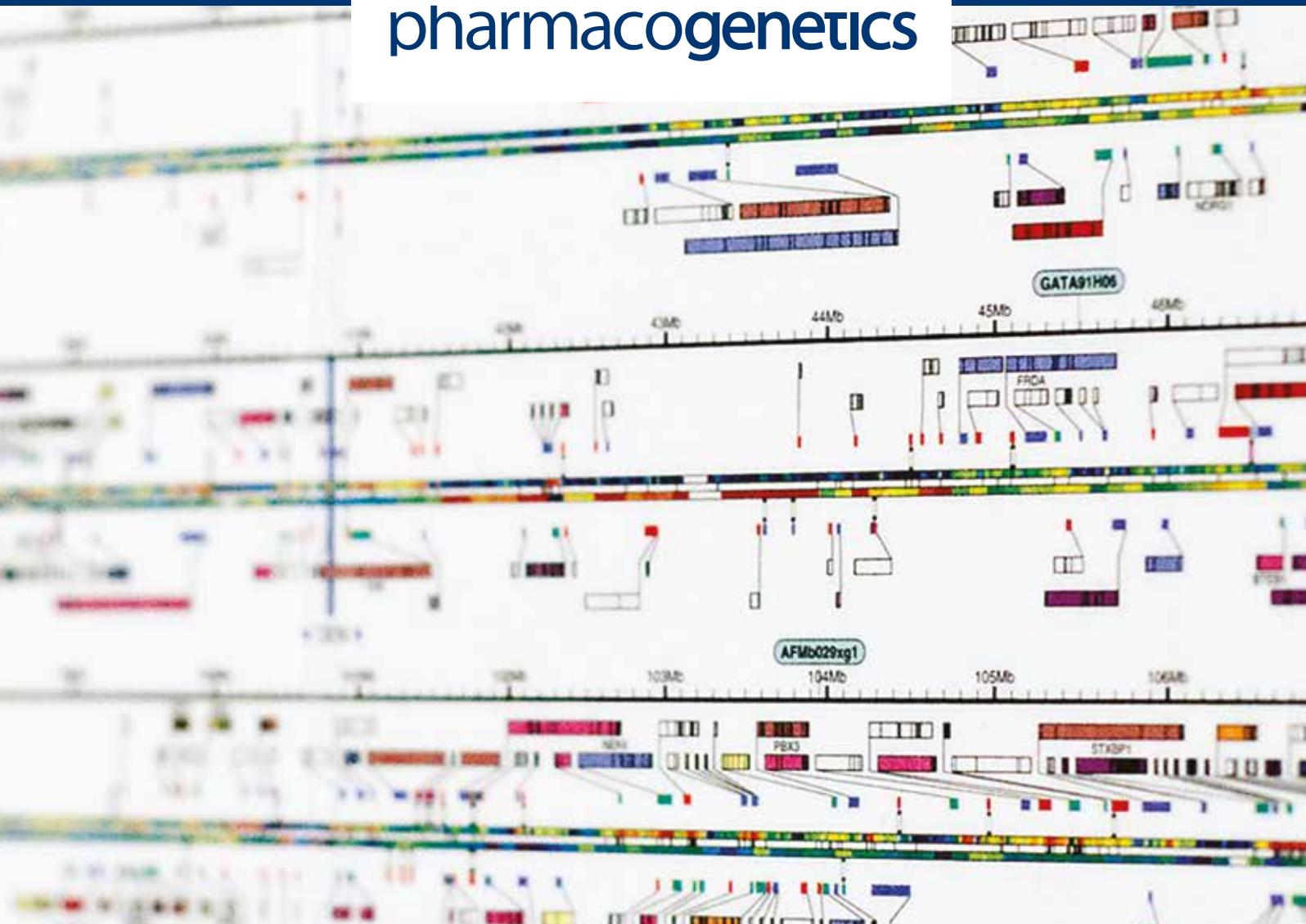


# easy<sup>PGX</sup><sup>®</sup>

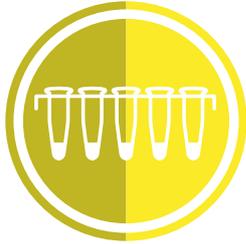
## Ready to you**USE**

### The qPCR solution in oncology

**diatech**  
pharmacogenetics



**easy**PGX<sup>®</sup>



**READY TO USE**

Reagents delivered in 8-well strips preloaded with a complete master mix



**EASY TO USE**

No need for freezing, thawing or pipetting on ice and the few remaining pipetting steps minimize the risk of errors or contamination



**HIGH SENSITIVITY**

Limit of detection as low as 0.5%



**FLEXIBLE SAMPLE REQUIREMENT**

Low DNA or RNA 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



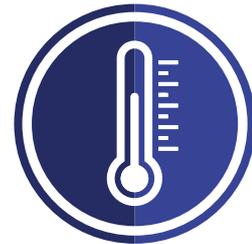
**FLEXIBLE USE**

Possibility to run multiple targets all in one experiment: same thermal profile for the somatic assays and color coded reagents



**AUTOMATIC DATA ANALYSIS**

Import data into Easy PGX dedicated software and get results



**TRANSPORT AND STORAGE AT ROOM TEMPERATURE**

Complete master mix in a dry format, stable at room temperature



**STANDARDS INCLUDED**

Positive and negative controls included for validation of each experimental session



**AUTOMATIC EVALUATION**

Inhibitors or pipetting errors detected by the internal reaction control



**REGULATORY**

Kits have been designed, developed and validated in accordance with the Directive 98/79/EC on in vitro diagnostic medical devices



**QUALITY ASSURANCE**

Manufactured under ISO 13485

**Easy<sub>PGX</sub> 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 KRAS gene.  
Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma\*.

**Easy<sub>PGX</sub> ready BRAF**  
cat. no. RT022 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the main mutations of codon 600 of the BRAF gene.  
Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma\*.

**Easy<sub>PGX</sub> ready EGFR**  
cat. no. RT023 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the main mutations of exons 18, 19, 20, 21 of the EGFR gene.  
Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma\*.

**Easy<sub>PGX</sub> ready NRAS**  
cat. no. RT024 (48 test, CE IVD)

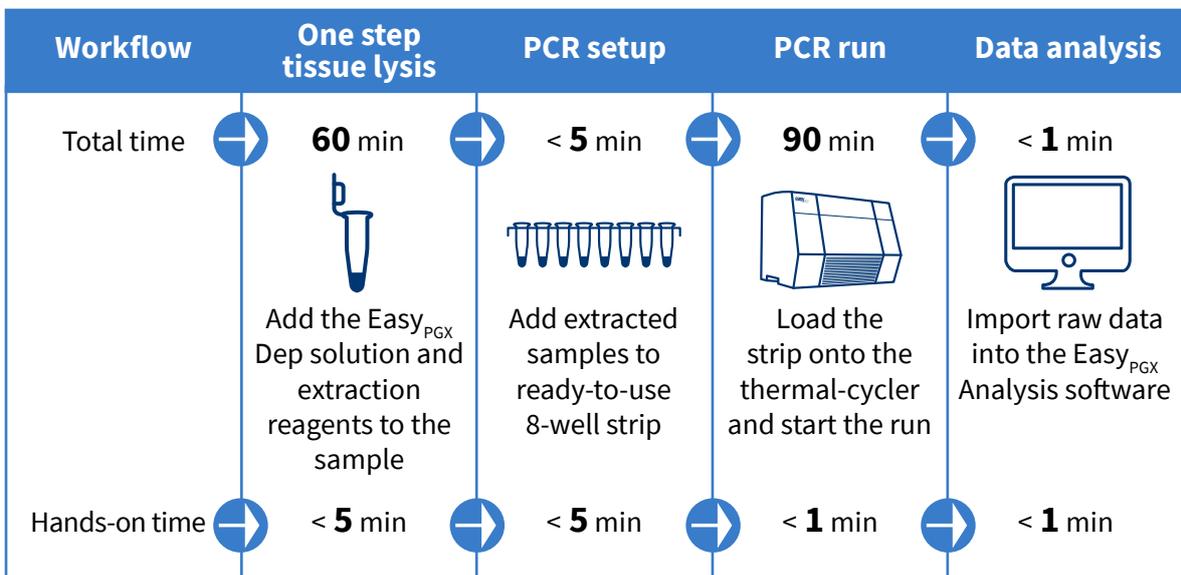
**MAIN FEATURES**

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

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma\*.

**Easy PGX system: from tissue to result in less than 3 hours**



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

**Easy<sub>PGX</sub><sup>®</sup> ready ALK, ROS1, RET, MET**  
cat. no. RT025 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the main chromosomal translocations involving ALK, ROS1, RET and the MET exon 14 skipping.

Each mix allows the co-amplification of one or more fusions plus an endogenous control gene.

**STARTING MATERIAL**

RNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and cytological samples.

**Easy<sub>PGX</sub><sup>®</sup> 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), DPYD\*13 (c.1679T>G), DPYD D949V (c.2846A>T) and DPYD IVS10 (c.1129-5923C>G), associated with the toxicity due to the treatment with Fluoropyrimidines.

Each mix allows the co-amplification of the mutant sequence as well as the wild-type sequence.

**STARTING MATERIAL**

DNA from whole blood.

**Easy<sub>PGX</sub><sup>®</sup> ready UGT1A1**  
cat. no. RT027 (48 test, CE IVD)

**MAIN FEATURES**

Detection, by allelic discrimination, of the UGT1A1 gene polymorphisms UGT1A1\*36 (TA)5, UGT1A1\*1 (TA)6, UGT1A1\*28 (TA)7 and UGT1A1\*37 (TA)8, associated with the toxicity due to the treatment with Irinotecan.

Each mix allows the co-amplification of the target polymorphisms plus an endogenous control gene.

**STARTING MATERIAL**

DNA from whole blood.

**Easy<sub>PGX</sub><sup>®</sup> 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 (codon 61) of the KRAS, NRAS, HRAS genes and of the codons 600 and 601 of the BRAF gene.

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

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues, and cytological samples.

## Color coded: multiple targets in one run



**Easy<sub>PGX</sub><sup>®</sup> ready FL-DNA**  
cat. no. RT029 (48 test, CE IVD)

**MAIN FEATURES**

Absolute quantitative detection of Fluorescence  
Long DNA from faecal specimens.  
Each mix allows the co-amplification of the target  
DNA (APC and TP53) plus an exogenous control gene.

**STARTING MATERIAL**

DNA from faecal specimens.

**Easy<sub>PGX</sub><sup>®</sup> ready EGFR PLUS**  
cat. no. RT030 (48 test, CE IVD)

**MAIN FEATURES**

Detection of T790M and C797S (c.2389 T>A, c.2390  
G>C) of the EGFR gene.  
Each mix allows the co-amplification of one or more  
mutated alleles plus an endogenous control gene.

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed  
paraffin-embedded (FFPE) tissues and plasma\*.

**Easy<sub>PGX</sub><sup>®</sup> ready IDH 1-2**  
cat. no. RT031 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the main mutations of IDH1 gene  
(codons 105 and 132) and IDH2 gene (codons 140 and  
172).  
Each mix allows the co-amplification of one or more  
mutated alleles plus an endogenous control gene.

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed  
paraffin-embedded (FFPE) tissues, peripheral whole  
blood and bone marrow.

**Easy<sub>PGX</sub><sup>®</sup> ready THYROID FUSION**  
cat. no. RT032 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the chromosomal translocations  
involving RET/PTC1: CCDC6-RET; RET/PTC2:  
PRKAR1A-RET; RET/PTC3: NCOA4-RET and  
PAX8/PPARG.  
Each mix allows the co-amplification of one or more  
fusions plus an endogenous control gene.

**STARTING MATERIAL**

RNA from fresh, frozen, formalin-fixed paraffin-  
embedded (FFPE) tissues and cytological samples.

## Reagents delivered in 8-well strips preloaded with a complete master mix



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

**Easy<sub>PGX</sub><sup>®</sup> ready MSI**  
cat. no. RT033 (48 test, CE IVD)

**MAIN FEATURES**

Detection of 8 mononucleotide "quasi - monomorphic" markers: BAT-25, BAT-26, NR-21, NR-22, NR-24, NR-27, CAT-25 and MONO-27 by Real Time PCR and subsequent analysis of the targets based on the denaturation profile. The test allows, accurately and with reduced "hands-on time", to detect the microsatellite instability in tumor samples.

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissue. Comparison with normal tissue or blood is not necessary for the analysis of results.

**Easy<sub>PGX</sub><sup>®</sup> ready HPV**  
cat. no. RT034 (48 test, CE IVD)

**MAIN FEATURES**

Identification of 14 High Risk genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) of Human Papilloma Virus (HPV) by amplifying the E6 and E7 oncogenes. Each mix allows the co-amplification of the genotype-specific HPV targets plus an endogenous control gene.

**STARTING MATERIAL**

DNA from cervical swabs and formalin-fixed paraffin-embedded (FFPE) tissue.

**Easy<sub>PGX</sub><sup>®</sup> ready NTRK FUSION**  
cat. no. RT035 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the main fusion variants of the NTRK1, NTRK2 and NTRK3 genes.

Each mix allows the co-amplification of one or more fusions plus an endogenous control gene.

**STARTING MATERIAL**

RNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and cytological samples.

**Easy<sub>PGX</sub><sup>®</sup> ready PIK3CA**  
cat. no. RT036 (48 test, CE IVD)

**MAIN FEATURES**

Detection of the main mutations of codons 345, 420, 542, 545, 546 1047 and 1049 of the PIK3CA gene.

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

**STARTING MATERIAL**

DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma\*.

## EasyPGX instrumental system



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

## 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 EasyPGX® ready EGFR, enables the mutational analysis of EGFR gene in the circulating tumour DNA (liquid biopsy) when the tumour 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.

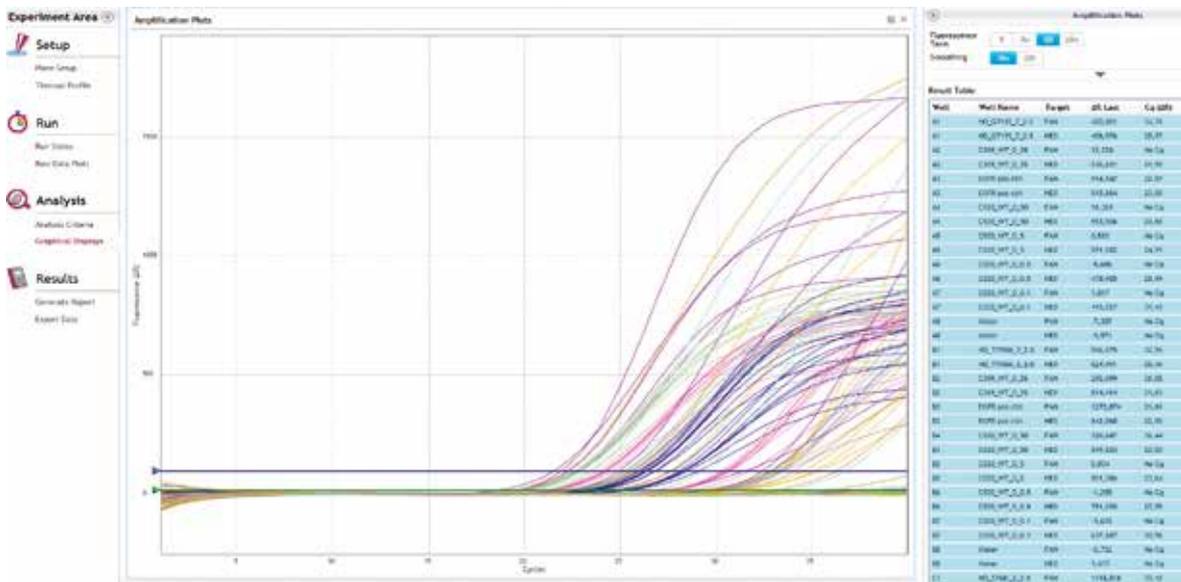
### STARTING MATERIAL

1-5 ml of fresh or frozen plasma.

### TURN AROUND TIME

3 hours.

## Real time reaction monitoring



## Automatic data analysis software

File Options Tools

Experimented

Name: Administration

Experiment description:

Add description here...

Platforms and application

Select instrument:

- AT100-96\_EasyPGX qPCR instrument (6)
- AT100\_EasyPGX ready (207)

Import data and analysis

Select files:

Open: C:\Users\ADMIN\Documents\EGFR\_100

[OK] [Cancel] [New]

**Analysis of the reaction controls:**

Run	Name	Type	CT	Delta Rn	Result															
1	Positive	FAM	24.6	0.95	OK	24.6	0.94	OK	25.2	1.04	OK	21.8	1.04	OK	21.8	1.02	OK	21.8	1.02	OK
1	Positive	ROX	24.8	0.97	OK	24.7	0.94	OK	25.4	1.04	OK	21.9	1.04	OK	21.9	1.02	OK	21.9	1.02	OK
1	Positive	FAM	24.8	0.97	OK	24.7	0.94	OK	25.4	1.04	OK	21.9	1.04	OK	21.9	1.02	OK	21.9	1.02	OK
1	Positive	ROX	24.8	0.97	OK	24.7	0.94	OK	25.4	1.04	OK	21.9	1.04	OK	21.9	1.02	OK	21.9	1.02	OK
2	Negative	FAM	8	0.94	OK															
2	Negative	ROX	8	0.94	OK															

**Analysis of the sample control mix and mutation assay:**

| Run | Name                | Type | CT | Delta Rn | Result |
|-----|---------------------|------|----|----------|--------|----|----------|--------|----|----------|--------|----|----------|--------|----|----------|--------|----|----------|--------|
| 1   | EGFR_FFPE_sample 1  | KAM  | 8  | 0.97     | OK     |
| 1   | EGFR_FFPE_sample 1  | ROX  | 8  | 0.97     | OK     |
| 2   | EGFR_FFPE_sample 2  | KAM  | 8  | 0.97     | OK     |
| 2   | EGFR_FFPE_sample 2  | ROX  | 8  | 0.97     | OK     |
| 3   | EGFR_FFPE_sample 3  | KAM  | 8  | 0.97     | OK     |
| 3   | EGFR_FFPE_sample 3  | ROX  | 8  | 0.97     | OK     |
| 4   | EGFR_FFPE_sample 4  | KAM  | 8  | 0.97     | OK     |
| 4   | EGFR_FFPE_sample 4  | ROX  | 8  | 0.97     | OK     |
| 5   | EGFR_FFPE_sample 5  | KAM  | 8  | 0.97     | OK     |
| 5   | EGFR_FFPE_sample 5  | ROX  | 8  | 0.97     | OK     |
| 6   | EGFR_FFPE_sample 6  | KAM  | 8  | 0.97     | OK     |
| 6   | EGFR_FFPE_sample 6  | ROX  | 8  | 0.97     | OK     |
| 7   | EGFR_FFPE_sample 7  | KAM  | 8  | 0.97     | OK     |
| 7   | EGFR_FFPE_sample 7  | ROX  | 8  | 0.97     | OK     |
| 8   | EGFR_FFPE_sample 8  | KAM  | 8  | 0.97     | OK     |
| 8   | EGFR_FFPE_sample 8  | ROX  | 8  | 0.97     | OK     |
| 9   | EGFR_FFPE_sample 9  | KAM  | 8  | 0.97     | OK     |
| 9   | EGFR_FFPE_sample 9  | ROX  | 8  | 0.97     | OK     |
| 10  | EGFR_FFPE_sample 10 | KAM  | 8  | 0.97     | OK     |
| 10  | EGFR_FFPE_sample 10 | ROX  | 8  | 0.97     | OK     |

**Warnings**

Code	Description
W01	Residual error in the set-up of the reaction, run. It is not possible to analyze the complete run (Troubleshooting)
W02	Residual contamination of a well possible to analyze the complete run (Troubleshooting)
W03	Insufficient amount of starting DNA or PCR inhibition (see Troubleshooting)
W04	Excess of DNA, samples must be diluted with water or that, by 10x in the range indicated (see Troubleshooting)
W05	Not sufficient template / PCR inhibition / mislabel during samples alignment (see Troubleshooting)
W06	Presence of excess of DNA, proceed with the analysis of the sample

### Colorectal Cancer



**Cat. no. Description**

RT021 EasyPGX ready KRAS  
 RT022 EasyPGX ready BRAF  
 RT024 EasyPGX ready NRAS  
 RT033 EasyPGX ready MSI  
 RT036 EasyPGX ready PIK3CA  
 RT035 EasyPGX ready NTRK Fusion  
 RT029 EasyPGX ready FL-DNA

### Lung Cancer



**Cat. no. Description**

RT023 EasyPGX ready EGFR  
 RT025 EasyPGX ready ALK, ROS1, RET, MET  
 RT021 EasyPGX ready KRAS  
 RT030 EasyPGX ready EGFR Plus  
 RT035 EasyPGX ready NTRK Fusion

### Melanoma



**Cat. no. Description**

RT022 EasyPGX ready BRAF  
 RT024 EasyPGX ready NRAS  
 RT035 EasyPGX ready NTRK Fusion

### Thyroid Cancer



**Cat. no. Description**

RT028 EasyPGX ready THYROID  
 RT032 EasyPGX ready THYROID Fusion  
 RT035 EasyPGX ready NTRK Fusion

### Cervical Cancer



**Cat. no. Description**

RT034 EasyPGX ready HPV  
 RT035 EasyPGX ready NTRK Fusion

### Breast Cancer



**Cat. no. Description**

RT036 EasyPGX ready PIK3CA  
 RT035 EasyPGX ready NTRK Fusion

### Glioblastoma



**Cat. no. Description**

RT031 EasyPGX ready IDH1-2  
 RT035 EasyPGX ready NTRK Fusion

### Genotyping Assays



**Cat. no. Description**

RT026 EasyPGX ready DPYD  
 RT027 EasyPGX ready UGT1A1

### Liquid Biopsy Assays



**Cat. no. Description**

RT021 EasyPGX ready KRAS  
 RT022 EasyPGX ready BRAF  
 RT023 EasyPGX ready EGFR  
 RT024 EasyPGX ready NRAS  
 RT030 EasyPGX ready EGFR Plus  
 RT036 EasyPGX ready PIK3CA

## System ordering information

Catalog number	Product description	Picture
RT800-96 	Easy <sub>PGX</sub> qPCR instrument 96	
RT800-SW 	Easy <sub>PGX</sub> analysis software	
RT801 	Easy <sub>PGX</sub> dry block	
RT802 	Easy <sub>PGX</sub> centrifuge/vortex 1.5 ml	
RT803 	Easy <sub>PGX</sub> centrifuge/vortex 8-well strips	

## Kit ordering information

Catalog number	Product description	Picture
RT021 	Easy <sub>PGX</sub> ready KRAS (48 test)	Green 
RT022 	Easy <sub>PGX</sub> ready BRAF (48 test)	Purple 
RT023 	Easy <sub>PGX</sub> ready EGFR (48 test)	White 
RT024 	Easy <sub>PGX</sub> ready NRAS (48 test)	Blue 
RT025 	Easy <sub>PGX</sub> ready ALK ROS1 RET MET (48 test)	Purple 
RT026 	Easy <sub>PGX</sub> ready DPYD (48 test)	Purple 
RT027 	Easy <sub>PGX</sub> ready UGT1A1 (48 test)	Clear 
RT028 	Easy <sub>PGX</sub> ready THYROID (48 test)	Black 
RT029 	Easy <sub>PGX</sub> ready FL-DNA (48 test)	White 
RT030 	Easy <sub>PGX</sub> ready EGFR Plus (48 test)	Red 
RT031 	Easy <sub>PGX</sub> ready IDH1-2 (48 test)	Clear 
RT032 	Easy <sub>PGX</sub> ready THYROID Fusion (48 test)	White 
RT033 	Easy <sub>PGX</sub> ready MSI (48 test)	Green / Black 
RT034 	Easy <sub>PGX</sub> ready HPV (48 test)	White 
RT035 	Easy <sub>PGX</sub> ready NTRK Fusion (48 test)	Blue 
RT036 	Easy <sub>PGX</sub> ready PIK3CA (48 test)	Red 

**diatech**  
pharmacogenetics

For information please contact:

# **diatech** pharmacogenetics

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