

easyPGX[®]

The dry qPCR solution in Oncohaematology



diatech
pharmacogenetics



easy *PGX*[®]

**Democratising molecular
oncology to accelerate
precision medicine**



EasyPGX®: The dry qPCR revolution in Oncohaematology

EasyPGX® is the complete RT-qPCR in vitro diagnostic solution with the most comprehensive portfolio of assays for molecular oncology.

With its revolutionary ready-to-use, dry-format, pre-aliquoted, 8-well reaction strips, **EasyPGX®** is suited to use in any laboratory setting, assuring rapid, high-performance, standardised results with easy handling.



A comprehensive solution for diagnosis, prognosis and MRD monitoring

Code	Product description		
		Qualitative	Quantitative
RT031	EasyPGX® ready IDH1-2 (48 test)	•	-
RT038	EasyPGX® ready BCR-ABL Fusion (48 test)	•	-
RT039	EasyPGX® ready BCR-ABL p210 (48 test)	-	•
RT040	EasyPGX® ready BCR-ABL p190 (48 test)	-	•
RT042	EasyPGX® ready PML-RARA Fusion (48 test)	•	-
RT043	EasyPGX® ready AML1-ETO Fusion (48 test)	•	-
RT044	EasyPGX® ready CBFβ-MYH11 Fusion (48 test)	•	-
RT046	EasyPGX® ready WT1 Quant (48 test)	-	•
RTX047	EasyPGX® ready NPM1 Screening (48 test)	•	-
RTX048	EasyPGX® ready NPM1 Quant (48 test)	-	•

Join the precision oncology revolution with EasyPGX[®]

READY-TO-USE

Ready-to-use, dry reagents, pre-aliquoted in 8-well RT-PCR strips



EASY TO USE

Fewer pipetting steps needed for reaction set up with a total Hands-on Time <20 min. No need for freezing-thawing cycles or pipetting on ice



AUTOMATIC DATA ANALYSIS

Includes dedicated automated data analysis and interpretation software



FLEXIBLE

Runs multiple assays in one experiment



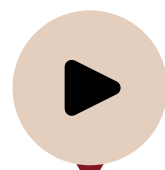
FAST

From nucleic acid to result with a TAT <3 hrs



FROM DNA/RNA TO RESULTS IN LESS THAN

TURNAROUND



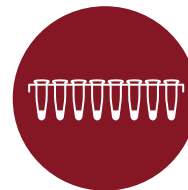
NUCLEIC ACID EXTRACTION



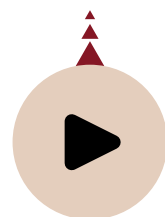
Use of DNA/RNA extraction solutions in line with EasyPGX[®] handbook recommendations

<15 min.

REACTION SET-UP



Add extracted samples to the ready-to-use 8-well strip



<15 min.

HANDS-ON TIME

IN 3 HOURS

TIME (TAT)

70/120*
min.

PCR RUN



Load the strip onto the thermal-cycler and start the run

<1
min.

DATA ANALYSIS



Import raw data into the EasyPGX® Analysis Software

<1
min.

(HOT)

<1
min.



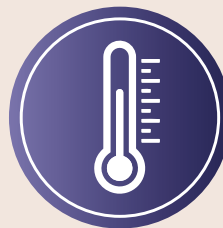
STANDARDS INCLUDED

Includes QC standards and quantification reference standards



INTERNAL QUALITY CONTROL

Endogenous internal control included in each single reaction for QC individual test QC



ROOM TEMPERATURE SHIPPING AND STORAGE

Complete master mix in a dry format that is stable at room temperature or +2/+8 °C



QUALITY ASSURANCE

Manufactured in compliance with ISO 13485



REGULATORY

Compliant with the current regulation (EU) 2017/746 [IVDR]

*PCR Run time can change depending on the EasyPGX® kit

Diagnosis and Prognosis Assays

EASYPGX READY BCR-ABL FUSION cod. RT038 (48 test)	
Fusions	18 BCR-ABL Qualitative detection of 18 BCR-ABL fusions and discrimination of e13a2, e1a2, e14a2, e13a3, e1a3, e14a3, e19a2, e19a3 variants, by one-step Real-Time RT-PCR
From	Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	Turnaround time from RNA to result in under 80 minutes

EASYPGX READY PML-RARA FUSION cod. RT042 (48 test)	
Fusions	PML-RARA bcr1, bcr3, bcr2 Qualitative detection and discrimination of PML-RARA bcr1, bcr3, bcr2 fusion variants, by one-step Real-Time RT-PCR
From	Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	Turnaround time from RNA to result in under 80 minutes



EASYPGX READY AML1-ETO FUSION cod. RT043 (48 test)	
Fusions	AML1-ETO t(8;21) Qualitative detection of AML1-ETO t(8;21) fusion, by one-step Real-Time RT-PCR
From	Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	Turnaround time from RNA to result in under 80 minutes



EASYPGX READY CBF-MYH11 cod. RT044 (48 test)	
Fusions	CBFB-MYH11 A, D and E Qualitative detection and discrimination of CBF-MYH11 A, D and E fusions caused by inv(16)/t(16;16), by one-step Real-Time RT-PCR
From	Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	Turnaround time from RNA to result in under 80 minutes



EASYPGX READY IDH1-2 cod. RT031 (48 test)	
Mutations	IDH1 105 - 132 IDH2 140 - 172 Qualitative detection of clinically relevant mutations of IDH1 gene codons 105 - 132 and IDH2 gene codons 140 - 172, by Real-Time PCR
From	Validated on DNA extracted from whole blood or bone marrow
TAT	Turnaround time from DNA to result in under 120 minutes



EASYPGX READY NPM1 SCREENING cod. RTX047 (48 test)	
Mutations	NPM1 A, B e D insertions Qualitative detection of NPM1 gene insertions and discrimination of NPM1 type A, B e D insertions, by Real-Time PCR
From	Validated on DNA extracted from whole blood or bone marrow
TAT	Turnaround time from DNA to result in under 120 minutes

MRD monitoring Assays

EASYPGX READY BCR-ABL p210 cod. RT039 (48 test)		
Fusions	BCR-ABL p210 e13a2 and e14a2	Quantitative detection of BCR-ABL fusion variants b2a2 (e13a2) and b3a2 (e14a2), encoding a 210 kDa chimeric protein, by one-step Real-Time RT-PCR
From		Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	 <90	Turnaround time from RNA to result in under 90 minutes

EASYPGX READY BCR-ABL p190 cod. RT040 (48 test)		
Fusions	BCR-ABL p190 e1a2	Quantitative detection of BCR-ABL fusion variant e1a2 encoding a 190 kDa chimeric protein, by one-step Real-Time RT-PCR
From		Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	 <90	Turnaround time from RNA to result in under 90 minutes

EASYPGX READY WT1 QUANT cod. RT046 (48 test)		
Target	WT1 GENE EXPRESSION	Quantitative detection of Wilms tumour1 (WT1) gene transcript, by one-step Real-Time RT-PCR
From		Validated on RNA extracted from bone marrow, peripheral blood and leukocyte suspensions (buffy coat)
TAT	 <90	Turnaround time from RNA to result in under 90 minutes

EASYPGX READY NPM1 QUANT cod. RTX048 (48 test)		
Target	NPM1 A, B, D	Quantitative detection of NPM1 Type A,B,D mutant transcripts, by two-steps Real-Time RT-PCR
From		Validated on RNA extracted from whole blood or bone marrow
TAT	 <180	Turnaround time from RNA to result in under 180 minutes



EasyPGX® Analysis Software: streamline your data analysis process

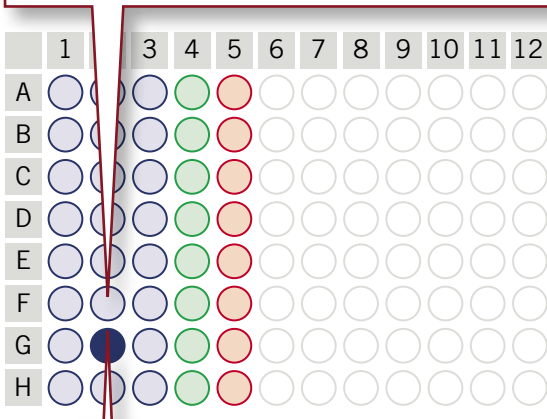
EasyPGX® Analysis Software is the dedicated automated data analysis solution for use with EasyPGX® ready-to-use kits.

- Complies with Regulation (EU) 2017 / 746 [IVDR].
- Complete automated data analysis with a turnaround time of under 5 minutes.
- No cloud or external data sharing required.
- Fully automated data analysis interpretation and raw data checking in a single software solution.
- Automated run and sample QC.
- Automatic calculation of results expressed in international units of measurement as per reference guidelines.
- Data export and reporting in various common file formats.

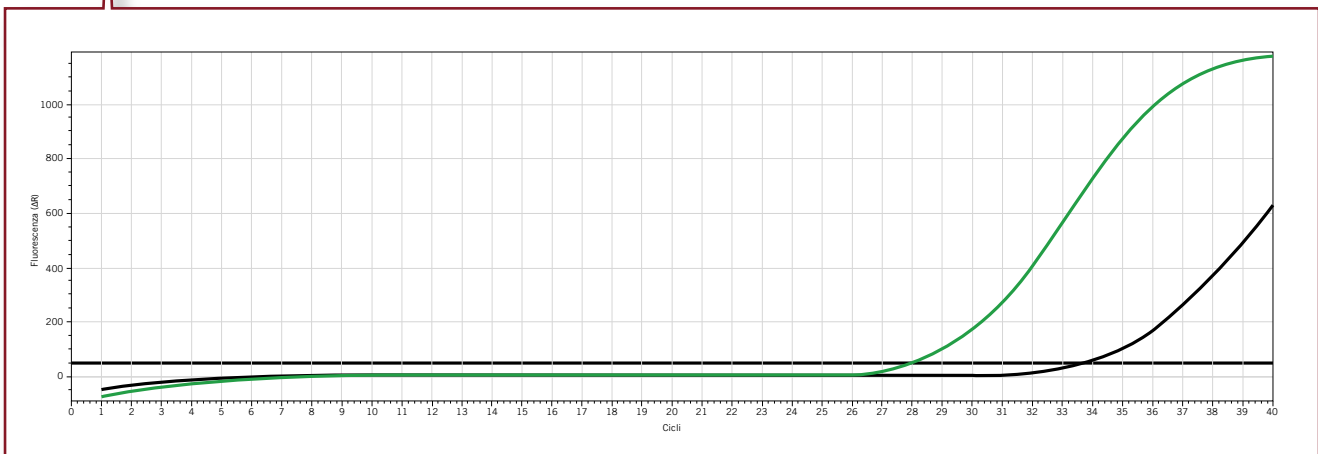
Standard Analysis			
No	Reaction	Kit	Result
1	Control	EasyPGX	OK
2	Sample	EasyPGX	OK
3	Reference	EasyPGX	OK

Reaction Controls Analysis							
No	Name	Kit	Type	Mean±SD	CV	Acceptance	Result
1	Control	EasyPGX	Internal	1000000	10%	Pass	OK
2	Reference	EasyPGX	External	1000000	10%	Pass	OK
3	Sample	EasyPGX	Internal	1000000	10%	Pass	OK

Samples Analysis								
No	Name	Kit	Type	Quantity (copies/mL)	Threshold Quantity (copies/mL)	95% CI (copies/mL)	Median Response	Result
1	Sample	EasyPGX	Internal	1000000	1000000	1000000	1000000	OK
2	Reference	EasyPGX	External	1000000	1000000	1000000	1000000	OK
3	Control	EasyPGX	Internal	1000000	1000000	1000000	1000000	OK



Automated variant calling and raw data checking in a single software solution.



System information

Product description

EasyPGX® qPCR instrument 96



EasyPGX® analysis software



Accessories

EasyPGX® centrifuge/vortex 1.5 ml



EasyPGX® centrifuge/vortex 8-well strips



EasyPGX[®], the most extensive IVD-compliant range of solid and blood cancer biomarkers

			Non-Small Cell Lung Cancer	Breast Cancer	Colorectal Cancer	Thyroid Cancer
Solid tumor 	RT021	EasyPGX [®] ready KRAS	•		•	•
	RT022	EasyPGX [®] ready BRAF	•		•	•
	RT023	EasyPGX [®] ready EGFR	•			
	RT024	EasyPGX [®] ready NRAS			•	•
	RT025	EasyPGX [®] ready ALK ROS1 RET MET	•			•
	RT026	EasyPGX [®] ready DPYD		•	•	
	RT027	EasyPGX [®] ready UGT1A1	•	•	•	
	RT028	EasyPGX [®] ready Thyroid				•
	RT030	EasyPGX [®] ready EGFR PLUS	•			
	RT031	EasyPGX [®] ready IDH1-2				
	RT032	EasyPGX [®] ready Thyroid Fusion				•
	RT033	EasyPGX [®] ready MSI			•	
	RT034	EasyPGX [®] ready HPV				
	RT035	EasyPGX [®] ready NTRK Fusion				
	RT036	EasyPGX [®] ready PIK3CA		•	•	
	RTX049	EasyPGX [®] ready MGMT				
	RTX050	EasyPGX [®] ready FGFR				
	RTX051	EasyPGX [®] ready ESR1		•		
RTX052	EasyPGX [®] ready MLH1			•		
Blood cancer 	RT031	EasyPGX [®] ready IDH1-2				
	RT038	EasyPGX [®] ready BCR-ABL Fusion				
	RT039	EasyPGX [®] ready BCR-ABL p210				
	RT040	EasyPGX [®] ready BCR-ABL p190				
	RT042	EasyPGX [®] ready PML-RARA Fusion				
	RT043	EasyPGX [®] ready AML1-ETO Fusion				
	RT044	EasyPGX [®] ready CBFβ-MYH11 Fusion				
	RT046	EasyPGX [®] ready WT1 Quant				
	RTX047	EasyPGX [®] ready NPM1 Screening				
	RTX048	EasyPGX [®] ready NPM1 Quant				

For information please contact:

diatech pharmacogenetics

Diatech Pharmacogenetics srl

Via Ignazio Silone 1b - 60035 Jesi (An) Italy

Phone +39 0731 213 243

export@diatechpgx.com

www.diatechpharmacogenetics.com

Follow us on LinkedIn 

For in vitro diagnostic use in compliance with the current version of Regulation (EU) 2017/746 (IVDR). EasyPGX® solution is available for sale in the EU and many other countries. Please check availability and regulatory status with your local Diatech Pharmacogenetics representative.

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