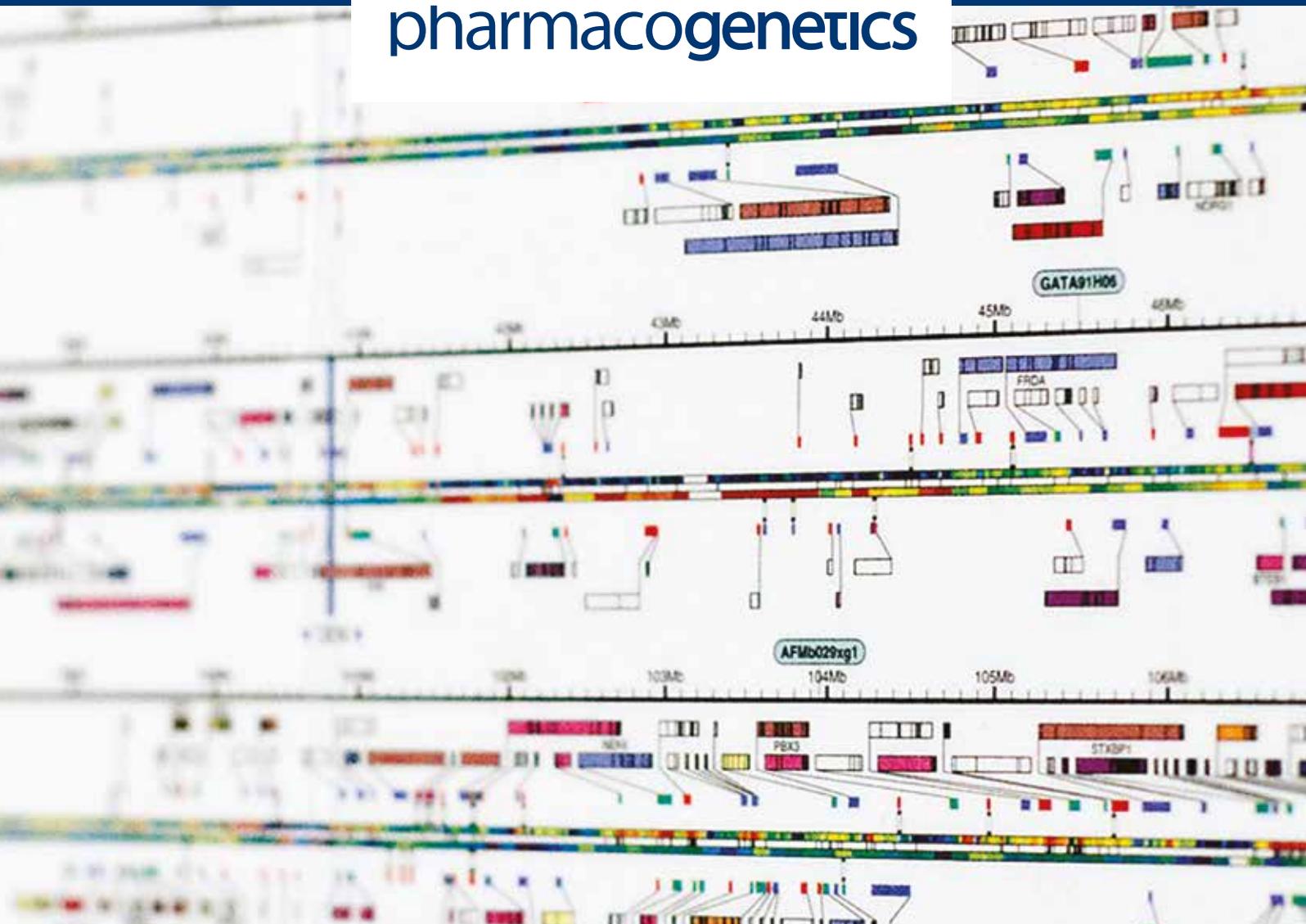


easy^{PGX}[®]

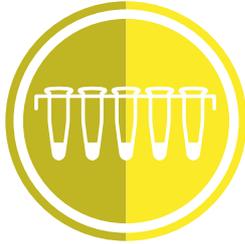
Ready to you**USE**

The qPCR solution in oncology

diatech
pharmacogenetics



easyPGX[®]



**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



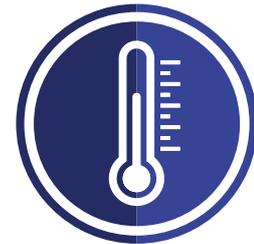
**FLEXIBLE
USE**

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_{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 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_{PGX} 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_{PGX} 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_{PGX} ready NRAS
cat. no. RT024 (48 test, CE IVD)

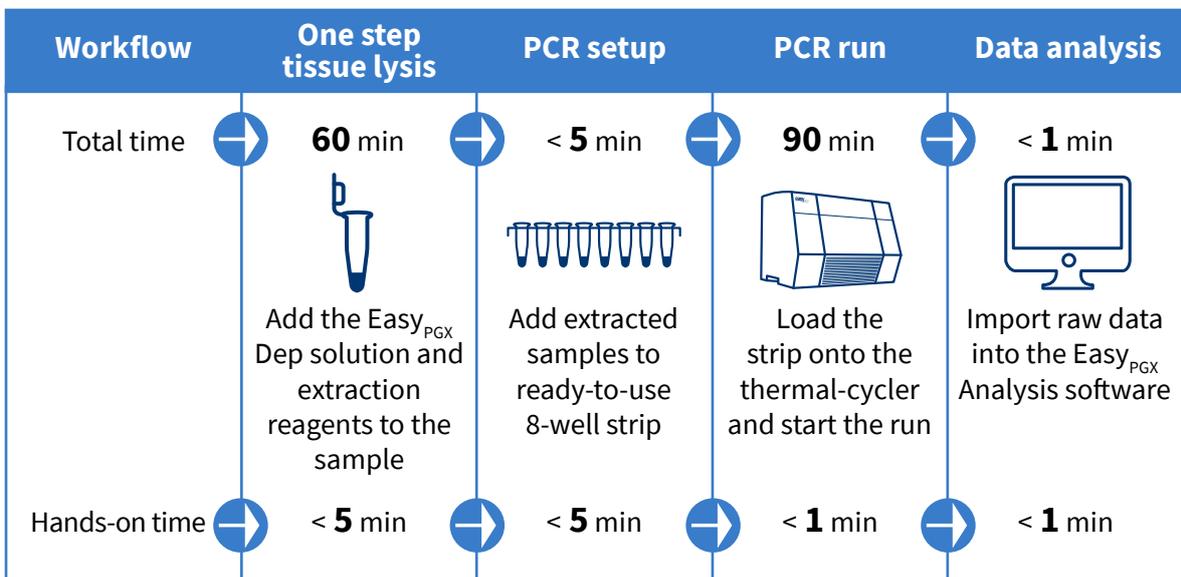
MAIN FEATURES

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 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_{PGX}[®] 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_{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), 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_{PGX}[®] 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_{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 (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_{PGX}[®] 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_{PGX}[®] 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_{PGX}[®] 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_{PGX}[®] 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_{PGX}[®] 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_{PGX}[®] 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_{PGX}[®] 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_{PGX}[®] 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.

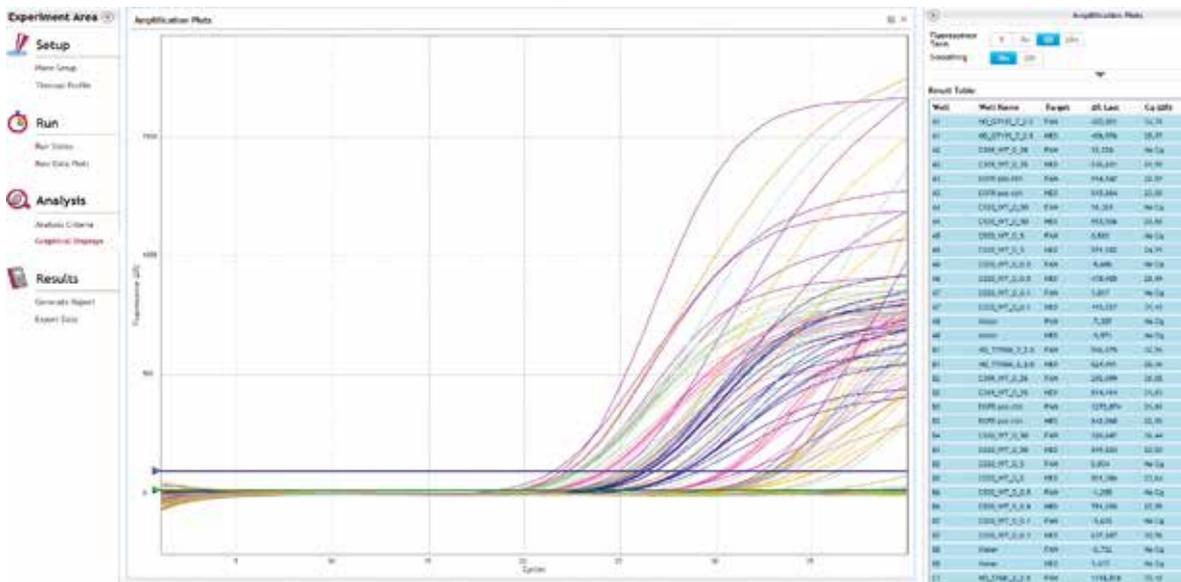
STARTING MATERIAL

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 86
- HT202_EasyPGX ready 8207

Import data and analysis

Select files:

Open: C:\Users\2017\My Documents\EGFR_101

[OK] [Cancel] [New]

Analysis of the reaction controls:

ML	Name	File	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23	Q24	Q25	Q26	Q27	Q28	Q29	Q30	Q31	Q32	Q33	Q34	Q35	Q36	Q37	Q38	Q39	Q40	Q41	Q42	Q43	Q44	Q45	Q46	Q47	Q48	Q49	Q50																																																																															
1	Positive	FAM	24.5	875	1.0	25.6	854	1.0	26.7	834	1.0	27.8	814	1.0	28.9	794	1.0	30.0	774	1.0	31.1	754	1.0	32.2	734	1.0	33.3	714	1.0	34.4	694	1.0	35.5	674	1.0	36.6	654	1.0	37.7	634	1.0	38.8	614	1.0	39.9	594	1.0	41.0	574	1.0	42.1	554	1.0	43.2	534	1.0	44.3	514	1.0	45.4	494	1.0	46.5	474	1.0	47.6	454	1.0	48.7	434	1.0	49.8	414	1.0	50.9	394	1.0																																																						
2	Negative	FAM	8	1000	1.0	9	1000	1.0	10	1000	1.0	11	1000	1.0	12	1000	1.0	13	1000	1.0	14	1000	1.0	15	1000	1.0	16	1000	1.0	17	1000	1.0	18	1000	1.0	19	1000	1.0	20	1000	1.0	21	1000	1.0	22	1000	1.0	23	1000	1.0	24	1000	1.0	25	1000	1.0	26	1000	1.0	27	1000	1.0	28	1000	1.0	29	1000	1.0	30	1000	1.0	31	1000	1.0	32	1000	1.0	33	1000	1.0	34	1000	1.0	35	1000	1.0	36	1000	1.0	37	1000	1.0	38	1000	1.0	39	1000	1.0	40	1000	1.0	41	1000	1.0	42	1000	1.0	43	1000	1.0	44	1000	1.0	45	1000	1.0	46	1000	1.0	47	1000	1.0	48	1000	1.0	49	1000	1.0	50	1000	1.0

Analysis of the sample control mix and mutation assay:

ML	Name	File	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23	Q24	Q25	Q26	Q27	Q28	Q29	Q30	Q31	Q32	Q33	Q34	Q35	Q36	Q37	Q38	Q39	Q40	Q41	Q42	Q43	Q44	Q45	Q46	Q47	Q48	Q49	Q50																																																																																																																						
1	EGFR_T790M_sample 1	KAM	18.2	245	1.0	17.8	250	1.0	17.4	255	1.0	17.0	260	1.0	16.6	265	1.0	16.2	270	1.0	15.8	275	1.0	15.4	280	1.0	15.0	285	1.0	14.6	290	1.0	14.2	295	1.0	13.8	300	1.0	13.4	305	1.0	13.0	310	1.0	12.6	315	1.0	12.2	320	1.0	11.8	325	1.0	11.4	330	1.0	11.0	335	1.0	10.6	340	1.0	10.2	345	1.0	9.8	350	1.0	9.4	355	1.0	9.0	360	1.0	8.6	365	1.0	8.2	370	1.0	7.8	375	1.0	7.4	380	1.0	7.0	385	1.0	6.6	390	1.0	6.2	395	1.0	5.8	400	1.0	5.4	405	1.0	5.0	410	1.0	4.6	415	1.0	4.2	420	1.0	3.8	425	1.0	3.4	430	1.0	3.0	435	1.0	2.6	440	1.0	2.2	445	1.0	1.8	450	1.0	1.4	455	1.0	1.0	460	1.0	0.6	465	1.0	0.2	470	1.0	0.0	475	1.0	0.0	480	1.0	0.0	485	1.0	0.0	490	1.0	0.0	495	1.0	0.0	500	1.0												
2	EGFR_T790M_sample 2	KAM	18.5	240	1.0	18.1	245	1.0	17.7	250	1.0	17.3	255	1.0	16.9	260	1.0	16.5	265	1.0	16.1	270	1.0	15.7	275	1.0	15.3	280	1.0	14.9	285	1.0	14.5	290	1.0	14.1	295	1.0	13.7	300	1.0	13.3	305	1.0	12.9	310	1.0	12.5	315	1.0	12.1	320	1.0	11.7	325	1.0	11.3	330	1.0	10.9	335	1.0	10.5	340	1.0	10.1	345	1.0	9.7	350	1.0	9.3	355	1.0	8.9	360	1.0	8.5	365	1.0	8.1	370	1.0	7.7	375	1.0	7.3	380	1.0	6.9	385	1.0	6.5	390	1.0	6.1	395	1.0	5.7	400	1.0	5.3	405	1.0	4.9	410	1.0	4.5	415	1.0	4.1	420	1.0	3.7	425	1.0	3.3	430	1.0	2.9	435	1.0	2.5	440	1.0	2.1	445	1.0	1.7	450	1.0	1.3	455	1.0	0.9	460	1.0	0.5	465	1.0	0.1	470	1.0	0.0	475	1.0	0.0	480	1.0	0.0	485	1.0	0.0	490	1.0	0.0	495	1.0	0.0	500	1.0									
3	EGFR_T790M_sample 3	KAM	18.8	235	1.0	18.4	240	1.0	18.0	245	1.0	17.6	250	1.0	17.2	255	1.0	16.8	260	1.0	16.4	265	1.0	16.0	270	1.0	15.6	275	1.0	15.2	280	1.0	14.8	285	1.0	14.4	290	1.0	14.0	295	1.0	13.6	300	1.0	13.2	305	1.0	12.8	310	1.0	12.4	315	1.0	12.0	320	1.0	11.6	325	1.0	11.2	330	1.0	10.8	335	1.0	10.4	340	1.0	10.0	345	1.0	9.6	350	1.0	9.2	355	1.0	8.8	360	1.0	8.4	365	1.0	8.0	370	1.0	7.6	375	1.0	7.2	380	1.0	6.8	385	1.0	6.4	390	1.0	6.0	395	1.0	5.6	400	1.0	5.2	405	1.0	4.8	410	1.0	4.4	415	1.0	4.0	420	1.0	3.6	425	1.0	3.2	430	1.0	2.8	435	1.0	2.4	440	1.0	2.0	445	1.0	1.6	450	1.0	1.2	455	1.0	0.8	460	1.0	0.4	465	1.0	0.0	470	1.0	0.0	475	1.0	0.0	480	1.0	0.0	485	1.0	0.0	490	1.0	0.0	495	1.0	0.0	500	1.0						
4	EGFR_T790M_sample 4	KAM	19.1	230	1.0	18.7	235	1.0	18.3	240	1.0	17.9	245	1.0	17.5	250	1.0	17.1	255	1.0	16.7	260	1.0	16.3	265	1.0	15.9	270	1.0	15.5	275	1.0	15.1	280	1.0	14.7	285	1.0	14.3	290	1.0	13.9	295	1.0	13.5	300	1.0	13.1	305	1.0	12.7	310	1.0	12.3	315	1.0	11.9	320	1.0	11.5	325	1.0	11.1	330	1.0	10.7	335	1.0	10.3	340	1.0	9.9	345	1.0	9.5	350	1.0	9.1	355	1.0	8.7	360	1.0	8.3	365	1.0	7.9	370	1.0	7.5	375	1.0	7.1	380	1.0	6.7	385	1.0	6.3	390	1.0	5.9	395	1.0	5.5	400	1.0	5.1	405	1.0	4.7	410	1.0	4.3	415	1.0	3.9	420	1.0	3.5	425	1.0	3.1	430	1.0	2.7	435	1.0	2.3	440	1.0	1.9	445	1.0	1.5	450	1.0	1.1	455	1.0	0.7	460	1.0	0.3	465	1.0	0.0	470	1.0	0.0	475	1.0	0.0	480	1.0	0.0	485	1.0	0.0	490	1.0	0.0	495	1.0	0.0	500	1.0			
5	EGFR_T790M_sample 5	KAM	19.4	225	1.0	19.0	230	1.0	18.6	235	1.0	18.2	240	1.0	17.8	245	1.0	17.4	250	1.0	17.0	255	1.0	16.6	260	1.0	16.2	265	1.0	15.8	270	1.0	15.4	275	1.0	15.0	280	1.0	14.6	285	1.0	14.2	290	1.0	13.8	295	1.0	13.4	300	1.0	13.0	305	1.0	12.6	310	1.0	12.2	315	1.0	11.8	320	1.0	11.4	325	1.0	11.0	330	1.0	10.6	335	1.0	10.2	340	1.0	9.8	345	1.0	9.4	350	1.0	9.0	355	1.0	8.6	360	1.0	8.2	365	1.0	7.8	370	1.0	7.4	375	1.0	7.0	380	1.0	6.6	385	1.0	6.2	390	1.0	5.8	395	1.0	5.4	400	1.0	5.0	405	1.0	4.6	410	1.0	4.2	415	1.0	3.8	420	1.0	3.4	425	1.0	3.0	430	1.0	2.6	435	1.0	2.2	440	1.0	1.8	445	1.0	1.4	450	1.0	1.0	455	1.0	0.6	460	1.0	0.2	465	1.0	0.0	470	1.0	0.0	475	1.0	0.0	480	1.0	0.0	485	1.0	0.0	490	1.0	0.0	495	1.0	0.0	500	1.0
6	EGFR_T790M_sample 6	KAM	19.7	220	1.0	19.3	225	1.0	18.9	230	1.0	18.5	235	1.0	18.1	240	1.0	17.7	245	1.0	17.3	250	1.0	16.9	255	1.0	16.5	260	1.0	16.1	265	1.0	15.7	270	1.0	15.3	275	1.0	14.9	280	1.0	14.5	285	1.0	14.1	290	1.0	13.7	295	1.0	13.3	300	1.0	12.9	305	1.0	12.5	310	1.0	12.1	315	1.0	11.7	320	1.0	11.3	325	1.0	10.9	330	1.0	10.5	335	1.0	10.1	340	1.0	9.7	345	1.0	9.3	350	1.0	8.9	355	1.0	8.5	360	1.0	8.1	365	1.0	7.7	370	1.0	7.3	375	1.0	6.9	380	1.0	6.5	385																																																																			

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 _{PGX} qPCR instrument 96	
RT800-SW 	Easy _{PGX} analysis software	
RT801 	Easy _{PGX} dry block	
RT802 	Easy _{PGX} centrifuge/vortex 1.5 ml	
RT803 	Easy _{PGX} centrifuge/vortex 8-well strips	

Kit ordering information

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

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