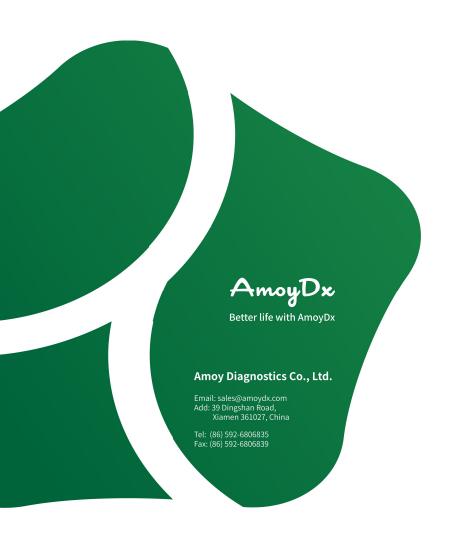




Solutions









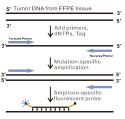


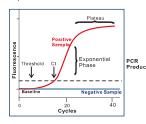


Technical Platform 1
ADx-ARMS® Technology1
Super-ARMS® Technology
RT-PCR Technology3
Products for Diagnostics 4
Lung Cancer4
Colorectal Cancer6
Cervical Cancer8
Leukemia9
DNA/RNA Extraction10
Ordering Information 11

ADx-ARMS® Technology

ADx-ARMS Real-time PCR





The first stage is designed for high specificity
The second stage is designed for high efficiency

Real-time PCR provides a robust quantitative output

Key words

Mature

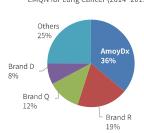
Form 2008 to 2019, ADx-ARMS technology benefits over 1,400,000 patients, and supported investigators to publish more than 110 SCI articles.

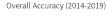
Reliable

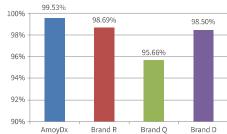
ADX-ARMS has maintained the most widely used technology for 6 consecutive years (2014~2019) in EMON external quality assessment scheme for lung cancer, with the highest accuracy of 99.53%.



Proportion of Commercial Test Methods EMQN for Lung Cancer (2014~2019)







Easy-to-use

Follow the standard qPCR procedure, get results within 90 minutes.

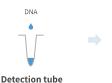




Extraction









Super-ARMS® Technology

A new revolution on qPCR platform

Compared to ADx-ARMS®, Super-ARMS® technology, by optimizing the PCR reaction system, primer/probe design, product structure and results interpretation, achieves a sensitivity up to 0.2% while maintaining high specificity.

Key words

High analytical sensitivity

Sensitivity up to 0.2%.



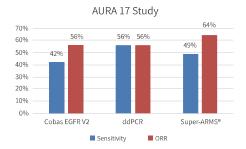
High clinical sensitivity [1]

Super-ARMS® EGFR shows impressive sensitivity and specificity in clinical practice.

EGFR Mutation		Tumor Tissue		
		+	-	Total
	+	50	0	50
Plasma	-	11	48	59
	Total	61	48	109
Sensitivity		82.0% 100%		
Specificity				

High predictive value for drug response^[2]

In AURA 17 study, patients with positive EGFR T790M mutation tested by Super-ARMS® EGFR achieved the highest objective response rate (ORR) during treatment with osimertinib.



[1] Li Y, Xu H,Su S, Ye J, Chen J, Jin X, et al. PLoS ONE 12(8): e0183331.

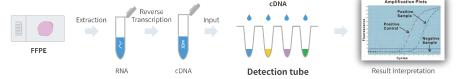
[2] C Zhou, YL Wu, et al., EMSO 1331P.



RT-PCR Technology

Reverse Transcription PCR (RT-PCR) analyzes gene alterations based on tumor mRNA, which includes two processes: reverse transcription of target RNA to generate cDNA and PCR amplification of target cDNA to detect gene alterations with specific primers and fluorescent probes.

Work flow



Key words

Objective

Interpret results by Ct values.

High sensitivity

Limit of detection is 125 copies/ rxn.

Multi-sample choice

Work with RNA from FFPE, FNA and cytology samples.

Global recognition[1]

Based on the biggest ROS1 clinical trial worldwide, AmoyDx ROS1 kit has been approved by MHLW* in Japan and MFDS** in South Korea as a companion diagnostic for crizotinib in Japan and Korea.

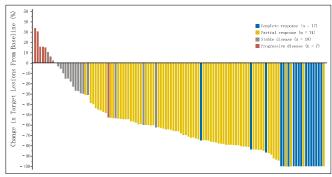


Fig. Best percent change in the target tumor burden from baseline as assessed by independent radiology review. Number of patients is based on the response evaluable population that excludes early death, indeterminate, and patients with nontarget lesions only.

Lung Cancer

Numerous oncogene alterations have been identified to be important for lung cancer pathogenesis and impact therapy selection, including EGFR, ALK, ROS1, BRAF, MET, HER2, RET, etc. Testing of non-small cell lung cancer (NSCLC) for multiple gene mutations is vital for identification of potentially efficacious targeted therapies.

Gene	Alteration	Frequency in NSCLC	Available Targeted Therapy
EGFR	Mutation	10~35%	Gefitinib, Erlotinib, Afatinib, Osimertinib, Dacomitinib
ALK	Fusion	3~7%	Crizotinib, Alectinib, Ceritinib, Brigatinib
ROS1	Fusion	2%	Crizotinib, Ceritinib, Entrectinib
BRAF	Mutation	1~4%	Trametinib, Dabrafenib
MET	Exon 14 skipping mutation	3%	Tepotinib, Capmatinib, Crizotinib
HER2	Mutation	2~4%	Ado-trastuzumab emtasine
RET	Fusion	1%	Selpercatinib, Cabozantinib, Vandetanib
NTRK	Fusion	1%	Larotrectinib, Entrectinib
KRAS	G12C mutation	11~16%	AMG510, MRTX849

AmoyDx® Pan Lung Cancer PCR Panel

Gene	EGFR / KRAS / BRAF / HER2 / ALK / ROS1 / RET / MET / NTRK1 / NTRK2 / NTRK3	Alteration	167 Variants
Qualification	n CE-IVD	Limit of Detection	RNA: 125 cp/rxn DNA: 1~5%

AmoyDx® Multi-Gene Mutations Detection Kit

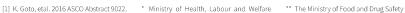
Gene	EGFR / KRAS / BRAF / NRAS / PIK3CA / HER2 / ALK / ROS1 / RET	Alteration	118 Variants
Qualification	CE-IVD, NMPA	Limit of Detection	RNA: 450 cp/rxn DNA: 1%

Super-ARMS® EGFR Mutation Detection Kit

Gene	EGFR	Alteration	42 Mutations
Coverage	99.03%	Limit of Detection	0.2~0.8%
Qualification	CE-IVD, NMPA*		

^{*}National Medical Products Administration (China)





Super-ARMS® EGFR T790M Mutation Detection Kit

Gene	EGFR	Alteration	T790M Mutation
Coverage	-	Limit of Detection	0.2%
Qualification	CE-IVD		

AmoyDx® EGFR 29 Mutations Detection Kit

Gene	EGFR	Alteration	29 Mutations
Coverage	98.43%	Limit of Detection	1%
Qualification	CE-IVD, NMPA		

AmoyDx® EML4-ALK Fusion Gene Detection Kit

Gene	EML4-ALK	Alteration	21 Fusions
Coverage	~90%	Limit of Detection	125 cp/rxn
Qualification	CE-IVD, NMPA		

AmoyDx® ROS1 Gene Fusions Detection Kit

Gene	ROS1	Alteration	14 Fusions
Coverage	~99%	Limit of Detection	125 cp/rxn
Qualification	CE-IVD, NMPA, MHLW, MFDS		

AmoyDx® ALK Gene Fusions and ROS1 Gene Fusions Detection Kit

Gene	ALK, ROS1	Alteration	26 ALK Fusions, 14 ROS1 Fusions
Coverage	~95%	Limit of Detection	125 cp/rxn
Qualification	CE-IVD, NMPA		

AmoyDx® RET Gene Fusions Detection Kit

Gene	RET	Alteration	9 Fusions
Qualification	CE-IVD	Limit of Detection	125 cp/rxn

AmoyDx® EGFR/ALK/ROS1 Mutations Detection Kit

Gene	EGFR, ALK, ROS1	Alteration	24 EGFR Mutations 21 ALK Fusions 13 ROS1 Fusions
Qualification	CE-IVD, NMPA	Limit of Detection	DNA: 1% RNA: 125 cp/rxn

AmoyDx® MET Mutation Detection Kit

Gene	MET	Alteration	Exon 14 skipping mutation
Qualification	CE-IVD	Limit of Detection	500 cp/rxn

AmoyDx® HER2 Mutation Detection Kit

Gene	HER2	Alteration	13 mutations
Qualification	RUO	Limit of Detection	1%

AmoyDx® NTRK Gene Fusions Detection Kit

Gene	NTRK1/NTRK2/NTRK3	Alteration	109 Fusions
Qualification	RUO	Limit of Detection	125~250 cp/rxn

Colorectal Cancer

Somatic mutations involve such genes as KRAS, NRAS, BRAF and PIK3CA have been known to be prognostic or predictive markers for specific therapies available in colorectal cancer. In total, somatic KRAS, NRAS and PIK3CA mutations occur in 20~50%, 1~6%, 10~30% of colorectal cancers respectively. And the most common BRAF mutations are V600 mutations in exon 15, which occur in 8~15% of colorectal cancers.

Patients without any known RAS mutations (exon 2, 3, 4) could benefit from Erbitux (cetuximab) or Vectibix (panitumumab). BRAF and PIK3CA mutations make response to cetuximab or panitumumab highly unlikely. Patients with metastatic colorectal cancer should have tumor tissue genotyped for RAS (KRAS and NRAS) and BRAF mutations.

AmoyDx® KRAS Mutation Detection Kit

Gene	KRAS	Alteration	19 Mutations
Coverage	>97.74%	Limit of Detection	1~5%
Qualification	CE-IVD, NMPA		

AmoyDx® NRAS Mutation Detection Kit

Gene	NRAS	Alteration	16 Mutations
Coverage	>87.37%	Limit of Detection	1~5%
Qualification	CE-IVD, NMPA		

AmoyDx® BRAF V600 Mutations Detection Kit

Gene	BRAF	Alteration	6 V600 Mutations
Coverage	95%	Limit of Detection	1%
Qualification	CE-IVD, NMPA		

AmoyDx® KRAS/NRAS Mutations Detection Kit

Gene	KRAS, NRAS	Alteration	19 KRAS Mutations 13 NRAS Mutations
Qualification	CE-IVD, NMPA	Limit of Detection	1~5%

AmoyDx® KRAS/NRAS/BRAF Mutations Detection Kit

Gene	KRAS, NRAS, BRAF	Alteration	17 KRAS Mutations 13 NRAS Mutations 1 BRAF Mutation
Qualification	CE-IVD, NMPA	Limit of Detection	1~5%

Super-ARMS® KRAS/NRAS/BRAF Mutations Detection Kit

(Minimum Order Quantity required)

Gene	KRAS, NRAS, BRAF	Alteration	18 KRAS Mutations 15 NRAS Mutations 6 BRAF Mutations
Qualification	CE-IVD	Limit of Detection	0.2~1%

AmoyDx® PIK3CA Rive Mutations Detection Kit

Gene	PIK3CA	Alteration	5 Mutations
Qualification	CE-IVD, NMPA	Limit of Detection	1~2%

AmoyDx® PIK3CA Mutation Detection Kit

Gene	PIK3CA	Alteration	11 Mutations
Qualification	RUO	Limit of Detection	1~2%

Cervical Cancer

Human papillomavirus (HPV) is a sexually transmitted DNA virus that establishes infection in squamous epithelial cells in the human body. There are more than 200 types of HPV, which can be classified into high or low-risk types depending upon their oncogenic potentials. High-risk HPVs are also called oncogenic HPVs, which have been confirmed to cause cancer. Low-risk HPVs can cause genital warts and low-grade changes in the cells, but rarely cause cancer.

Virtually all cervical cancers are caused by high-risk HPV infections. Approximately 99.7% of cervical cancers are caused by high-risk HPV infection. In particular, HPV16 and HPV18 are known to cause around 70% of cervical cancer cases.

The most common high-risk HPV types	Other high-risk HPV types
16, 18	31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68
Probably high-risk HPV types	The most common low-risk HPV types
26, 53, 66, 70, 73, 82	6, 11

AmoyDx® HPV Detection Kit

(Minimum Order Quantity required)

	Detecting Capability	Kit Format	Limit of Detection
High-risk HPV	HPV16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, and 82	1 reaction tube, 3 fluorescents labeled	HPV16: 1000 cp/rxn, HPV45, 53, 59, 73: 50 cp/rxn, Other HPVs: 500 cp/rxn
HPV Genotyping	19 High-risk HPVs: HPV16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, 82 2 Low-risk HPVs: HPV6, 11	8 reaction tubes, 3 fluorescents labeled	100 cp/rxn

Leukemia

Leukemia is characterized by the abnormal proliferation of blood precursor cells of myeloid or lymphoid origin. There are four types of leukemia - acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL) and chronic myeloid leukemia (CML). Recently, biomarkers of different leukemia subtypes based on genetic have been reported, such as JAK2, C-KIT, BCR-ABL, etc.

AmoyDx® JAK2 Mutation Detection Kit

Gene	JAK2	Alteration	V617F Mutation
Qualification	CE-IVD	Limit of Detection	1%

DNA/RNA Extraction

AmoyDx® DNA/RNA Extraction Kits

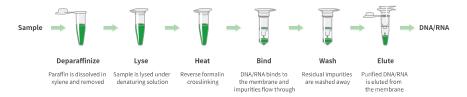
Highlights

- Simple and quick
- · High purity and high yield
- Simultaneous DNA & RNA
- · Good and stable PCR results

Sample types

FFPE tissue, fresh and frozen tissue, pleural effusion, whold blood, serum, plasma, cytology sample.

Principle and Procedure



Performance *

Kit (FFPE RNA)	A260	A260/A280	RNA Conc. (ng/ul)	Ct Value **
AmoyDx	2.72	1.91	106.24	23.62
	(0.84~3.56)	(1.89~1.93)	(33.78~142.53)	(21.70~25.55)
Competitor	1.62	1.92	64.74	24.05
	(0.76~2.47)	(1.88~1.96)	(30.51~98.98)	(21.36~26.74)

^{*} The data is from GC Lab in South Korea.

^{**} The samples were extracted RNA using both AmoyDx and competitor's kit, and the Ct values were obtained in ROS1 gene fusion testing.

Ordering Information

The Cat. No. marked with "*" requires minimum purchase quantity, please consult your account manager or distributor before order placing.

Kit	Cat. No.	Specification	Validated Instruments
Super-ARMS® EGFR	8.01.20213X012E	12 tests/kit	Mx3000P, ABI7500, LightCycler480 II, SLAN-96S, Rotor-Gene Q (36 wells) , Cobas® z480
Super-ARMS® EGFR T790M	8.01.20212X024D	24 tests/kit	Mx3000P, ABI7500, LightCycler480 II, SLAN-96S
	8.01.20201W010A	10 tests/kit	Mx3000P, ABI7300, ABI7500, ABI7900HT
	8.01.20201W010B	10 tests/kit	LightCycler480 II, Bio-Rad CFX96, Cobas® z480
ADx-ARMS® EGFR	8.01.20201W010D	10 tests/kit	SLAN-96S
7.5.7,1,1,1,0	8.01.20201X024E	24 tests/kit	Mx3000P, ABI7300, ABI7500, ABI7900HT, ABI StepOnePlus, LightCycler480 II, Bio-Rad CFX96, SLAN-96S
	8.01.20201X024F	24 tests/kit	Rotor-Gene Q/6000 (72 wells)
EML4-ALK	8.01.22001X024H	24 tests/kit	Mx3000P, ABI7500, LightCycler480 II, Bio-Rad CFX 96, Rotor-Gene Q/6000 (72 wells), SLAN-96S
	8.01.23201W012A	12 tests/kit	Mx3000P, ABI7500
ROS1	8.01.23201X012H	12 tests/kit	Mx3000P, ABI7500, LightCycler480 II, Bio-Rad CFX 96, Rotor-Gene Q/6000 (72 wells), SLAN-96S
	8.01.24401W008A	8 tests/kit	Mx3000P, ABI7500
ALK/ROS1	8.01.24401W008B	8 tests/kit	LightCycler480 II
	8.01.24401W008D	8 tests/kit	SLAN-96S

Ordering Information

Kit	Cat. No.	Specification	Validated Instruments
	8.01.25501W008A	8 tests/kit	Mx3000P
EGFR/ALK/ROS1	8.01.25501W008D	8 tests/kit	SLAN-96S
	8.01.25501W008J	8 tests/kit	ABI7500
RET Fusion	8.01.23301X012H	12 tests/kit	Mx3000P, ABI 7500, LightCycler480 II, Bio-Rad CFX96, Rotor-Gene Q/6000 (72 wells)
HER2	8.01.26801X024H	24 tests/kit	Stratagene Mx3000P™, ABI 7500, ABI 7900HT, ABI StepOnePlus, LightCycler 480, Bio-Rad CFX96, Rotor-Gene Q/6000 (72 wells), SLAN-96S
	8.01.26301W006A	6 tests/kit	Stratagene Mx3000P™
Multi-Gene	8.01.26301W006B	6 tests/kit	LightCycler480 II, Cobas® z480
mater defic	8.01.26301W006D	6 tests/kit	SLAN-96S
	8.01.26301W006J	6 tests/kit	ABI 7500
Pan LC Panel	8.0131202W008J	8 tests/kit	QuantStudio 5
	8.0131202W008B	8 tests/kit	LightCycler480 II
MET Skipping	8.01.26101X024H	24 tests/kit	Mx3000P, ABI7500, LightCycler480 II, SLAN-96S, Rotor-Gene Q(72 wells)
	8.01.20102W006A	8 tests/kit	Mx3000P, ABI7500
KRAS	8.01.20102W006B	8 tests/kit	LightCycler480 II, Cobas® z480
NNAS	8.01.20102X024H	24 tests/kit	Mx3000P, ABI7500, LightCycler480 II, Bio-Rad CFX96, Rotor-Gene Q/6000 (72 wells), SLAN-96S
NDAC	8.01.25001W008A	8 tests/kit	Mx3000P, ABI7500
NRAS	8.01.25001X024H	24 tests/kit	Mx3000P, ABI7500, LightCycler480 II, Bio-Rad CFX96, SLAN-96S





Ordering Information

Kit	Cat. No.	Specification	Validated Instruments
BRAF	8.01.20302X024E	24 tests/kit	Mx3000P, ABI7500, ABI7900HT, ABI StepOnePlus, LightCycler480 II, Bio-Rad CFX96, SLAN-96S
	8.0120303X024E*	24 tests/kit	3000P, SLAN-96S, Rotor-Gene Q (72 wells)
BRAF V2	8.0120303X024B*	24 tests/kit	LightCycler480 II
	8.0120303X024C*	24 tests/kit	Bio-Rad CFX96
	8.01.25402W006A	6 tests/kit	Mx3000P, ABI7500
KRAS/NRAS	8.01.25402W006D	6 tests/kit	SLAN-96S
KRAS/NRAS	8.01.25402X024H	24 tests/kit	Mx3000P, ABI7500, LightCycler480 II, Bio-Rad CFX96, Rotor-Gene Q/6000 (72 wells), SLAN-96S
	8.01.25403W006A	6 tests/kit	Mx3000P, ABI7500
KRAS/NRAS/BRAF	8.01.25403W006B*	6 tests/kit	LightCycler480 II
	8.01.25403W006D	6 tests/kit	SLAN-96S
Super-ARMS® KRAS/NRAS /BRAF	8.01.25404X024E*	24 tests/kit	Mx3000P, ABI7500, SLAN-96S
PIK3CA	8.01.21601X024E	24 tests/kit	Mx3000P, ABI7500, LightCycler480, Bio-Rad CFX96, SLAN-96S
PIKSCA	8.0121601X012F	12 tests/kit	Rotor-Gene Q/6000 (72 wells)
PIK3CA 11	8.0121602X024E	24 tests/kit	Mx3000P, ABI7500, LightCycler480, Bio-Rad CFX96, SLAN-96S
NTRK Fusion	8.0126001X024E	24 tests/kit	Stratagene Mx3000P™, ABI7500, QuantStudio 5, LightCycler480 II, SLAN-96S
HPV High-risk	8.01.25802X048E	48 tests/kit	Mx3000P, ABI 7500, LightCycler480, Bio-Rad CFX96, SLAN-96S, Rotor Gene Q/6000 (72 wells)
HPV Genotyping	8.01.25803X048E	48 tests/kit	Mx3000P, ABI 7500, SLAN-96S LightCycler480 II, Bio-Rad CFX96

Ordering Information

Kit	Cat. No.	Specification	Validated Instruments
TERT/HRAS	8.01.27701X024B	24 tests/kit	ABI7500, LightCycler480 II
TEXT/TITAS	8.01.27701X024D	24 tests/kit	Mx3000P, SLAN-96S
JAK2	8.01.20801X024E	24 tests/kit	Mx3000P, ABI 7500, ABI7900HT, ABI StepOnePlus, LightCycler480 II, Bio-Rad CFX96
FFPE DNA	8.02.23501X036G	36 tests/Kit	
FFPE RNA	8.02.24101X036G	36 tests/Kit	
FFPE DNA/RNA	8.02.23601X036G	36 tests/Kit	
Circulating DNA	8.02.26201X024G	24 tests/Kit	
Blood DNA	8.02.24201X036G	36 tests/Kit	
Tissue DNA	8.02.24301X036G	36 tests/Kit	
Tissue RNA	8.02.24601X036G	36 tests/Kit	
Cell-free DNA Tube	8.04.26401X010G	10 tests/Kit	





