

# Molecular Pathology

## Real-Time PCR Assays



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*Sensitive Real-Time PCR Detection for Mutations, Fusion Transcripts and Pathogens*

### ► Products of AmoyDx® for Real-Time PCR

Since 2015 Zytomed Systems offers products for Real-Time PCR from our partner company AmoyDx®. Besides kits for mutation detection, products for the detection of fusion transcripts

(*ALK*, *ROS1*, *RET*) and pathogens (HPV) from different starting materials are also available. The PCR assays are compatible with many common Real-Time PCR instruments.

### ► Kit Formats

AmoyDx® kits are available in two formats. The „pre-loaded“ format provides the user with specific PCR mixes (buffers, primers, probes and nucleotides) in PCR tube strips. Only the Taq Polymerase, which is also included in the kit, and the DNA/cfDNA/RNA

sample need to be added. The „bulk“ format, on the other hand, includes PCR mixes available in larger quantities, which need to be pipetted into suitable PCR tubes by the user.

### Advantages of the AmoyDx® Real-Time PCR Assays:

- High analytical sensitivity
- Results within 90 minutes
- External and internal control
- Positive control included
- Compatible with many common Real-Time PCR instruments such as Rotor-Gene Q, LightCycler® 480 II, QuantStudio™ 5, SLAN®-96S and many more

### ► Product Overview

*Detection of Mutations from DNA*

Description	Amount	Format	Status	Order no.
<b>AmoyDx® BCR-ABL Mutation Detection Kit</b> Detection of the T315I mutation in the <i>BCR-ABL</i> fusion gene	1 Kit (24 Tests)	Bulk	RUO	ADX-AB01-R
				ADX-AB01-RG72-R
<b>AmoyDx® BRAF Mutation Detection Kit (V2)</b> Detection of 7 V600 mutations in the <i>BRAF</i> gene	1 Kit (24 Tests)	Bulk	RUO	ADX-BR06-BR
				ADX-BR06-CR
				ADX-BR06-ER
<b>AmoyDx® BRAF V600 Mutations Detection Kit</b> Detection of 6 V600 mutations in the <i>BRAF</i> gene	1 Kit (24 Tests)	Bulk	CE/IVD	ADX-BR04
<b>AmoyDx® EGFR 29 Mutations Detection Kit</b> Detection of 29 mutations in exons 18-21 of the <i>EGFR</i> gene	1 Kit (10 Tests)	pre-loaded	CE/IVD	ADX-EG01-A
				ADX-EG01-B
				ADX-EG01-D
	1 Kit (24 Tests)	Bulk	CE/IVD	ADX-EG07
RUO			ADX-EG07-RG72-R	

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Detection of Mutations from DNA (continued)

Description	Amount	Format	Status	Order no.
<b>AmoyDx® EGFR/ALK/ROS1 Mutations Detection Kit</b> Detection of 24 <i>EGFR</i> mutations (exons 18-21), 21 <i>ALK</i> fusions and 13 <i>ROS1</i> fusions	1 Kit (8 Tests)	pre-loaded	RUO	ADX-EAR01-AR
				ADX-EAR01-DR
				ADX-EAR01-JR
<b>AmoyDx® HER2 Mutation Detection Kit</b> Detection of 13 mutations in the <i>HER2</i> gene	1 Kit (24 Tests)	Bulk	RUO	ADX-HE01-R
<b>AmoyDx® KRAS Mutation Detection Kit</b> Detection of 19 mutations in the <i>KRAS</i> gene (codons 12, 13, 59, 61, 117 and 146)	1 Kit (6 Tests)	pre-loaded	CE/IVD	ADX-KR05-A
	1 Kit (24 Tests)	Bulk		ADX-KR05-B
				ADX-KR07
<b>AmoyDx® KRAS/NRAS Mutations Detection Kit</b> Detection of 19 <i>KRAS</i> mutations (exons 2, 3 and 4) and 13 <i>NRAS</i> mutations (exons 2, 3 and 4)	1 Kit (6 Tests)	pre-loaded	CE/IVD	ADX-KN03-A
	1 Kit (24 Tests)	Bulk		ADX-KN03-D
<b>AmoyDx® KRAS/NRAS/BRAF Mutations Detection Kit</b> Detection of 17 <i>KRAS</i> mutations (exons 2, 3 and 4), 13 <i>NRAS</i> mutations (exons 2, 3 and 4) as well as the <i>BRAF</i> V600E mutation (exon 15)	1 Kit (6 Tests)	pre-loaded	CE/IVD	ADX-KN04-A
				ADX-KN04-B
				ADX-KN04-D
<b>AmoyDx® Multi-Gene Mutations Detection Kit</b> Detection of 118 hotspot mutations and fusions in the genes <i>EGFR</i> , <i>KRAS</i> , <i>BRAF</i> , <i>NRAS</i> , <i>HER2</i> , <i>PIK3CA</i> , <i>ALK</i> , <i>ROS1</i> and <i>RET</i>	1 Kit (6 Tests)	pre-loaded	CE/IVD	ADX-LM01-A
				ADX-LM01-B
				ADX-LM01-D
				ADX-LM01-J
<b>AmoyDx® NRAS Mutation Detection Kit</b> Detection of 16 mutations in the <i>NRAS</i> gene (codons 12, 13, 59, 61, 117 and 146)	1 Kit (24 Tests)	Bulk	CE/IVD	ADX-NR01
	1 Kit (8 Tests)	pre-loaded		ADX-NR02
<b>AmoyDx® Pan Lung Cancer PCR Panel</b> Detection of 167 hotspot mutations and fusions in the genes <i>EGFR</i> , <i>ALK</i> , <i>ROS1</i> , <i>KRAS</i> , <i>BRAF</i> , <i>HER2</i> , <i>RET</i> , <i>MET</i> , <i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i>	1 Kit (8 Tests)	pre-loaded	CE/IVD	ADX-LG01-B
			RUO	ADX-LG01-J
				ADX-LG01-DR
<b>AmoyDx® PIK3CA Five Mutations Detection Kit</b> Detection of 5 mutations in the <i>PIK3CA</i> gene	1 Kit (24 Tests)	Bulk	RUO	ADX-PI01-R
<b>AmoyDx® PIK3CA Mutation Detection Kit</b> Detection of 11 mutations in the <i>PIK3CA</i> gene	1 Kit (24 Tests)	Bulk	CE/IVD	ADX-PI02
<b>AmoyDx® TERT/HRAS Mutations Detection Kit</b> Detection of 2 <i>TERT</i> promoter mutations and 6 <i>HRAS</i> mutations	1 Kit (24 Tests)	Bulk	RUO	ADX-TH01-BR
				ADX-TH01-DR

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### Detection of Mutations from cDNA

Description	Amount	Format	Status	Order no.
<b>AmoyDx® EGFR 29 Mutations Detection Kit</b> Detection of 29 mutations in exons 18-21 of the <i>EGFR</i> gene	1 Kit (10 Tests)	pre-loaded	CE/IVD	ADX-EG01-A
				ADX-EG01-B
				ADX-EG01-D
	1 Kit (24 Tests)	Bulk	CE/IVD	ADX-EG07
	RUO		ADX-EG07-RG72-R	
<b>Super-ARMS® EGFR Mutation Detection Kit</b> Detection of 31 <i>EGFR</i> mutations in exons 18-21	1 Kit (12 Tests)	Bulk	CE/IVD	ADX-EG21
			RUO	ADX-EG21-RG36-R

### Detection of Fusion Transcripts from RNA

Description	Amount	Format	Status	Order no.
<b>AmoyDx® ALK Gene Fusions and ROS1 Gene Fusions Detection Kit</b> Detection of 14 <i>ALK</i> fusions and 14 <i>ROS1</i> fusions	1 Kit (8 Tests)	pre-loaded	CE/IVD	ADX-AR01-A
				ADX-AR01-D
<b>AmoyDx® EGFR/ALK/ROS1 Mutations Detection Kit</b> Detection of 24 <i>EGFR</i> mutations (exons 18-21), 21 <i>ALK</i> fusions and 13 <i>ROS1</i> fusions	1 Kit (8 Tests)	pre-loaded	RUO	ADX-EAR01-AR
				ADX-EAR01-DR
				ADX-EAR01-JR
<b>AmoyDx® EML4-ALK Fusion Gene Detection Kit</b> Detection of 21 <i>EML4-ALK</i> fusions	1 Kit (24 Tests)	Bulk	RUO	ADX-AE01-R
<b>AmoyDx® MET Mutation Detection Kit</b> Detection of <i>MET</i> exon 14 skipping	1 Kit (24 Tests)	Bulk	RUO	ADX-ME02-R
<b>AmoyDx® Multi-Gene Mutations Detection Kit</b> Detection of 118 hotspot mutations and fusions in the genes <i>EGFR</i> , <i>KRAS</i> , <i>BRAF</i> , <i>NRAS</i> , <i>HER2</i> , <i>PIK3CA</i> , <i>ALK</i> , <i>ROS1</i> and <i>RET</i>	1 Kit (6 Tests)	pre-loaded	CE/IVD	ADX-LM01-A
				ADX-LM01-B
				ADX-LM01-D
				ADX-LM01-J
<b>AmoyDx® NTRK Gene Fusions Detection Kit</b> Detection of 109 fusions in the genes <i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i>	1 Kit (24 Tests)	Bulk	CE/IVD	ADX-NT01
<b>AmoyDx® Pan Lung Cancer PCR Panel</b> Detection of 167 hotspot mutations and fusions in the genes <i>EGFR</i> , <i>ALK</i> , <i>ROS1</i> , <i>KRAS</i> , <i>BRAF</i> , <i>HER2</i> , <i>RET</i> , <i>MET</i> , <i>NTRK1</i> , <i>NTRK2</i> and <i>NTRK3</i>	1 Kit (8 Tests)	pre-loaded	CE/IVD	ADX-LG01-B
				ADX-LG01-J
			RUO	ADX-LG01-DR
<b>AmoyDx® RET Gene Fusions Detection Kit</b> Detection of 9 <i>RET</i> fusions	1 Kit (12 Tests)	Bulk	RUO	ADX-RE05-R
<b>AmoyDx® ROS1 Gene Fusions Detection Kit</b> Detection of 14 <i>ROS1</i> fusions	1 Kit (12 Tests)	Bulk	CE/IVD	ADX-RO03

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### Pathogen Detection

Description	Amount	Format	Status	Order no.
<b>AmoyDx<sup>®</sup> Human Papillomavirus (HPV) Genotyping Detection Kit</b> Detection of 19 high-risk and 2 low-risk HPV types	1 Kit (48 Tests)	Bulk	RUO	ADX-HP04-R

### AmoyDx<sup>®</sup> Real-Time PCR Instrument

Description	Status	Order no.
<b>SLAN<sup>®</sup>-96S Real-Time PCR System*</b> Instrument features a 96 x 0.2 ml Peltier heating block, a 4.0 °C/s max. ramp rate, a temperature accuracy $\pm 0.10$ °C, 4 fluorescence channels (FAM, HEX, ROX, Cy5) and a lid heater	CE/IVD**	SLAN-96S

\*Available in Germany and Austria

\*\*Instrument is CE/IVD-certified according to IVDR

Subject to change



For questions regarding the compatibility of your Real-Time PCR instrument, do not hesitate to contact our Molecular Pathology Team at [molpath@zytomed-systems.de](mailto:molpath@zytomed-systems.de).



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