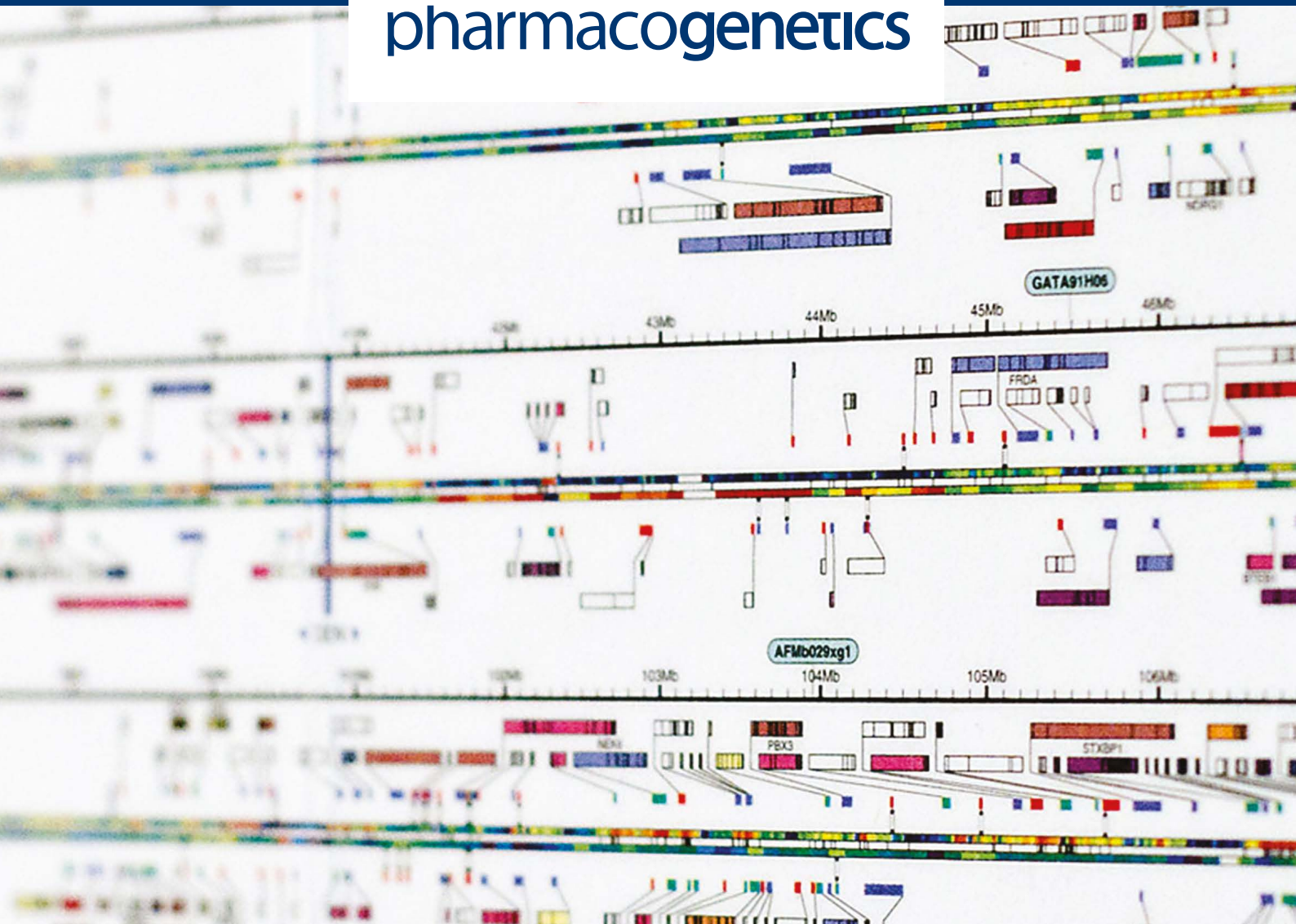
easyPGX®

Ready to youuse

diatech pharmacogenetics



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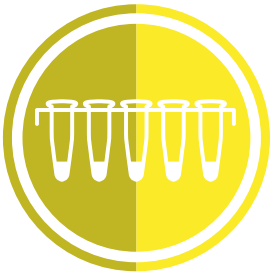


READY TO USE

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

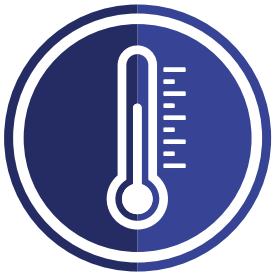
From tissue to result in less than 3 hours with only 10 minutes of hands-on time

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

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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.

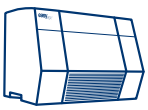
STARTING MATERIAL
DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma*.

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

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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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

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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.

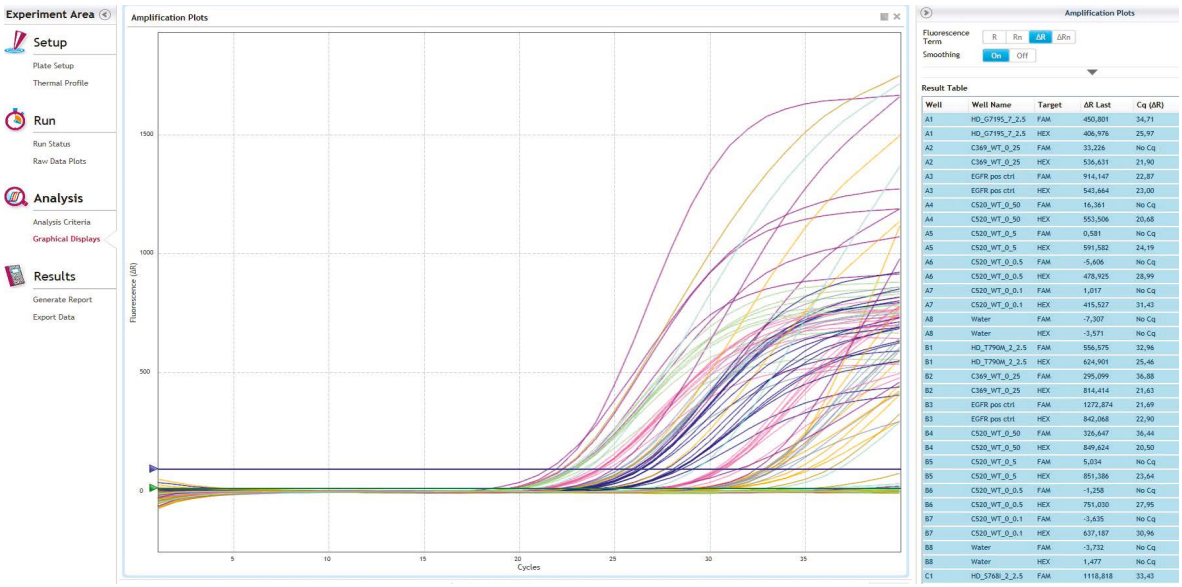
STARTING MATERIAL
DNA from fresh, frozen, formalin-fixed paraffin-embedded (FFPE) tissues and plasma*.

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.

Real time reaction monitoring



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

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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.

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.

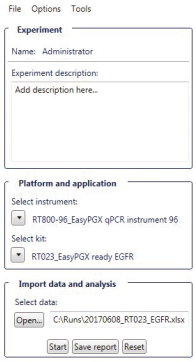
STARTING MATERIAL

1-5 ml of fresh or frozen plasma.

TURN AROUND TIME

3 hours.

Automatic data analysis software



Analysis of the reaction controls:

N.	Name	Dye	G719x Cq	G719x ΔR	G719x Result	T790M Cq	T790M ΔR	T790M Result	S768I Cq	S768I ΔR	S768I Result	ex20ins Cq	ex20ins ΔR	ex20ins Result	L858R Cq	L858R ΔR	L858R Result	L861Q Cq	L861Q ΔR	L861Q Result	ex19del Cq	ex19del ΔR	ex19del Result	CTRL Cq	CTRL ΔR	CTRL Result
1	Positive	FAM	24,4	673	OK	19,4	934	OK	20,2	2236	OK	21,8	1043	OK	20,6	2302	OK	21,0	830	OK	21,0	1520	OK	24,1	1142	OK
		HEX	24,8	495	OK	24,2	698	OK	23,4	1184	OK	23,9	584	OK	23,3	1542	OK	24,1	749	OK	23,4	1072	OK	24,7	527	OK
2	Negative	FAM		6	OK		2	OK		6	OK		46	OK		5	OK		-1	OK	34,2	305	OK		2	OK
		HEX		7	OK		4	OK		13	OK		9	OK		19	OK		11	OK		10	OK		3	OK

Analysis of the sample control mix and mutation assay:

N.	Name	Dye	G719x ΔCq	G719x ΔR	G719x Result	T790M ΔCq	T790M ΔR	T790M Result	S768I ΔCq	S768I ΔR	S768I Result	ex20ins ΔCq	ex20ins ΔR	ex20ins Result	L858R ΔCq	L858R ΔR	L858R Result	L861Q ΔCq	L861Q ΔR	L861Q Result	ex19del ΔCq	ex19del ΔR	ex19del Result	CTRL Cq	CTRL ΔR	CTRL Result
1	EGFR_FFPE_sample 1	FAM		4	WT		3	WT		10	WT		16	WT		3	WT		5	WT	3,1	314	WT	30,7	528	OK
		HEX	2,3	245	OK	1,7	393	OK	1,5	519	OK	1,2	308	OK	1,3	684	OK	1,5	551	OK	0,9	584	OK	30,4	288	OK
2	EGFR_FFPE_sample 2	FAM		4	WT		12	WT		2	WT		16	WT		9	WT	0,4	534	MUT	3,9	250	WT	30,4	882	OK
		HEX	-0,1	387	OK	-0,4	508	OK	-0,9	808	OK	-1,0	301	OK	-0,8	922	OK	-0,3	574	OK	-0,2	641	OK	31,3	379	OK
3	EGFR_FFPE_sample 3	FAM		5	WT	1,5	695	MUT		-3	WT		12	WT		9	WT		7	WT	-0,6	1528	MUT	27,9	1113	OK
		HEX	0,6	412	OK	-0,1	645	OK	-0,3	1060	OK	-0,6	453	OK	-1,0	1412	OK	-0,5	708	OK	-0,6	976	OK	28,0	545	OK
4	EGFR_FFPE_sample 4	FAM	3,5	525	MUT		7	WT	-0,2	2271	MUT		18	WT		9	WT		6	WT	6,3	225	WT	27,1	1220	OK
		HEX	0,6	487	OK	0,1	719	OK	-0,3	1223	OK	-0,3	586	OK	-0,6	1515	OK	-0,1	756	OK	-0,6	1104	OK	26,2	652	OK
5	EGFR_FFPE_sample 5	FAM		19	WT		2	WT		13	WT		16	WT		11	WT		6	WT	3,2	294	WT	30,3	861	OK
		HEX	0,1	418	OK	0,2	590	OK	-0,8	1150	OK	-0,7	375	OK	-1,0	1231	OK	-0,5	744	OK	0,0	809	OK	29,9	476	OK
6	EGFR_FFPE_sample 6	FAM		7	WT		2	WT		21	WT		16	WT		11	WT		2	WT	5,1	284	WT	28,9	1041	OK
		HEX	0,5	422	OK	-0,1	651	OK	-1,3	1205	OK	-0,9	500	OK	-0,2	1300	OK	-0,5	752	OK	-0,7	995	OK	28,8	548	OK
7	EGFR_FFPE_sample 7	FAM		9	WT		9	WT		13	WT		16	WT	2,3	970	MUT		8	WT	4,9	255	WT	28,9	886	OK
		HEX	-0,3	552	OK	-0,5	639	OK	-1,2	1094	OK	-0,9	484	OK	-1,3	1372	OK	-1,3	772	OK	-1,1	993	OK	28,9	445	OK
8	EGFR_FFPE_sample 8	FAM		4	WT		4	WT		13	WT		18	WT		14	WT		6	WT	-1,4	1375	MUT	30,1	927	OK
		HEX	0,4	434	OK	0,2	640	OK	-0,7	1104	OK	-0,2	373	OK	-0,8	1295	OK	-0,2	726	OK	-0,2	903	OK	29,3	540	OK
9	EGFR_FFPE_sample 9	FAM		13	WT		6	WT		15	WT		21	WT		29	WT		6	WT	0,0	1304	MUT	29,6	993	OK
		HEX	0,6	453	OK	0,3	620	OK	-0,9	586	OK	-0,1	394	OK	-0,9	1329	OK	0,0	735	OK	-0,4	936	OK	28,9	585	OK
10	EGFR_FFPE_sample10	FAM		4	WT		24	WT		17	WT		14	WT		11	WT		5	WT	4,2	290	WT	29,3	936	OK
		HEX	0,3	374	OK	0,1	573	OK	-1,2	1083	OK	-0,9	472	OK	-1,2	1363	OK	-0,7	677	OK	-1,0	987	OK	28,4	498	OK

Warnings

Code	Description
e01	Possible error in the set up of the reaction /run: it is not possible to analyze the samples (see Troubleshooting)
e02	Possible contamination: it is not possible to analyze the samples (see Troubleshooting)
e03	Suboptimal amount of starting DNA or PCR inhibition (see Troubleshooting)
e04	Excess of DNA. Sample must be diluted with water so that Cq falls in the range indicated (see Troubleshooting)
e05	Not sufficient template / PCR inhibition / mistake during samples dispensation (see Troubleshooting)
e06	Probable excess of DNA. Proceed with the analysis of the sample.

easyPGX 1.0.0

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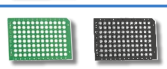
System ordering information

Catalog number	Product description	Picture
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 8-well strips	
RT803 CE IVD	Easy$_{PGX}$ centrifuge/vortex 1.5 ml	

Kit ordering information

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

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