



ADPS™

EGFR

Mutation Test Kit V1

**Bringing precision medicine
to more patients!**

MAF Up to 0.01% | Specificity \geq 99% | Turnaround time of 1.5 hours
Applicable to both tissue and liquid biopsy samples

EGFR



Gain information
for personalized treatment
with accurate,
rapid **EGFR Mutation** testing

EGFR is a membrane protein that transmits signals that promote cell growth and proliferation, and is strongly associated with certain types of cancer. EGFR mutations are identified in approximately 20% NSCLC patients in Western populations and 40 to 55% of NSCLC patients in East Asian populations. Most EGFR mutations occur in exons 18–21.

EGFR mutations are targeted by specific tyrosine kinase inhibitors (TKIs), and the EGFR T790M mutation is used as a resistance biomarker. Therefore, the analysis of EGFR mutations in NSCLC patients can help personalize treatment for patients.

The ADPS™ EGFR Mutation Test Kit v1 detects mutations in exons 18 to 21 of the EGFR gene with a detection sensitivity ranging from 0.01% to 0.1%. It is designed to allow testing of both tissue and plasma samples with a single kit. Healthcare professionals can prescribe EGFR TKIs based on the test results.

Improve Patient Management with Liquid Biopsies

The ADPS™ EGFR Mutation Test Kit v1 is compatible with both invasive tissue biopsies and ultra-sensitive liquid biopsies. While it is preferred to use fresh tumor samples for EGFR analysis after first-line TKI treatment, liquid biopsy can be used as a complementary option for patients for whom invasive biopsy procedures are inconvenient.

Liquid biopsy has the advantage of being a non-invasive procedure that allows frequent sampling and testing. The ADPS™ EGFR Mutation Test Kit v1 can detect mutations down to 10 copies/mL, making liquid biopsy more feasible for patient management.

| Key Features

Provides accurate diagnosis with a high sensitivity ranging from 0.01% to 0.1% and high specificity of $\geq 99\%$



Provides same-day results with a 1.5-hour turnaround time



Compatible with most qPCR instruments (only for RUO products)



Applicable to both tissue and blood samples



Provides consistent, objective, and reproducible results



Product Information

Catalog Number	(IVD) D8000APA, (RUO) R8000APA
Target Mutations	Mutations in EGFR exons 18, 19, 20, and 21
Assay	qPCR
Sample Type	DNA extracted from paraffin-embedded or fresh/frozen tissue biopsy or liquid biopsy
Number of Reactions Per Sample	4 reactions (4 MMXs)
Internal Control	EGFR exon 4
Detection Sensitivity	0.01% to 0.1% for FFPET, 10 to 60 copies/mL for Plasma
Specificity	≥ 99%
Precision (% CV)	≤ 5% (CV, coefficient of variation)
Storage Conditions	-20±5°C
Shelf Life	18 months
Maximum Number of Freeze-thaw Cycles	5 times
Compatible Equipment	IVD - AB7500Fast, RUO - AB7500Fast, CFX96, Roter-Gene Q, LightCycler 480, QuantStudio 5



Detected Mutation

Exon	Mutation	EGFR Nucleic Acid Sequence	COSMIC ID
Exon 18	G719X	c.2155G>A	6252
		c.2155G>T	6253
		c.2156G>C	6239
		c.2240_2251del12	6210
		c.2239_2247del9	6218
		c.2238_2255del18	6220
		c.2235_2249del15	6223
		c.2236_2250del15	6225
		c.2239_2253del15	6254
		c.2239_2256del18	6255
Exon 19	Ex19Del	c.2237_2254del18	12367
		c.2240_2254del15	12369
		c.2240_2257del18	12370
		c.2239_2248TTAAGAGAAG>C	12382
		c.2239_2251>C	12383
		c.2237_2255 > T	12384
		c.2235_2255 > AAT	12385
		c.2237_2252 > T	12386
		c.2239_2258 > CA	12387
		c.2239_2256 > CAA	12403
		c.2237_2253>TTGCT	12416
		c.2238_2252>GCA	12419

Exon	Mutation	EGFR Nucleic Acid Sequence	COSMIC ID
Exon 19	Ex19Del	2238_2248>GC	12422
		2237_2251del15	12678
		2236_2253del18	12728
		2235_2248>AATTC	13550
		2235_2252>AAT	13551
		2235_2251>AATTC	13552
		2253_2276del24	13556
		2237_2257>TCT	18427
		2238_2252del15	23571
		2233_2247del15	26038
Exon 20	S768I T790M	c.2303G>T	6241
		c.2369C>T	6240
		c.2307_2308ins9GCCAGCGTG	12376
Exon 20	Ex20Ins	c.2319_2320insCAC	12377
		c.2310_2311insGGT	12378
		c.2311_2312ins9GCGTGGACA	13428
		c.2309_2310AC>CCAGCGTGGAT	13558
Exon 21	L858R L861Q	c.2573T>G	6224
		c.2573_2574TG>GT	12429
		c.2582T>A	6213

Applicable to Both Tissue and Plasma Samples

Tissue Sample Workflow

Samples for ADPS™ EGFR Mutation Test Kit v1

Nucleic Acid Extraction

- DNA extraction: QIAamp DSP DNA FFPE Tissue Kit
- DNA usage: < 100 ng

Reagent Preparation

Component	Volume
ADPS master mixture	10.0 µL
Sample DNA (up to 19.8 ng/µL)	9.5 µL
Smart DNA Polymerase (1 U/µL)	0.5 µL

qPCR Parameter

Stage	Cycles	Temperature	Time	Data Collection
1	1	95 °C	5 min	
		95 °C	10 sec	
2	45	60 °C	30 sec	Collection
		72 °C	10 sec	

Liquid Sample Workflow

DNA Samples for ADPS™ EGFR Mutation Test Kit 1

Nucleic Acid Extraction

- DNA extraction: QIAamp DSP Circulating NA Kit

Reagent Preparation

Component	Volume
ADPS master mixture	10.0 µL
Sample DNA	9.5 µL
Smart DNA Polymerase (1 U/µL)	0.5 µL

qPCR Parameter

Stage	Cycles	Temperature	Time	Data Collection
1	1	95 °C	5 min	
		95 °C	10 sec	
2	45	60 °C	30 sec	Collection
		72 °C	10 sec	

Compatible Instrument

- **CE-IVD:** Applied Biosystems 7500 Fast (ThermoFisher)
- **RUO:** all qPCR instruments with FAM, VIC and CY5 channels

Detection Limits

1) FFPE Sample LoD

+ Analytical performance is the same for IVD and RUO products.

MMX	EGFR Mutation Group	EGFR Nucleotide Sequence	Specimen Type	Final LoD
MMX1	S768I	c.2303G>T	Reference standard*	0.01%
		c.2235_2249del15	Clinical specimen**	0.02%
	Ex19del	c.2235_2249del15	Clinical specimen	0.01%
		c.2235_2249del15	Clinical specimen	0.01%
		c.2240_2257del18	Clinical specimen	0.01%
MMX2	T790M	c.2369C>T	Clinical specimen	0.02%
		c.2369C>T	Clinical specimen	0.02%
MMX3	L861Q	c.2582T>A	Reference standard	0.01%
	G719X	c.2155G>A	Clinical specimen	0.1%
MMX4	Ex20Ins	c.2307_2308ins9GCCAGCGTG	Reference standard	0.01%
		c.2573T>G	Clinical specimen	0.01%
	L858R	c.2573T>G	Clinical specimen	0.01%
		c.2573T>G	Clinical specimen	0.02%
		c.2573T>G	Clinical specimen	0.02%

* FFPE standard (Horizon Discovery)

** Clinical sample tested by NGS (Seoul Asan Medical Center)

2) Plasma Sample LoD

+ Analytical performance is the same for IVD and RUO products.

MMX	EGFR Mutation Group	Cell Line	EGFR Nucleotide Sequence	Final LoD
MMX1	S768I	RKO (S768I/+)	c.2303G>T	10
	Ex19del	NCI-H1650	c.2235_2249del15	10
MMX2	T790M	NCI-H1975	c.2369C>T	20
MMX3	L861Q	RKO (L861Q/+)	c.2582T>A	10
	G719X (G719S)	SW48	c.2155G>A	60
MMX4	Ex20Ins	RKO (V769_D770insASV/+)	c.2307_2308ins9GCCAGCGTG	20
	L858R	NCI-H1975	c.2573T>G	20

* Test substance: Artificial sample (plasma with fragmented cell line gDNA added) - Plasma: Plasma from healthy donor purchased from Innovative Research



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