

HLB Panagene

For Global Standard of Molecular Diagnostics

2025 - 2026



HLB Panagene

ONCOLOGY

OncoTector™

- ▶ Advanced MDx
- ▶ Create Custom Panel

PRODUCTS

BRAF

OncoTector™ BRAF



PNAA-1001

Codon 600 (V600E)

24 Tests/Kit

KRAS

OncoTector™ KRAS



PNAA-2001

Codon 12, 13 (G12C, G12D, G12V, G12A, G12S, G12R, G13C, G13D)

24 Tests/Kit

ROS1

OncoTector™ ROS1



PNAA-6001

ROS1 gene fusion (14 mutations)

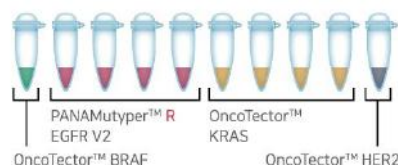
24 Tests/Kit

Number of reaction tubes per test

Detect DNA target

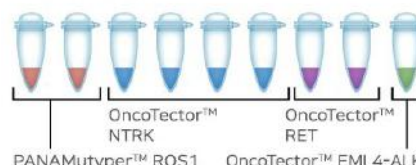
Detect RNA target

DNA Panel



あらゆる種類のバイオマーカーを
単一反応条件下で
検出可能

RNA Panel



● 感度 (Sensitivity)

- ・ 液体生検サンプルから少量の標的突然変異を検出可能
- ・ PNAプローブの組み合わせにより、非標的DNAの増幅を選択的に抑制し、標的DNAの増幅を促すことで性能が向上



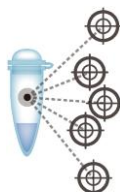
● 検査所要時間 (Turnaround Time, TAT)

- ・ 最適化されたPCRプロトコルにより、最大1時間以内に高速TATを提供
- ・ パネルで構成し、複数のキットを一度に実行可能



● 多重分析 (Multiplex)

- ・ 単一反応で10個以上のターゲットを同時検出可能
- ・ フュージョンアンプリコンの形成と汎用プロービングを通じて多重分析能力を極大化



● 定量分析 (Quantification)

- ・ 単一反応における基準 (reference) と Target増幅を同時に確認して正確な定量が可能



● 装備互換性 (Instrument Compatibility)

- ・ 商用化されたリアルタイムPCR装置と互換可能
- ・ 他のPCR装置への拡張も容易



Bio-Rad CFX96



ThermoFisher QuantStudio 5



ThermoFisher 7500/7900



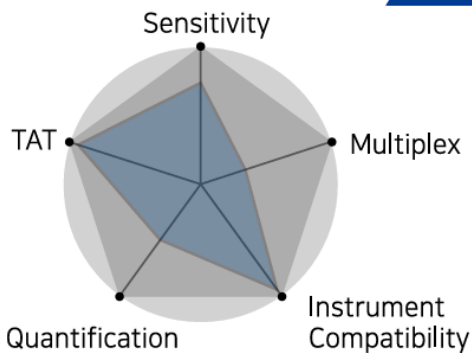
ThermoFisher StepOnePlus



For more information, please visit | www.hlbpanagene.com

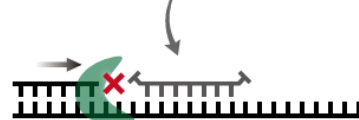
TECHNOLOGY

PNAClamp™



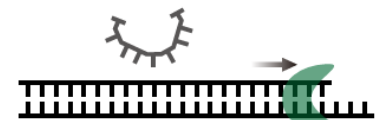
Clamping PNA probe

PNA基盤技術はDNA混合物内で変異した標的DNA配列のみを選択的に増幅



Wild-type DNA

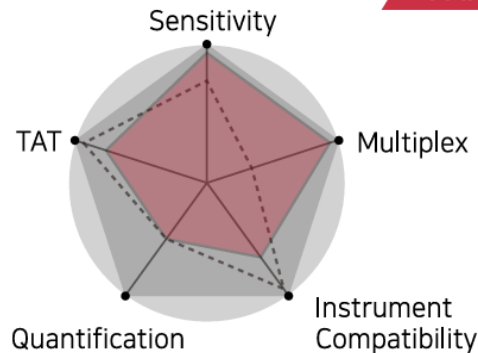
Inhibit PCR



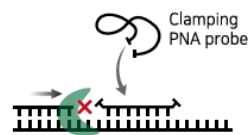
Mutant DNA

Amplify target

PANAMutyper™



PNAClamp™ (highly sensitive detection),
PANA RealTyper™ (advanced multiplex target detection)
技術を結合



Wild-type DNA

Inhibit PCR

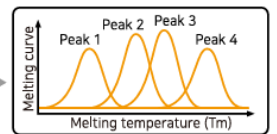
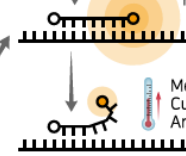


Mutant DNA

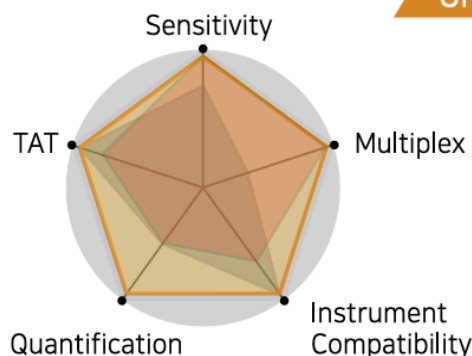
Amplify target

Clamping PNA probe
Detection PNA probe
Quencher
Reporter

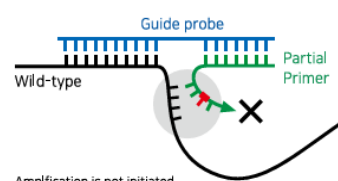
Use various reporters



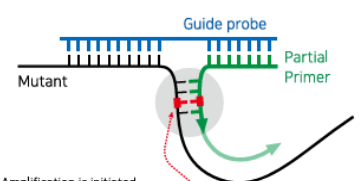
OncoTector™



Partial primer (標的DNAに相補的な短い塩基配列により独立的に増幅を開始しにくい)と guide probe (Partial primerの標的結合を促進する)を使用し、標的DNAを非常に高い特異性で増幅できる

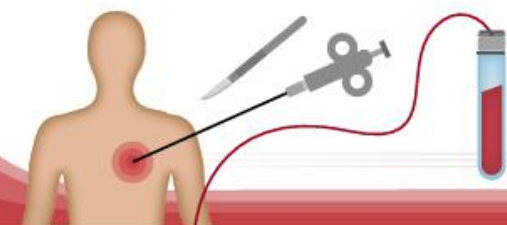


Amplification is not initiated because a sequence mismatch exists



Amplification is initiated with the help of guide probe with the sequence being perfect match
Mutation site

PNAClamp™ and AssiProbe™ technologies can be combined to create synergies



- ▶ Liquid Biopsy
- ▶ High Sensitivity

ONCOLOGY

PANAMutyper™

PRODUCTS

EGFR PANAMutyper™ **R** EGFR

PNAR-3001

Exon 18, 19, 20, 21 (47 mutations)

24 Tests/Kit

Liquid Biopsy

EGFR PANAMutyper™ **R** EGFR **V2**

PNAR-3002

Exon 18, 19, 20, 21 (+ C797S mutation)

24 Tests/Kit

Liquid Biopsy

ROS1 PANAMutyper™ **ROS1**

PNAR-6001

ROS1 gene fusion (20 mutations)

24 Tests/Kit

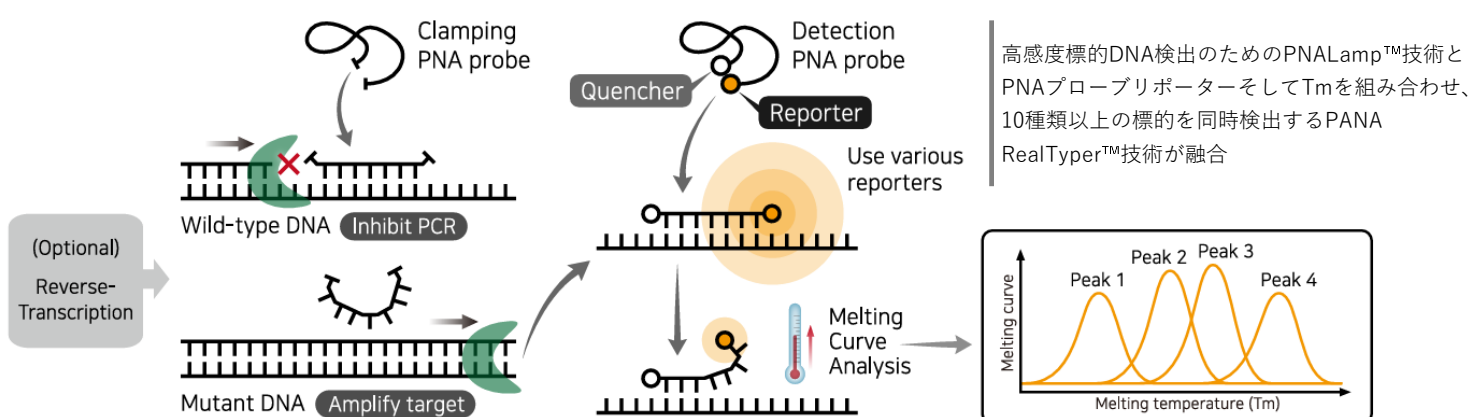
Screening

- Detect DNA target
- Detect RNA target

FEATURES

- ・ 非常に高い感度と特異性を提供
- ・ 多重遺伝子型分析可能 (PANAMutyper™ Rseries)
- ・ 液体・組織生検サンプルすべて診断に使用可能 (PANAMutyper™ Rseries)
- ・ RNA標的検出のためのOne - step RT - PCR可能
- ・ HLB Panagene MDx Analyzer'により検査結果を簡単に解析可能

TECHNOLOGY



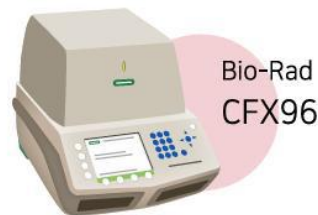
For more information, please visit | www.hlbpanagene.com

COMPARISON OF MUTATION DETECTION METHODS

	PANAMutyper™ R (HLB Panagene)	Company A	Company B	Company C	Company D
Technology	PNA-based clamping PCR & MCA	ddPCR & flow cytometry	TaqMan	ddPCR	NGS
Sample	25 ng (2 ml plasma)	2 ml plasma	10 ng	10 ng	10 - 250 ng
Genotyping	YES	YES	YES	YES	YES
Multiplex	YES	YES	NO	NO	YES
Running time	< 3 hours	10 days	< 3 hours	2 days	2 days
Workflow	Simple	Complicated	Simple	Complicated	Complicated
Instrument	Real-time PCR	Droplet digital PCR Flow cytometry	Real-time PCR	Droplet digital PCR Droplet generator	Library machine PCR, NGS
Sensitivity	0.1~0.01% (0.1% Guaranteed)	0.1~0.01%	0.1%	0.1~0.01%	1 - 5%

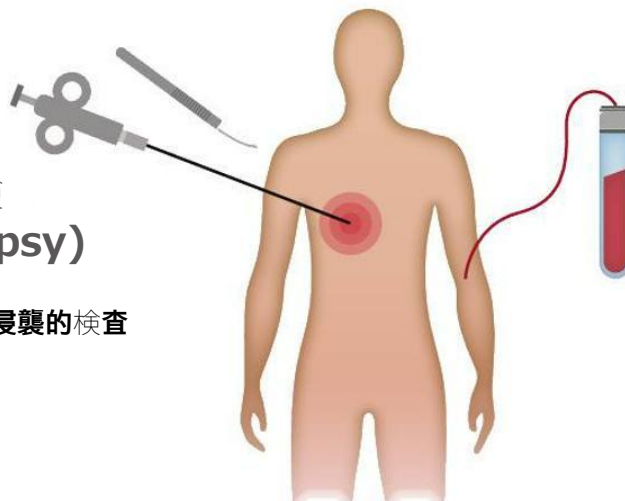
SPECIMEN / COMPATIBLE INSTRUMENT

- 組織 (Tissue – Fresh, FFPE)
- 生検 (Biopsy)
- 血漿 (Plasma), (PANAMutyper™ R series)



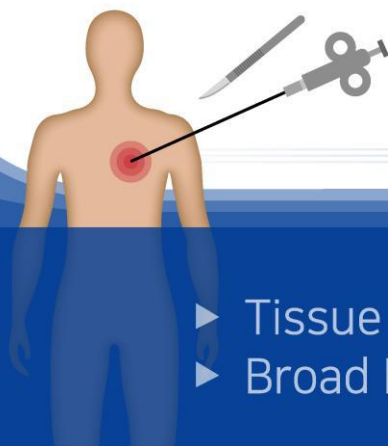
組織生検 (Tissue Biopsy)

患者の組織を採取する侵襲的検査



液体生検 (Liquid Biopsy)

患者の体液による非侵襲的検査



- ▶ Tissue Biopsy
- ▶ Broad Biomarker Coverage

ONCOLOGY

PNAClamp™

PRODUCTS

EGFR PNAClamp™ EGFR
PNAC-3002
 Exon 18, 19, 20, 21 (40 mutations)
 25 Tests/Kit

KRAS PNAClamp™ KRAS
PNAC-1006
 Codon 12, 13, 59, 61, 117, 146 (40 mutations)
 25 Tests/Kit

NRAS PNAClamp™ NRAS
PNAC-1101
 Codon 12, 13, 59, 61, 117, 146 (43 mutations)
 25 Tests/Kit

BRAF PNAClamp™ BRAF
PNAC-2001
 Codon 600 (V600, 5 mutations)
 50 Tests/Kit

PIK3CA PNAClamp™ PIK3CA
PNAC-4001
 Codon 420, 542, 545, 546, 1047 (14 mutations)
 25 Tests/Kit

 Liquid Biopsy

IDH1 PNAClamp™ IDH1
PNAC-5001
 Codon 132 (R132, 5 mutations)
 25 Tests/Kit

IDH2 PNAClamp™ IDH2
PNAC-5101
 Codon 140, 172 (R140, R172, 11 mutations)
 25 Tests/Kit

JAK2 PNAClamp™ JAK2
PNAC-6001
 Codon 617 (V617F)
 25 Tests/Kit

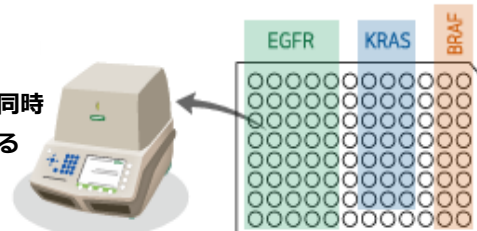
BCR-ABL PNAClamp™ BCR-ABL
PNAC-7001
 Codon 315 (T315I)
 25 Tests/Kit

c-KIT PNAClamp™ c-KIT
PNAC-8001
 Codon 816 (D816, 5 mutations)
 25 Tests/Kit

TERT PNAClamp™ TERT
PNAC-9001
 C228, C250 (promoter mutations)
 25 Tests/Kit

CFX96 only

様々な種類の
PNAClampkitを
一つのプレートで同時
にテスト、分析する
ことができる



 Detect DNA target

For more information, please visit | www.hlbpanagene.com

FEATURES

- 様々な種類のリアルタイムPCR機器との互換性
- 1つのプレートで様々なバイオマーカーを検査できる(例:EGFR、KRAS、BRAFなど)
- 高い感度と特異度を示す
- 少量のDNAだけで検査できる
- 「HLB Panagene MDx Analyzer」で検査結果を簡単に解釈できる

SPECIMEN / COMPATIBLE INSTRUMENT

- 組織 (Tissue – Fresh, FFPE)
- 生検 (Biopsy)
- 胸膜滲出液等 (Pleural effusions, etc)



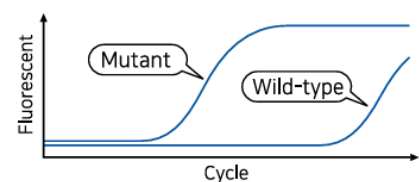
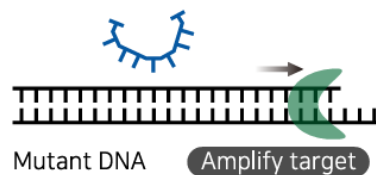
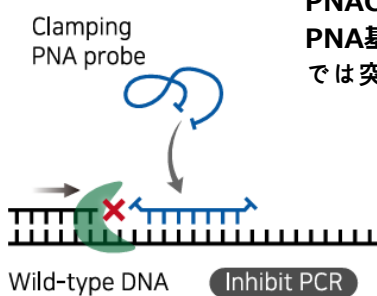
Guarantee Multiple PCR Platforms

Qiagen Rotor-Gene Q

Roche LC480 II

TECHNOLOGY

PNAClamp™技術はDNA混合物内で突然変異標的DNA序列だけを選択的に増幅するPNA基盤技術、PNAプローブwild-type DNAだけに結合して増幅を抑制し、PCR過程では突然変異DNAだけが増幅されます。



COMPARISON OF MUTATION DETECTION METHODS

	PNAClamp™ (HLB Panagene)	Company A	Company B
Technology	PNA-mediated clamping PCR (real-time PCR)	Scorpions™ & ARMS™ (real-time PCR)	Direct sequencing (Sanger sequencing)
Sensitivity	< 1%	< 1%	15 - 25%
Running time	2.5 hours	3 hours	11 hours
Simplicity	++++	++	+
Reproducibility	+++	++	++

► Multiplex detection

PANA RealTyper™

PRODUCTS/ DETAILED TARGET INFORMATION

HPV PANA RealTyper™ HPV Genotyping



PNAM-1001 48 Tests/Kit
40 HPV subtypes
(genotyping 22 + screening 18)

Genotyping subtypes

High risk - 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 70, 73, 82

Low risk - 6, 11

Screening subtypes

30, 32, 34, 40, 42, 43, 44, 54, 55, 61, 62, 67, 74, 81, 83, 84, 87, 90

HPV PANA RealTyper™ HPV 32 Genotyping



PNAM-1101 48 Tests/Kit
32 HPV subtypes (genotyping 32)

Genotyping subtypes

High risk - 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 70, 73, 82

Low risk - 6, 11, 32, 34, 40, 42, 43, 44, 54, 61, 72, 81

HPV PANA RealTyper™ HPV Screening



PNAM-5001 96 Tests/Kit
16 HPV subtypes
(genotyping 4 + screening 12)

Genotyping subtypes

High risk - 16, 18

Low risk - 6, 11

Screening subtypes

31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

STD PANA RealTyper™ STD 13



PNAM-2001 / PNAM-2003
13 STD pathogens
48 / 96 Tests/Kit

STD PANA RealTyper™ STD 7



PNAM-2001-A
7 STD pathogens
96 Tests/Kit

Genotyping species

Chlamydia trachomatis (CT)
Ureaplasma parvum (UP)
Trichomonas vaginalis (TV)
Mycoplasma genitalium (MG)
Mycoplasma hominis (MH)
Neisseria gonorrhoeae (NG)
Ureaplasma urealyticum (UU)
Haemophilus ducreyi (HD)
Treponema pallidum (TP)
Candida albicans (CA)
Gardnerella vaginalis (GV)
Herpes simplex virus type 1 (HSV1)
Herpes simplex virus type 2 (HSV2)

7

13

CRE PANA RealTyper™ CRE Genotyping



PNAM-4001 / PNAM-4002
6 CRE types
48 / 96 Tests/Kit

Genotyping subtypes

KPC (*Klebsiella pneumoniae* Carbapenemase)
IMP (Imipenemase)
GES (Guiana extended-spectrum)
NDM (New Delhi Metallo- β -lactamase)
VIM (Verona Integron-encoded Metallo- β -lactamase)
OXA48 (Oxacillinase)

For more information, please visit | www.hlbpanagene.com

FEATURES

- 高い感度と特異度
- 多重遺伝子型分析可能
- 高い再現性

**TB/
NTM**

PANA qPCR™ TB/NTM

PNAQ-1001

100 Tests/Kit

4 TB types, 19 non-TB acid-fast bacteria types

 N Number of reaction tubes per test

SPECIMEN / INSTRUMENT

**HPV
STD**

- 綿棒サンプル (Swab sample)
- 液状基盤細胞検査サンプル(Liquid based cytology sample)
- 尿 (STD)



Bio-Rad
CFX96

CRE

- 純粋培養菌(CRE)

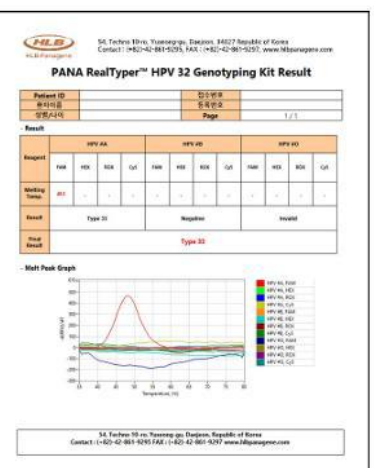
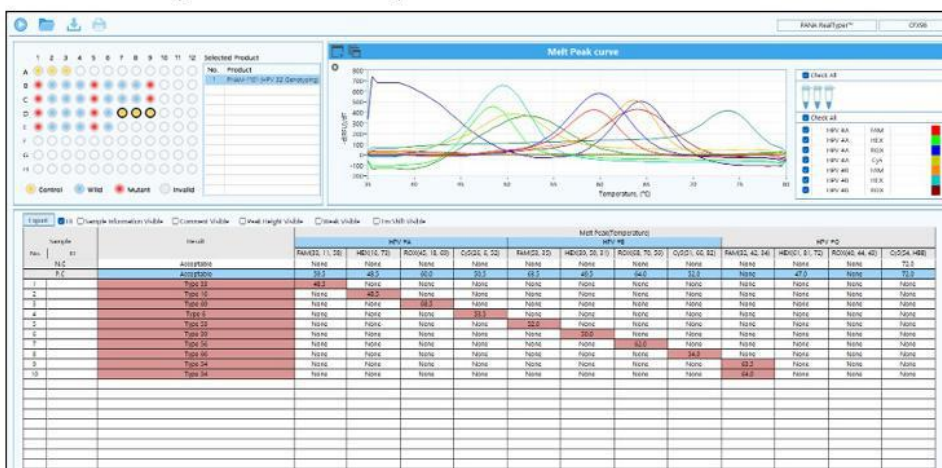
TB/NTM

- 痰、組織、便、尿
- 気管支洗浄液
- 体液(胸膜液、血液、骨髓液、脳脊髄液)
- 培養検査(固体培養及び液体培養)



ThermoFisher
QuantStudio 5

HLB Panagene MDx Analyzer





Automatic Nucleic Acid Extraction

PANAMAX™

PRODUCTS - INSTRUMENT

PANAMAX™ 48

PNAE-1001
48 samples/run



PANAMAX™ 16

PNAE-2001
16 samples/run

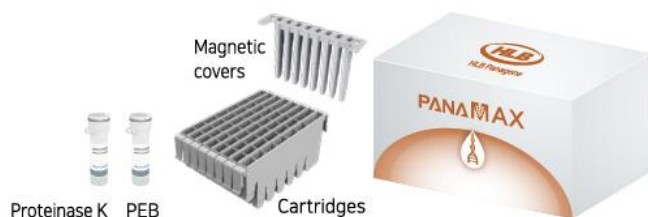


FEATURES

- 様々な種類のサンプル処理が可能
- Whole blood, Plasma, Cultured cells, Urine, Swab, BAL, Sputum, FFPE tissue
- 使いやすい
- multi-pipette 호환 가능, 10.1 inch touch screen
- 低騒音核酸抽出プロトコルおよび構造

	Specifications	
	PANAMAX™ 48	PANAMAX™ 16
Type	Silica magnetic bead technology	
No. of samples	1 to 48	1 to 16
Volume	200 µl to 5,000 µl	
TAT	25 - 90 minutes (depending on the sample and the running mode)	
Extraction volume	50 ~ 100 µl	
Extraction kit	Pre-filled, Ready-to-use	
Storage temperature	+15°C ~ +30°C	
Heating block	+30°C ~ +100°C	
Additional features	UV, Self check (Human error prevention), Firmware update, USB interface, Barcode reading (optional)	
PC	Built in PC with Touch Screen	Tablet Interface
Size (W x D x H) / Weight	420 x 380 x 545 mm / 27 Kg	380 x 304 x 370 mm / 17 Kg
Power	100 - 240V AC, 50-60Hz, 4A	

PRODUCTS - KIT



Viral PANAMAX™ Viral DNA/RNA

PNAK-1001 / PNAK-1002

From human Cervical swab, Vaginal swab, Nasal swab, Throat swab, Sputum
48 / 432 Preps/Kit

For more information, please visit | www.hlbpanagene.com

PRODUCTS - KIT

* FFPE: formalin fixed, paraffin embed

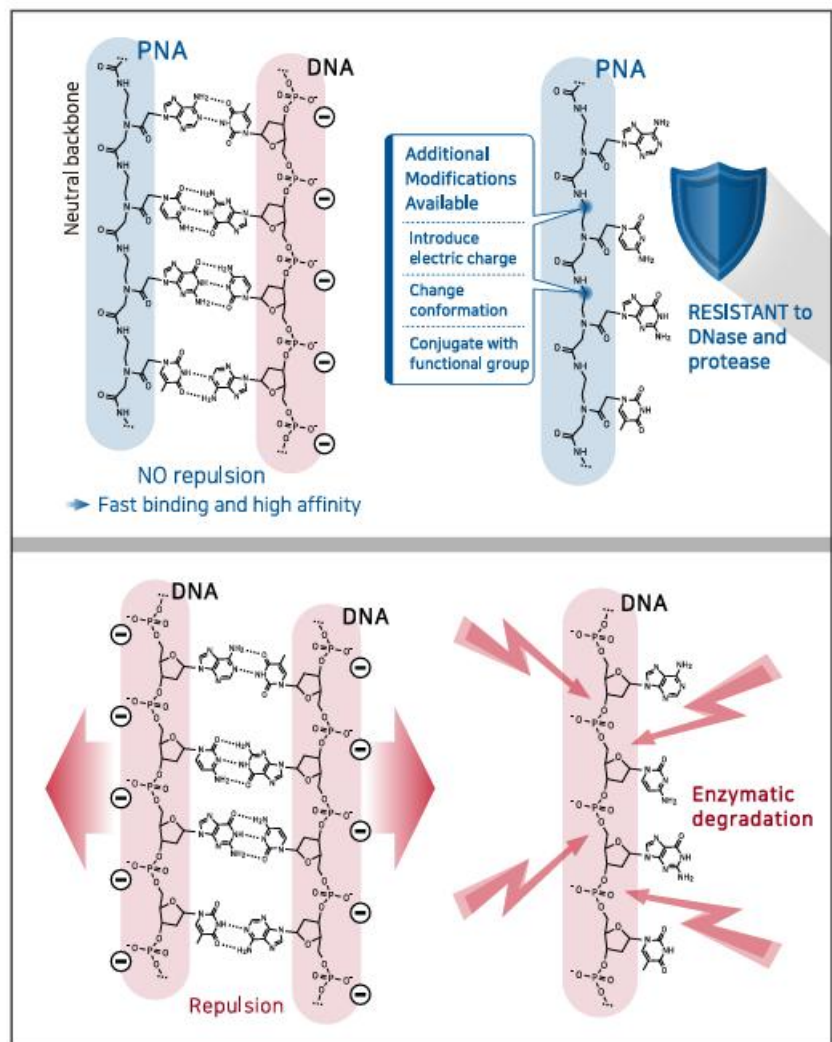
Plasma	PANAMAX™ Plasma ccfDNA PANAMAX™ Large volume Plasma ccfDNA PNAK-2001 / PNAK-5001 From human plasma sample 48 / 24 Preps/Kit
FFPE	PANAMAX™ FFPE DNA PNAK-3001 48 Preps/Kit From human FFPE tissue sample
FFPE	PANAMAX™ FFPE RNA PNAK-4001 48 Preps/Kit From human FFPE tissue sample
Blood	PANAMAX™ Blood DNA PNAK-6001 48 Preps/Kit From human whole blood
FFPE	PANAMAX™ FFPE Plus DNA PNAK-7001 48 Preps/Kit From human FFPE tissue sample
Viral	PANAMAX™ Viral Plus DNA PNAK-8001 48 Preps/Kit From human Cervical swab, LBC (liquid base cytology) sample
Tissue, Cell	PANAMAX™ Tissue/Cultured Cell DNA PNAK-9001 48 Preps/Kit From animal tissue, cultured cell
Animal	PANAMAX™ Animal tissue DNA PNAK-10001 48 Preps/Kit From animal tissue or blood sample
Plant	PANAMAX™ Plant DNA PNAK-11001 48 Preps/Kit From plant tissue sample
Food	PANAMAX™ Food DNA PNAK-12001 48 Preps/Kit From a wide range of food samples
Viral	PANAMAX™ Rapid Viral DNA/RNA PNAK-13001 48 Preps/Kit From human Cervical swab, human Vaginal swab
Blood	PANAMAX™ Large volume Blood DNA PNAK-14001 24 Preps/Kit From human whole blood
FFPE	PANAMAX™ FFPE DNA/RNA PNAK-15001 24 Preps/Kit From human FFPE tissue sample
Bacteria	PANAMAX™ Bacteria DNA PNAK-16001 48 Preps/Kit From Gram-negative bacteria, gram-positive bacteria, virus from Stool, Swab, Plasma, Urine sample

Key Raw Material for
HLB Panagene's Platform Technology

PNA (Peptide Nucleic Acid)

ADVANTAGES

- Neutral backboneは標的DNAに対する強い結合親和性を可能にする
- PNAの高いT_mは高い特異性を提供することができる
- 酵素的分解に対する抵抗性で高い安定性を確保
- 付随的な修正が簡単



APPLICATIONS

- microRNA阻害剤
- 抗原&アンチセンス (antisense & antisense)
- 診断プローブ
- 分子生物学とゲノム研究

PNA vs DNA	PNA	DNA
Binding affinity (with DNA)	At least 1°C higher T _m per base	-
Hybridization rate	100 - 5,000 times faster	-
Salt conc. in hybridization	Independent	Dependent
ΔT _m for single nucleotide mismatch	< 15°C	< 10°C
Chemical stability	Stable	Unstable in acidic or basic condition
Biological stability	Enzyme-resistant	Degradable by nuclease
Water solubility	Moderate (can be improved with modification)	High
General probe length	13 - 18 mer	25 - 30 mer

HLB Panagene provides Sample to Ans



ONCOLOGY		Products	Cat. No.	Details	Test
PANAMutyper™ R	EGFR	PNAR-3001		Exon 18, 19, 20, 21 (47 mutations)	24
	EGFR V2	PNAR-3002		Exon 18, 19, 20, 21 (+C797S, 46 mutations)	24
PANAMutyper™	ROS1	PNAR-6001		ROS1 gene fusion (20 mutations)	24
PNAClamp™	EGFR	PNAC-3002		Exon 18, 19, 20, 21 (40 mutations)	25
	KRAS	PNAC-1006		Codon 12, 13, 59, 61, 117, 146 (40 mutations)	25
	NRAS	PNAC-1101		Codon 12, 13, 59, 61, 117, 146 (43 mutations)	25
	BRAF	PNAC-2001		Codon 600 (V600, 5 mutations)	50
	PIK3CA	PNAC-4001		Codon 420, 542, 545, 546, 1047 (14 mutations)	25
	IDH1	PNAC-5001		Codon 132 (R132, 5 mutations)	25
	IDH2	PNAC-5101		Codon 140, 172 (R140, R172, 11 mutations)	25
	JAK2	PNAC-6001		Codon 617 (V617F)	25
	BCR-ABL	PNAC-7001		Codon 315 (T315I)	25
	c-KIT	PNAC-8001		Codon 816 (D816, 5 mutations)	25
	TERT	PNAC-9001		C228, C250 (2 promoter mutations)	25
OncoTector™	BRAF	PNAA-1001		Codon 600 (V600E)	24
	KRAS	PNAA-2001		Codon 12, 13 (G12C, G12D, G12V, G12A, G12S, G12R, G13C, G13D)	24
	ROS1	PNAA-6001		ROS1 gene fusion (14 mutations)	24
	c-MET RUO	-		Exon 14 Skipping	24
	EML4-ALK RUO	-		EML4-ALK gene fusion (20 mutations)	24
	RET RUO	-		RET gene fusion (18+ mutations)	24
	HER2 RUO	-		Exon 20 (19 mutations)	24
	NTRK RUO	-		Under development	-
	EGFR RUO	-		Under development	-
	FGFR RUO	-		Under development	-
	POLE RUO	-		Under development	-

INFECTIOUS DISEASES

	Products	Cat. No.	Details	Test
PANA RealTyper™	HPV	PNAM-1001	40 HPV types (22 genotyping + 18 screening)	48
	HPV 32 Genotyping	PNAM-1101	32 HPV (32 genotyping)	48
	HPV Screening	PNAM-5001	16 HPV types (4 genotyping + 12 screening)	96
	STD (13)	PNAM-2001 / PNAM-2003	13 STD pathogens	48 / 96
	STD (7)	PNAM-2001-A	7 STD pathogens	96
	CRE	PNAM-4001 / PNAM-4002	6 CRE types	48 / 96
PANA qPCR™	TB/NTM	PNAQ-1001	4 TB types, 19 non-TB acid-fast bacteria types	100
PathoTector™	STD 13 RUO	-	Under development	-
	STD 29 RUO	-	Under development	-
	HPV 32 RUO	-	Under development	-
	Mycoplasma RUO	-	Under development	-

EXTRACTION

	Products	Cat. No.	Details	Prep
Automated NA Extraction System	PANAMAX™ 48	PNAE-1001	Up to 48 samples per run	1~48
	PANAMAX™ 16	PNAE-2001	Up to 16 samples per run	1~16
Nucleic Acid Extraction Kit	Viral DNA/RNA	PNAK-1001 PNAK-1002	From human Cervical swab, Vaginal swab, Nasal swab, Throat swab, Sputum, Bronchoalveolar Lavage, Urine, Serum, and Plasma	48 432
	Plasma ccfDNA	PNAK-2001	From human Plasma sample	48
	Large volume Plasma ccfDNA	PNAK-5001	From human Plasma sample	24
	FFPE DNA	PNAK-3001	From human Formalin fixed, paraffin embedded (FFPE) tissue sample	48
	FFPE RNA	PNAK-4001	From human Formalin fixed, paraffin embedded (FFPE) tissue sample	48
	Blood DNA	PNAK-6001	From human Whole blood	48
	Viral Plus DNA	PNAK-8001	From human Cervical swab, LBC (liquid base cytology) sample	48
	FFPE Plus DNA	PNAK-7001	From human Formalin fixed, paraffin embedded (FFPE) tissue sample	48
	Tissue/Cultured Cell DNA	PNAK-9001	From animal tissue, Cultured cell	48
	Animal tissue DNA RUO	PNAK-10001	From animal tissue or blood sample	48
	Plant DNA RUO	PNAK-11001	From plant tissue sample	48
	Food DNA RUO	PNAK-12001	From a wide range of food samples	48
	Rapid Viral DNA/RNA RUO	PNAK-13001	From human Cervical swab, human Vaginal swab	48
	Large volume Blood DNA RUO	PNAK-14001	From human Whole blood	24
	FFPE DNA/RNA RUO	PNAK-15001	From human Formalin Fixed, paraffin embedded(FFPE) tissue sample	24
	Bacteria DNA RUO	PNAK-16001	Gram-negative bacteria, gram-positive bacteria, virus from Stool, Swab, Plasma, Urine sample	48



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