

easyPGX[®]

Ready to yo**use**

The qPCR solution in Oncohematology

diatech
pharmacogenetics



easy*PGX*[®]



EasyPGX® Ready is the best in class RT-PCR diagnostic solution for oncohematology with a fast and simple workflow based on dry and ready to use reagent format.



EasyPGX® main features:

 READY TO USE Dry and ready to use reagents format pre aliquoted in 8 wells RT PCR strip	 EASY TO USE Less pipettings steps needed for reaction setup with a total HoT < 10 min	 FAST Turn around time <90 min	 FLEXIBLE Possibility to test more than 1 assay for each single run	 AUTOMATIC DATA ANALYSIS Dedicated software for automatic data analysis and interpretation included
 STANDARDS INCLUDED QC standard and quantification reference standards included	 INTERNAL QUALITY CONTROL Endogenous internal control included in each single reaction for QC of each test	 REGULATORY Kits have been designed, developed and validated in accordance with the Directive 98/79/EC on in vitro diagnostic medical devices	 TRANSPORT AND STORAGE AT ROOM TEMPERATURE Complete master mix in a dry format, stable at room temperature	 QUALITY ASSURANCE Manufactured under ISO 13485

One single solution for diagnosis, prognosis and MRD monitoring

Code	Product description	 Qualitative	 Quantitative
RT031	Easy _{PGX} ® ready IDH1-2 (48 test)	•	-
RT038	Easy _{PGX} ® ready BCR-ABL Fusion (48 test)	•	-
RT039	Easy _{PGX} ® ready BCR-ABL p210 (48 test)	-	•
RT040	Easy _{PGX} ® ready BCR-ABL p190 (48 test)	-	•
RT042	Easy _{PGX} ® ready PML-RARA Fusion (48 test)	•	-
RT043	Easy _{PGX} ® ready AML1-ETO Fusion (48 test)	•	-
RT044	Easy _{PGX} ® ready CBFB-MYH11 Fusion (48 test)	•	-
RT046	Easy _{PGX} ® ready WT1 Quant (48 test)	-	•
RT047	Easy _{PGX} ® ready NPM1 Screening (48 test)	•	-
RT048	Easy _{PGX} ® ready NPM1 Quant (48 test)	-	•

COMING
SOON

EasyPGX[®] ready: a complete portfolio for rapid diagnosis and prognosis



- One step Real-Time PCR
- Validated for RNA extracted from whole blood, bone marrow and buffy coat
- TAT from RNA to result < 80 min
- Hands on Time < 10 min
- Same thermal profile for all different RNA kits
- Qualitative detection and discrimination of principal fusion variants in one single run

EasyPGX[®] ready BCR-ABL Fusion

Qualitative detection and discrimination of principal BCR/ABL fusion variants.*



EasyPGX[®] ready AML1-ETO Fusion

Qualitative detection of AML1-ETO t(8;21) fusion.

EasyPGX[®] ready PML-RARA Fusion

Qualitative detection and discrimination of principal PML/RARA/ABL fusion variants.**

EasyPGX[®] ready CBFB-MYH11 Fusion

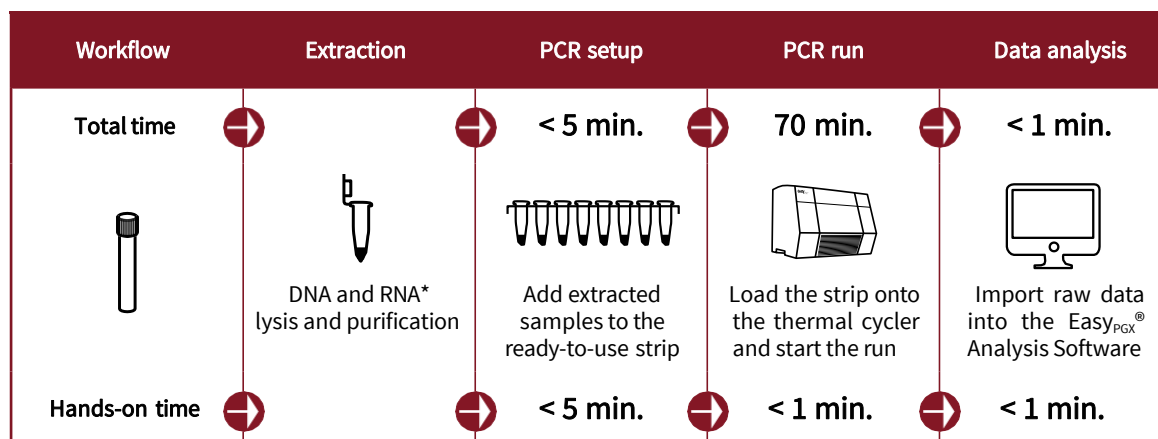
Qualitative detection and discrimination of CBFB-MYH11 A, D and E fusions caused by inv(16)/t(16;16).**

Qualitative detection and discrimination of principal fusion variants in one single run

*EasyPGX [®] ready BCR-ABL Fusion				
Assay	Fluorescence channels			
	Cy5	FAM	ROX	HEX
Well 1	all variants	-	-	ABL
Well 2	e13a2 (b2a2)	e1a2	e14a2 (b3a2)	ABL
Well 3	e13a3 (b2a3)	e1a3	e14a3 (b3a3)	ABL
Well 4	e19a2	e19a3	-	ABL

**EasyPGX [®] ready PML-RARA Fusion Easy PGX [®] ready CBFB-MYH11				
Assay	Fluorescence channels			
	FAM	ROX	Cy5	HEX
CBFB-MYH11 mix	CBFB-MYH11 type A	CBFB-MYH11 type D	CBFB-MYH11 type E	internal control
PML-RARA mix	bcr3	bcr1	bcr1-2-3	internal control

Workflow



*Use extraction solutions compatible with those described in the user manual.

EasyPGX® ready: a complete portfolio for rapid diagnosis and prognosis

EasyPGX® ready IDH1-2 (code RT031 – 48 test, CE IVD) is a validated kit for in vitro diagnostic use for the qualitative detection by Real-Time PCR of the principal IDH1/2 mutations in genomic DNA isolated from blood, bone marrow or tumor tissue (FFPE).



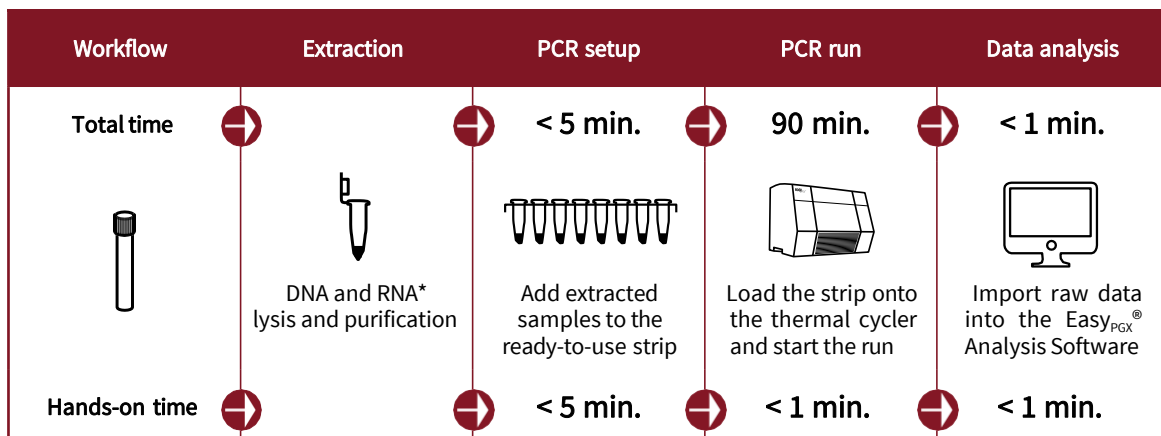
- Sensitivity up to 1% AF
- From DNA to result in less than 2 hours with an hands-on time of less than 10 minutes
- Dry reagents, ready-to-use in pre-loaded strips
- Rapid DNA-extraction for FFPE-samples included
- Automatic data analysis with dedicated software
- CE IVD

EasyPGX® ready IDH1-2	
Codon	Detected mutation
105	G105G
132	R132H, R132C, R132S*, R132G*, R132L*, R132I*, R132V*
140	R140G*, R140W*, R140Q*, R140L*
172	R172K, R172G*, R172W*, R172T*, R172M*, R172S (c. 516G>C)*, R172S (c. 516G>T)*

*Not distinguishable mutations



Workflow



*Use extraction solutions compatible with those described in the user manual.

EasyPGX® ready: a complete portfolio for MRD monitoring

EasyPGX® ready BCR-ABL p210 (code RT039- 48 test CE-IVD)

Kit for quantification — by One Step Real-Time RT-PCR — of BCR-ABL fusion variants b2a2 (e13a2) and b3a2 (e14a2), encoding a 210 kDa chimeric protein, in total RNA isolated from peripheral blood or bone marrow.

EasyPGX® ready BCR-ABL p190 (code RT040- 48 test CE-IVD)

Kit for quantification — by One Step Real-Time RT-PCR — of BCR-ABL fusion variant e1a2 encoding a 190 kDa chimeric protein, in total RNA isolated from peripheral blood or bone marrow.



Kits include:

- 5 quantification standards (105 -101 copies/rxn) calibrated with IRMM ERM-AD623 BCR-ABL1.
- p210 RNA reference standard for results alignments to international scale (%IS)

Maximum sensitivity:

- International scale (%IS) BCR-ABL p210: 0.0015%
- BCR-ABL p190: 0.001%

Flexibility:

- Same thermal profile for all EasyPGX qualitative and quantitative RNA kits
- Up to 41 clinical samples for each single run

Automatic data analysis:

- Dedicated software solution with automatic calculation of molecular response (MR) and international scale (%IS).



EasyPGX® Real-Time PCR System



- RT-PCR instrument with 96 wells peltier block
- Up to 6 LED optical channels
- Integrated touch screen
- Automatic data analysis and interpretation software
- System complete of all accessory instrumentation needed for EasyPGX ready workflow
- CE-IVD



EasyPGX® Analysis Software: automatic data analysis solution

EasyPGX® Analysis Software is the automatic data analysis software dedicated to the use with EasyPGX ready kits.



- CE- IVD
- Complete automated data analysis with a turnaround time < 5 min
- No cloud or external data analysis solution
- Totally automatic data analysis interpretation with the possibility to check raw data in one single software
- Run and sample automatic QC
- Automatic calculation of molecular response (MR) and International Scale (%IS)
- LIMS connectivity
- Data export and report on different common formats

Control Mix and Mutation Assay Analysis Report

N.	Name	Dye	BCR-ABL mix 1	BCR-ABL mix 2	BCR-ABL mix 3	BCR-ABL mix 4	Interpretation
			Result	Result	Result	Result	
1	92801	FAM	-	Neg	Neg	Neg	p210 e13a2 (b2a2)
		ROX	-	Neg	Neg	-	
		CY5	Pos	Pos	Neg	Neg	
2	92787	FAM	-	Pos	Neg	Neg	p190 e1a2
		ROX	-	Neg	Neg	-	
		CY5	Pos	Neg	Neg	Neg	
3	92721	FAM	-	Neg	Neg	Neg	p210 e14a2 (b3a2)
		ROX	-	Pos	Neg	-	
		CY5	Pos	Neg	Neg	Neg	
4	92692	FAM	-	Neg	Neg	Neg	p210 e13a2 (b2a2)
		ROX	-	Neg	Neg	-	
		CY5	Pos	Pos	Neg	Neg	

From Molecular Biology to Personalized Medicine

“The right drug, for the right patient, at the right time”: this summarizes Diatech Pharmacogenetics mission; to always create innovative diagnostic solutions and advance the world of pharmacogenetics and precision medicine for better patient outcome.

Diatech Pharmacogenetics Milestones



450

In more than 40 countries worldwide
A decentralized testing approach to improve patients access to personalised medicine.



**More than
one million
tests
performed
per year**

Worldwide with Diatech molecular testing solutions

EGFR 36.000+ / year
KRAS 38.000+ / year
BRAF 37.000+ / year
NRAS 31.000+ / year
PIK3CA 15.000+ / year



25 years

Experience in molecular biology with a specific focus on IVD development, production and commercialization.



80

CE-IVD products

One of the largest IVD portfolio with a main focus on precision medicine.



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