easyPGX®

The dry qPCR revolution against cancer

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easyPGX®
Democratising
molecular oncology
to accelerate
personalised therapy

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EasyPGX®: the dry qPCR revolution against cancer

Improve your diagnostic routine to accelerate personalized medicine in oncology

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.

Comprehensive clinical solution: a comprehensive portfolio focusing on clinically-relevant oncological biomarkers.

Results from any sample: best-in-class performance with low quality, low quantity samples.

Developed for diagnostic routines: high accuracy and standardisation for safe results.

Democratising precision oncology: simple and standardised workflow suited to any lab.

The right treatment at the right time: from sample to results in under 3 hours.

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Focus on what really matters to patients

The number of biomarkers used in oncology grows constantly, generating a mass of complex information regarding the genetic make-up of each cancer patient. Focusing on providing timely, clinically-relevant biomarkers results is crucial to supporting physicians in the clinical decision-making process, allowing them to identify and initiate the best treatment for each patient as soon as possible.

ESCAT Tier I molecular biomarkers

Non-Small Cell Lung Cancer[1,2] (NSCLC)
EGFR ex19del, L858R
EGFR T790M
Uncommon EGFR mutations
BRAF V600E
ALK fusions and mutations
ROS1 fusions and mutations
RET fusions
MET ex14 skipping mutations
NTRK fusions
KRAS G12C
EGFR exon 20 insertions

Breast Cancer[1] (BC)
ERBB2 amplifications
BRCA1/2 germline mutations
PIK3CA mutations
MSI-H
NTRK fusions

Colorectal Cancer[1] (CRC)
BRAF V600E
MSI-H
NTRK fusions

Prostate Cancer[1] (PC)
BRCA1/2 somatic mutations
MSI-H

Gastric Cancer[1] (GC)
ERBB2 amplifications
MSI-H
NTRK fusions

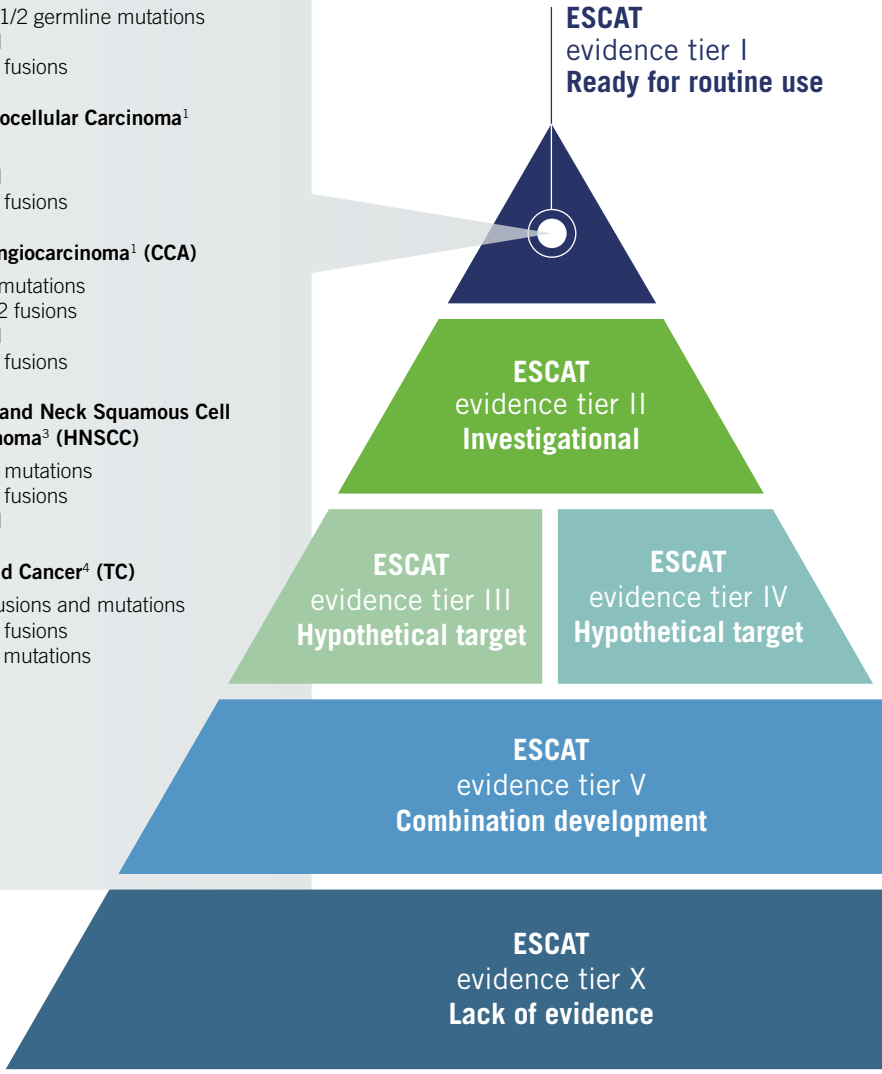
Pancreatic Ductal Adenocarcinoma[1] (PDAC)
BRCA1/2 germline mutations
MSI-H
NTRK fusions

Hepatocellular Carcinoma[1] (HCC)
MSI-H
NTRK fusions

Cholangiocarcinoma[1] (CCA)
IDH1 mutations
FGFR2 fusions
MSI-H
NTRK fusions

Head and Neck Squamous Cell Carcinoma[3] (HNSCC)
HRAS mutations
NTRK fusions
MSI-H

Thyroid Cancer[4] (TC)
RET fusions and mutations
NTRK fusions
BRAF mutations



[1]Mosele F et al. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group. Ann Oncol. 2020 Nov;31(11):1491-1505.

[2]Hendriks LE et al. Oncogene-addicted metastatic non-small-cell lung cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol 2023 (in press).

[3]Marret G et al. Genomic Alterations in Head and Neck Squamous Cell Carcinoma: Level of Evidence According to ESMO Scale for Clinical Actionability of Molecular Targets (ESCAT). JCO Precis Oncol. 2021 Nov;5:215-226.

[4]Filetti S et al. ESMO Clinical Practice Guideline update on the use of systemic therapy in advanced thyroid cancer. Ann Oncol. 2022 Jul;33(7):674-684.

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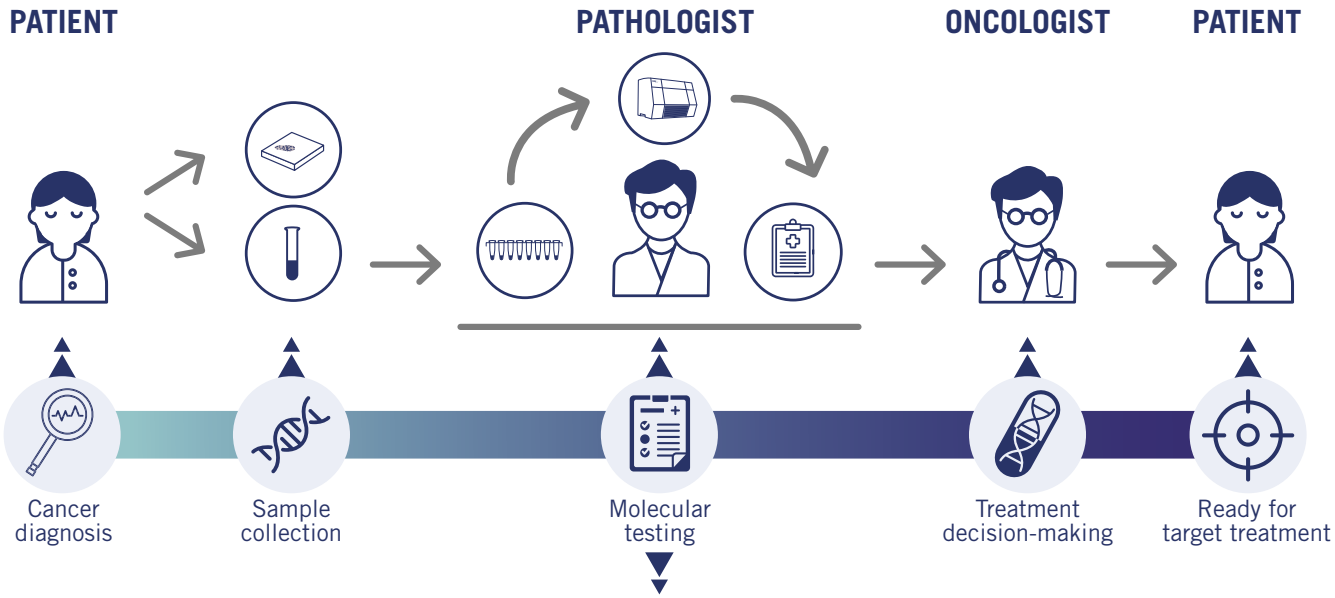
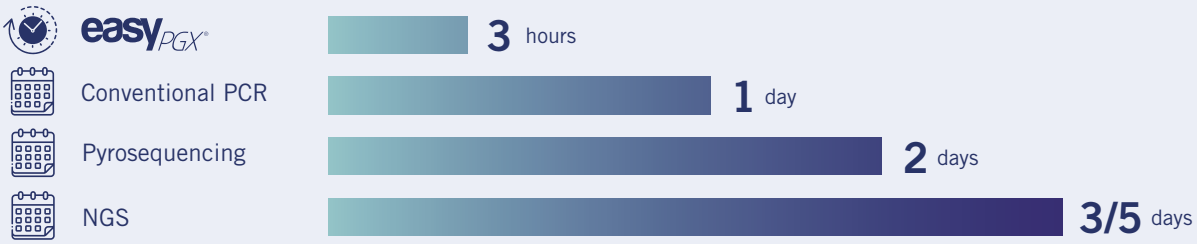
EasyPGX®, the RT-PCR system developed with patients in mind

With a sample-to-result time of under 3 hours, **EasyPGX®** is the best in class RT-PCR solution for accelerating patient care, helping oncologists everywhere make rapid treatment decisions.



Turnaround Time



The **EasyPGX®** assay portfolio focuses on the main clinically-relevant routine biomarkers for the most common solid tumours in accordance with the ESMO scale for clinical actionability of molecular targets (ESCAT) Tier I and main international guidelines.

Colorectal Cancer	Non-Small Cell Lung Cancer	Thyroid Cancer	Cutaneous Melanoma	Hepatocel-lular Carcinoma	Cholangio-carcinoma	Breast Cancer	Cervical Cancer	Glioma	Head and Neck Cancer
Clinical biomarkers included in EasyPGX® assay portfolio									
KRAS, BRAF, NRAS, DPYD, UGT1A1, MSI, NTRK, PIK3CA	KRAS, BRAF, ALK, ROS1, RET, MET, NTRK, EGFR, MSI	HRAS, KRAS, BRAF, NRAS, RET, NTRK, MSI, PPARG, ALK	BRAF, NTRK, MSI	MSI, NTRK	IDH1-2, MSI, NTRK, DPYD	DPYD, UGT1A1-2, MSI, NTRK, PIK3CA	HPV, MSI, NTRK	IDH1-2, NTRK, MSI, MGMT	MSI, DPYD, HPV, NTRK, HRAS

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Join the personalized oncology revolution with EasyPGX® System

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 HoT <10 min. No need for freezing-thawing cycles or pipetting on ice.

HIGH SENSITIVITY
Limit of detection as low as 0.5%.

FLEXIBLE SAMPLE REQUIREMENTS
Validated for low quantity and low quality DNA, ct DNA and RNA from different input materials such as FFPE and liquid biopsies.

FAST
From sample to result in under 3 hours.

FASTER TREATMENT DECISIONS: FROM

TURNAROUND TIME (TAT)

60 min. — <5 min.

ONE-STEP TISSUE LYSIS

Rapid FFPE DNA extraction reagents included

<5 min.

HANDS-ON TIME (HOT)

PCR SETUP

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

<5 min.

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TISSUE TO RESULT IN UNDER 3 HOURS

90 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.

<1 min.

FLEXIBLE

Runs multiple targets in one experiment.

AUTOMATIC DATA ANALYSIS

Includes dedicated automated data analysis and interpretation software.

ROOM TEMPERATURE SHIPPING AND STORAGE

Complete master mix in a dry format that is stable at room temperature.

STANDARDS INCLUDED

Includes positive and negative controls for the validation of each session.

REGULATORY

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

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EasyPGX®: the most comprehensive qPCR IVD biomarker portfolio for precision oncology

EASYPGX® READY KRAS cat. no. RT021 (48 test)	
Mutation **22** Codons **12, 13, 59, 61, 117, 146**	Detection of the most common mutations in exon 2 (codons 12, 13), exon 3 (codons 59, 61) and 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.
Cancer Types 	Colorectal Cancer, NSCLC, Thyroid Cancer.
Starting Material 	DNA from formalin-fixed paraffin-embedded (FFPE) tissues and plasma.

EASYPGX® READY BRAF cat. no. RT022 (48 test)	
Mutation **5** Codons **600**	Detection of the most common mutations in codon 600 of the BRAF gene. Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.
Cancer Types 	Colorectal Cancer, NSCLC, Melanoma, Thyroid Cancer.
Starting Material 	DNA from formalin-fixed paraffin-embedded (FFPE) tissues and plasma.

EASYPGX® READY EGFR cat. no. RT023 (48 test)	
Mutation **86** Exons **18, 19, 20, 21**	Detection of the most common mutations in 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.
Cancer Types 	NSCLC.
Starting Material 	DNA from formalin-fixed paraffin-embedded (FFPE) tissues and plasma.

EASYPGX® NRAS cat. no. RT024 (48 test)	
Mutation **20** Codons **12, 13, 59, 61, 117, 146**	Detection of the most common mutations in exon 2 (codons 12, 13), exon 3 (codons 59, 61) and 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.
Cancer Types 	Colorectal Cancer, Thyroid Cancer.
Starting Material 	DNA from formalin-fixed paraffin-embedded (FFPE) tissues and plasma.

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EASYPGX® READY ALK, ROS1, RET MET cat. no. RT025 (48 test)

Fusions	**23** **ALK, ROS1, RET & MET exon 14 skipping**	Detection of the most common chromosomal translocations involving ALK, ROS1, RET and MET exon 14 skipping, and ALK gene 5'/3' portion expression imbalances. Each mix allows the co-amplification of one or more fusions plus an endogenous control gene.
Cancer Types		NSCLC, Thyroid Cancer.
Starting Material		RNA from formalin-fixed paraffin-embedded (FFPE) tissues and cytological samples.

EASYPGX® READY DPYD cat. no. RT026 (48 test)

Polymorphisms	**5** **DPYD*2A, DPYD*13, DPYD D949V, DPYD IVS10, DPYD*6**	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), DPYD*6 (V732I, c. 2194G>A) associated with fluoropyrimidine-induced toxicity. Each mix allows the co-amplification of the mutant sequence as well as the wild-type sequence.
Assay Type		Drug induced toxicity genotyping assay.
Starting Material		DNA from whole blood.

EASYPGX® READY UGT1A1 cat. no. RT027 (48 test)

Polymorphisms	**5** **UGT1A1*1, UGT1A1*6, UGT1A1*28, UGT1A1*36, UGT1A1*37**	Detection, by allelic discrimination, of the UGT1A1 gene polymorphisms UGT1A1*36 (TA)5, UGT1A1*1 (TA)6, UGT1A1*6 (c. 211G > A), UGT1A1*28 (TA)7 and UGT1A1*37 (TA)8 associated with irinotecan-induced toxicity. Each mix allows the co-amplification of the mutant sequence as well as the wild-type sequence.
Assay Type		Drug induced toxicity genotyping assay.
Starting Material		DNA from whole blood.

EASYPGX® READY THYROID cat. no. RT028 (48 test)

Mutation Codons	**37** **RAS 12, 13, 61** **BRAF 600, 601**	Detection of the most common mutations in exon 2 (codons 12,13) and exon 3 (codon 61) of the KRAS, NRAS, HRAS genes and 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.
Cancer Types		Thyroid Cancer.
Starting Material		DNA from formalin-fixed paraffin-embedded (FFPE) tissues and cytological samples.

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EASYPGX® READY EGFR PLUS cat. no. RT030 (48 test)

Mutation	3	Detection of T790M and C797S (c.2389 T>A, c.2390 G>C) mutations of the EGFR gene. Each mix allows the co-amplification of one or more mutated alleles plus an endogenous control gene.
Codons	797, 790	
Cancer Types		NSCLC.
Starting Material	 	DNA from formalin-fixed paraffin-embedded (FFPE) tissues and plasma.

EASYPGX® READY IDH1-2 cat. no. RT031 (48 test)

Mutation	19	Detection of the most common mutations of the 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.
Codons	105, 132, 140, 172	
Cancer Types	 	Glioma, Cholangiocarcinoma.
Starting Material	 	DNA from formalin-fixed paraffin-embedded (FFPE) tissues, peripheral whole blood and bone marrow.

EASYPGX® READY THYROID FUSION cat. no. RT032 (48 test)

Fusions	7 RET, PPARG	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.
Cancer Types		Thyroid Cancer.
Starting Material		RNA from formalin-fixed paraffin-embedded (FFPE) tissues and cytology samples.

EASYPGX® READY MSI cat. no. RT033 (48 test)

MSI biomarkers	8 BAT-25, BAT-26, NR-21, NR-22, NR-24, NR-27, CAT-25, MONO-27	Detection of 8 “quasi-monomorphic” mononucleotide markers: BAT- 25, BAT-26, NR-21, NR-22, NR-24, NR-27, CAT-25 and MONO-27 by RT-PCR and subsequent analysis of the targets based on the denaturation profile. The test allows fast and accurate detection of microsatellite instability in tumour samples.
Cancer Types		Agnostic biomarker.
Starting Material		DNA from formalin-fixed paraffin-embedded (FFPE) tissue. Comparison with normal tissue or blood is not required for result analysis.

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EASYPGX® READY HPV cat. no. RT034 (48 test)

Genotypes	**14** **16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68**	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.
Cancer Types		Cervical Cancer, Head and Neck Cancer.
Starting Material		DNA from cervical swabs and formalin-fixed paraffin-embedded (FFPE) tissue.

EASYPGX® READY NTRK FUSION cat. no. RT035 (48 test)

Fusions	**32** **NTRK1, NTRK2, NTRK3**	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.
Cancer Types		Agnostic biomarker.
Starting Material		RNA from formalin-fixed paraffin-embedded (FFPE) tissues and cytology samples.

EASYPGX® READY PIK3CA cat. no. RT036 (48 test)

Mutation Codons	**24** **345, 420, 542, 545, 546, 1047, 1049**	Detection of the most common mutations in codon 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.
Cancer Types		Colorectal Cancer, Breast Cancer.
Starting Material		DNA from formalin-fixed paraffin-embedded (FFPE) tissues and plasma.

EASYPGX® READY MGMT cat. no. RTX049 (48 test)

CpG sites	**12** **MGMT promoter**	Qualitative detection, by RT-PCR and subsequent analysis of the targets based on the denaturation profile, of the methylation status of 12 CpG sites located in the promoter of the MGMT gene. The kit includes reagents for sodium bisulfite treatment of DNA extracted before methylation analysis, which converts unmethylated cytosines to uracil.
Cancer Types		Glioma.
Starting Material		DNA from formalin-fixed paraffin-embedded (FFPE) tissues.

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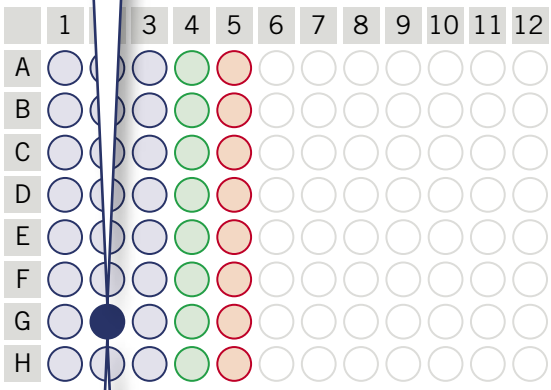
EasyPGX® Analysis Software: streamline your data analysis process

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

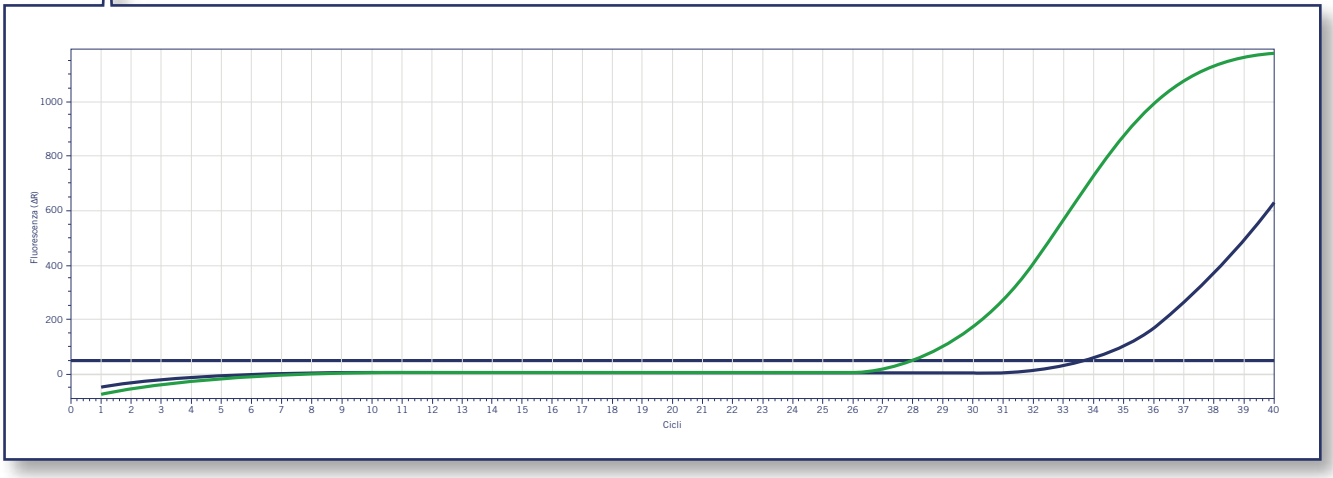
- Complies with the regulation (EU) 2017/746 [IVDR]
- Complete automated data analysis with a turnaround time of under 5 minutes
- No cloud or external data sharing required
- Fully-automated data analysis interpretation and raw data checking in a single software solution
- Automated variant calling and results interpretation
- LIMS connectivity
- Data export and reporting in various common file formats

Analysis of the Sample Control Mix and Mutation Assay

		EGFR G719x	EGFR T790M	EGFR S768I	EGFR ex20ins	EGFR L858R	EGFR L861Q	EGFR ex19del
N.	Name	Result	Result	Result	Result	Result	Result	Result
1	1	WT	WT	WT	WT	WT	WT	MUT
2	2	WT	WT	WT	WT	WT	MUT	WT
3	3	WT	WT	WT	WT	MUT	WT	WT



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® dry block	
EasyPGX® centrifuge/vortex 1.5 ml	
EasyPGX® centrifuge/vortex 8-well strips	
EasyPGX® hybridization tool	
EasyPGX® dry block 96-well plate	

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

			Colorectal Cancer	Non-Small Cell Lung Cancer	Thyroid Cancer
					
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 CBFB-MYH11 Fusion			
	RT046	EasyPGX® ready WT1 Quant			
	RTX047	EasyPGX® ready NPM1 Screening			
	RTX048	EasyPGX® ready NPM1 Quant			
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			

Updated to January 2024

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Cutaneous or Malignant Melanoma	Cholangiocar-cinoma	Breast Cancer	Cervical Cancer	Glioma	Head and Neck Cancer	Leukaemia	Agnostic Biomarker	Liquid Biopsy Assays
				●		●		
						●		
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For In Vitro diagnostic use compliant with the current EU IVDR regulation (2017/746) in Europe. EasyPGX® solution is available for sale in EU and many other countries. Please check availability and regulatory status with the local Diatech Pharmacogenetics representative.