Pioneer in Precision Medicine

Deliver Precision Medicine for Better Health Care

We are committed to the delivery of safe, high quality products and services to yield improved healthcare options for our customers and their patients.

PLEXBIO™

Multiplex Solution for Better Health

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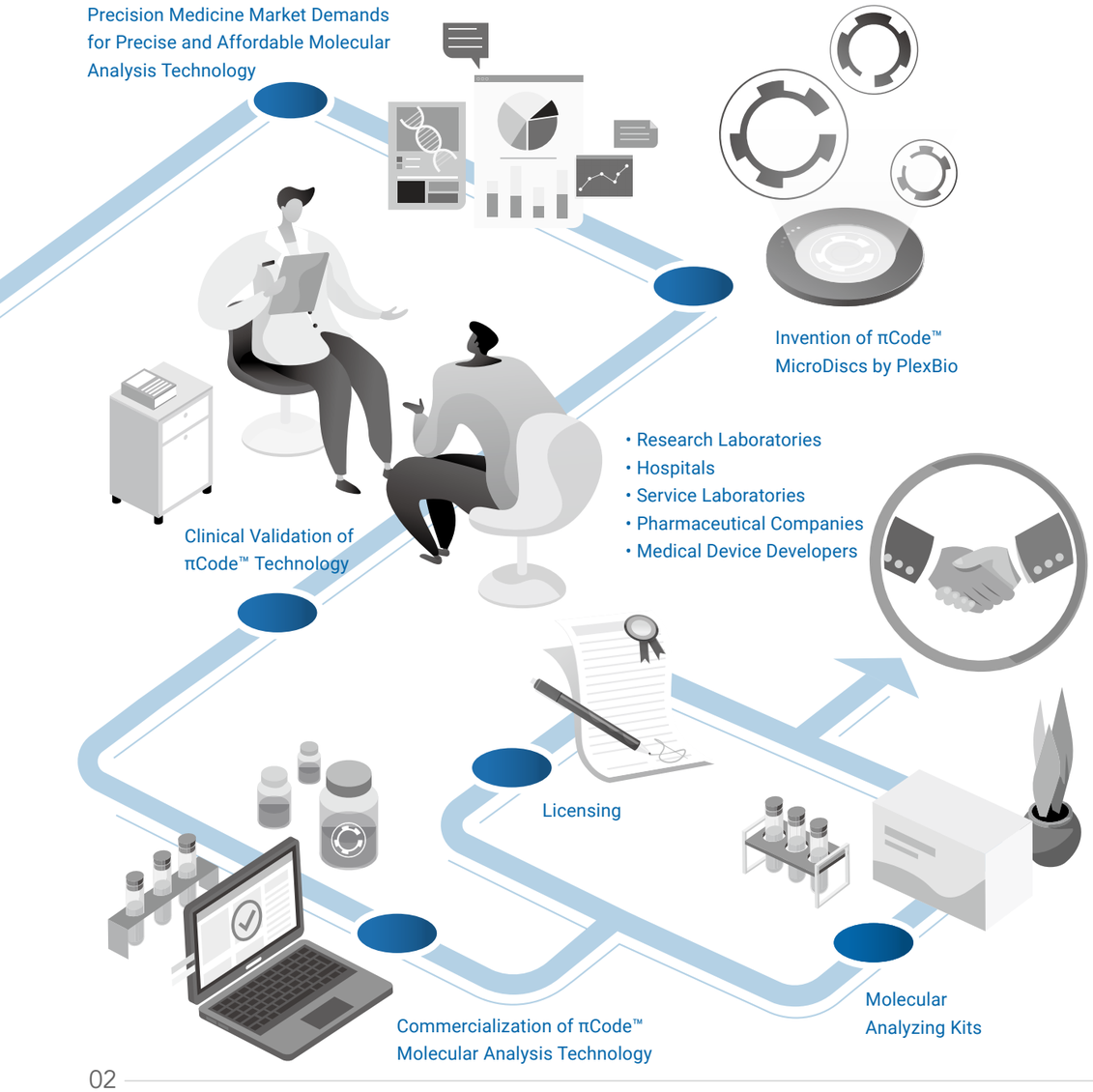
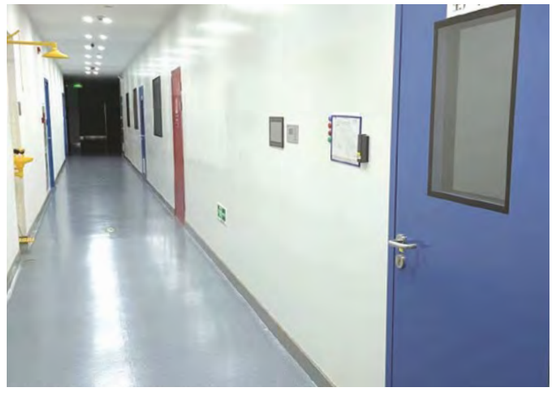
PlexBio is a world-leading IVD product inventor and manufacturer based in Taiwan. We possess the state-of-the-art patented technology - IntelliPlex™ platform and Precision Image Code (πCode™) MicroDiscs. This core technology allows multiplex assays to be applied to a variety of clinical diagnostics, enabling precision medicine to become routine practice.

We specifically focus on cancer diagnostics and monitoring, and have developed cancer panels covering over hundreds of gene mutations that can be simultaneously analyzed using noninvasive liquid biopsy from patients. We are committed to continuing our innovation to provide the most advanced IVD products for precision medicine.



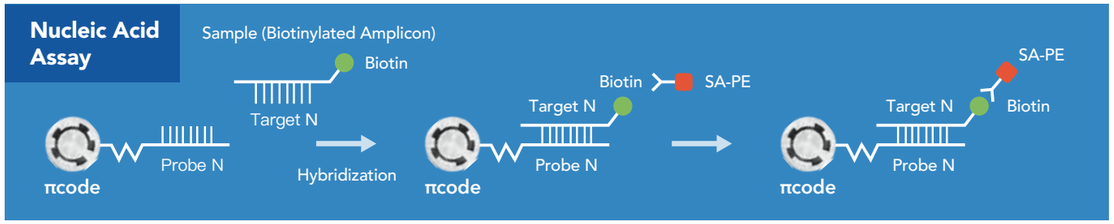
PlexBio Is Among The Top 500 Fastest Growing Technology Companies In Asia Pacific

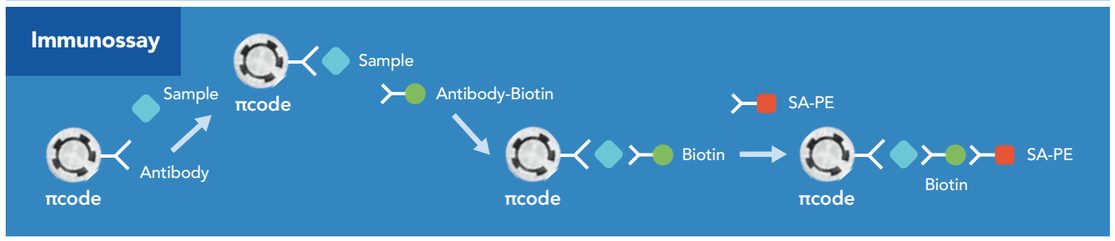
PlexBio is a world-leading innovator in the field of molecular diagnostics. Based in Taiwan, the company has been recognized consistently to be among the top 500 technology businesses in Asia-Pacific for the past three years running.

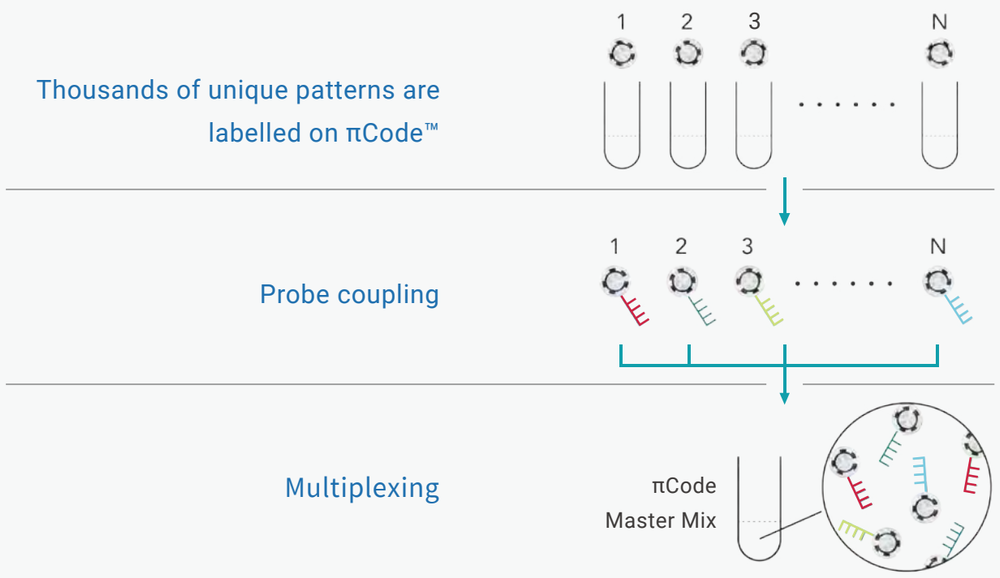


πCode™ System Overview

πCode™ MicroDisc is an innovative molecular analysis technology combining the advance in nanotechnology and semiconductor technology. πCode™ MicroDiscs are made of silicon wafers and have an extremely tiny size of 40 µm in diameter. Each πCode™ MicroDisc has an assigned distinct circular image pattern imprinted on its surface, and a specific capture agent, which can be either nucleic acid probe or antibody, conjugated to its surface. They are manufactured to generate more than 85,000 distinct circular image patterns for multiplexing applications. πCode™ MicroDiscs tagged with different capture agents are pooled, enabling specific detection of multiple analytes in one-well reaction.

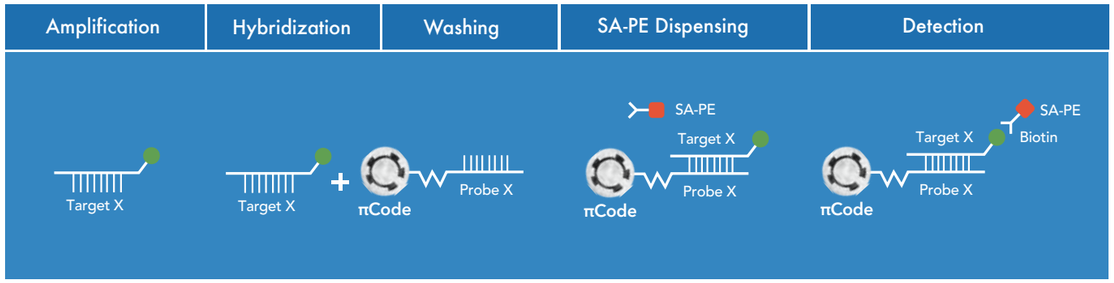


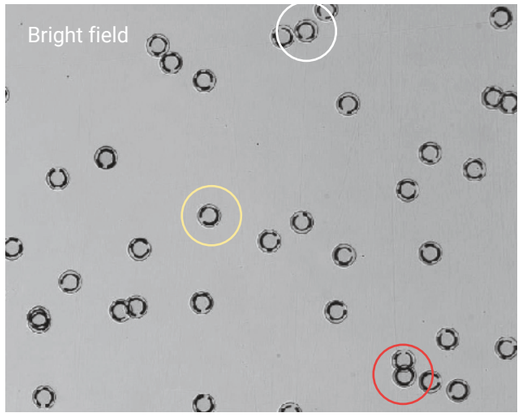


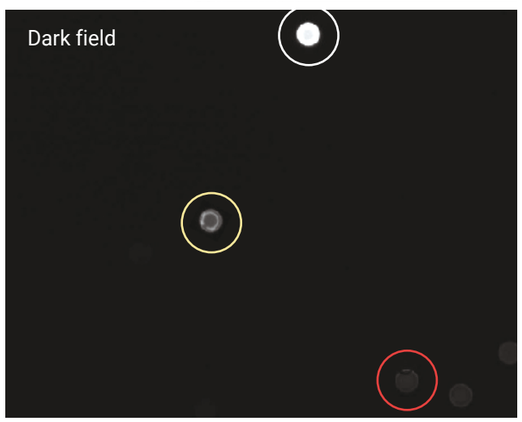


Automated Result Analysis

Result analysis is always a critical step determining the outcomes of every single assay. Some assays, for example NGS, can take up to days to analyze results, which would be unfavorable in some circumstance. With πCode™ assay, any successful hybridization of probes and their specific targets would emit fluorescence, which is detected and analyzed by fully automated PlexBio™ 100 Fluorescent Analyzer.







PlexBio™ 100 Fluorescent Analyzer takes dark field and bright field images. The dark field images, which are used to detect fluorescence signals, are colocalized with the bright field images in order to identify the unique circular patterns imprinted on the πCode™ MicroDiscs with positive signals. The system automatedly processes result interpretation and deliver result reports in 30 minutes.

PlexBio™ 100 Fluorescent Analyzer

IntelliPlex
Multiplexing Assay Workflow

Current Integrated Systems

Manual Extraction

Thermal Cycler

IntelliPlex™ 1000
πCode Processor

PlexBio™ 100
Fluorescent Analyzer

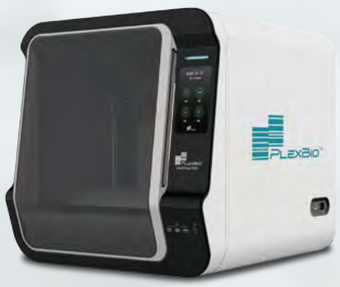
STEP 01 — **EXTRACTION**

STEP 02 — **AMPLIFICATION**

STEP 03 — **HYBRIDIZATION to SIGNALING**

STEP 04 — **DETECTION**

Future Automated Systems



TRIO 240 Automated
Nucleic Acid Extractor

IP5000
Automation System

CAT. 80033

IntelliPlex™ 1000 πCode™ Processor

The IntelliPlex™ 1000 πCode Processor is a fully automated workstation designed for πCode™ processing.Its 4-in-1 capabilities include πCode MicroDisc hybridization, washing, incubation, and labeling.

Instrument software includes built-in modes for PlexBio assays and the ability to program customized molecular or immunoassays on the 7-inch industrial touchscreen panel.

Touchscreen

+ Intuitive a 7-inch industrial panel
+ Real-time display of processing status

Shaking & Incubation

+ Adjustable time and temperature

Washing

+ Minimization of MicroDisc loss with movable magnetic plate
+ Automatic rinsing prevents tube blocking

Fluorescence Labeling

+ Automated fluorescence reagent dispensing

SPECIFICATIONS	
Model	IW100
OPERATION CONDITIONS	
Temperature/ Humidity	18° C ~ 32° C (64° F ~ 90° F)/20 ~ 80% RH, non-condensing
Altitude	Up to 2000 meters (6561 ft) above mean sea level
Storage Conditions	-10° C ~ 70° C (14° F ~ 158° F)/10 ~ 80% RH, non-condensing
PERFORMANCE	
Supported plates	96-well plate (Plexbio; Cat. No. 80025 or Greiner Bio-one; Cat. No. 655101)
Processing time (full plate)	3 ~ 8 min (one-time wash)
Shaking	Max. rate: 1200rpm
Incubator	Temperature range from RT+5° C to 60° C
Safety	Plate position sensor and door sensor
Temperature accuracy	± 0.5° C
Temperature uniformity	1° C
Shaking accuracy	≤ 10%
Dispensing accuracy	≤ ± 6%
Dispensing uniformity	≤ 4% CV
MicroDisc loss	Around ≥ 75% of MicroDiscs retained after whole processes.
Residual volume	≤ 5 µl/well (Measured under completed wash processes)
PHYSICAL CHARACTERISTICS	
Power	100-240V, 50-60Hz, 250W
Dimensions	Without Bottle Carrier:(W)408mm*(D)540mm*(H)470mm With Bottle Carrier: (W)554mm*(D)540mm*(H)470mm
Weight	38 kg (84 lbs)
Fuse rating	T 5A H 250V

CAT. 80000

PlexBio™ 100 Fluorescent Analyzer

The PlexBio™ 100 Fluorescent Analyzer is part of a multiplex suspension array platform which utilizes Precision Image Code (πCode™) MicroDisc technology for multiplexing both molecular and immunoassays. The PlexBio™ 100 Fluorescent Analyzer is a robust optical imaging system that decodes πCode MicroDiscs through fluorescence detection and high-contrast imaging.

Compatibilty

+ Compatible for detecting both molecular and immunoassay

Capacity

+ A high-throughput system analyzes up to 100-200 targets simultaneously in a single well

Convenience

+ Easy to maintain and no fluidic system that reduces the risk of contamination

Cost-effectiveness

+ Multiplexing improves productivity by reducing time, reagent, and sample volume

SPECIFICATIONS	
Model	PB100
OPTICS	
Coding	Image Pattern
Optics (Excitation)	LED
Optics (Detection)	CCD imager
A/D resolution	14 bits
Focus Lens	10x magnification
PERFORMANCE	
Supported plates	96-well plate (Plexbio; Cat. No. 80025 or Greiner Bio-one; Cat. No. 655101)
πCode Classification Accuracy	≥ 98%
πCode Recognition Precision (CV)	≤ 2.5%
MFI Precision (CV)	≤ 1.5%
Daily Start-Up	≤ 15 min
Reading Time	1 well ≤ 50 sec
PHYSICAL CHARACTERISTICS	
Power	100-240V, 50-60Hz
Dimensions	27.3 cm W x 54 cm D x 44.1 cm H
Weight	25 kg (55.0 lbs)
Connection	USB and Ethernet

CAT. 80042

TRIO 240
Automated Nucleic Acid Extractor

The IntelliPrep TRIO 240 System is an easy-to-use liquid handling workstation from nucleic acid (NA) extraction to PCR setup for downstream applications. It provides nucleic acid purification from a wide range of primary sample types, and can process up to 24 samples in a single run.

Product Highlights

Multifunctional Workstation

✚ Integrated with extraction, quantification, and PCR set up

Fully Automated Program

✚ One-step sample scanning for all subsequent automated procedure

Minimum Process Time

✚ Significantly reduces operation time and human error, and compeletes the process in 85 minutes

Built-in UV Sterilization

✚ Eliminates the risk of cross-contamination for reliable assay results

TRIO 240 Workflow

QR Code Reading for Assays → Auto-Sample Scanning → Nucleic Acid Extraction → Nucleic Acid Quantification → PCR Plate Setup

SPECIFICATIONS	
Model	TRIO 240
Throughput	Up to 24 samples per run
Storage Conditions	-10~70 ° C, 10 ~ 80% RH non-condensing
Operation Conditions	15~35 ° C, 10 ~ 80% RH non-condensing
Extraction Performance	
Pipette Type	Fixed 24 channel
Pipette Range	50 µL~1000 µL
Pipette Consistency	50 µL < 5% ; 100 µL < 1% ; 500 µL < 0.5%
Pipette Accuracy	50 µL < ±7% ; 100 µL < ±3% ; 500 µL < ±2.5%
Temperature Control Range	Ambient ~ 95° C
Temperature Control Accuracy	±5°C at 60°C
Temperature Control Uniformity	8°C at 60°C
Robot Arm Positioning Accuracy	±0.1 mm
Processing Time	85 minutes, varies by kit
Physical Characteristics	
Power	100-240V, 50-60Hz
Dimensions	660 mm x 830 mm x 759 mm (WxDxH)
Weight	110 kg (242.5 lbs)

CAT. 80041

IP5000
Automation System

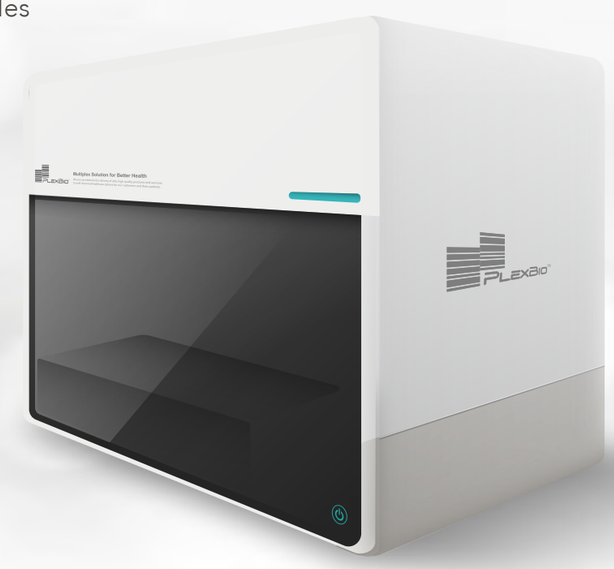
Automated integrating workstations from PCR amplification to πCode detection and analysis, the precise liquid handling modules effectively simplified assay workflow without repeatedly moving in and out for reaction plates, reducing human error risks and cross-contaminations to achieve reliable assay performance.

PRODUCT HIGHLIGHTS

- Seamless workflow from PCR amplification, Hybridization, Washing, Signaling to πCode Detection and Analysis
- Automated Reporting
- Reduce 90% Hands-on Time
- Precise Liquid Handling
- High-throughput for 96-sample reporting in 4 hours
- Save Time, Labor, Reagents and Samples

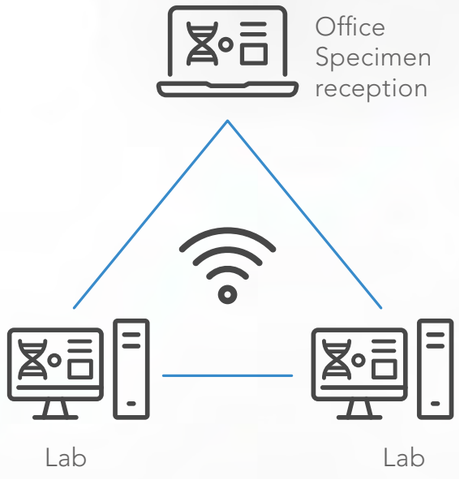
PATENTS

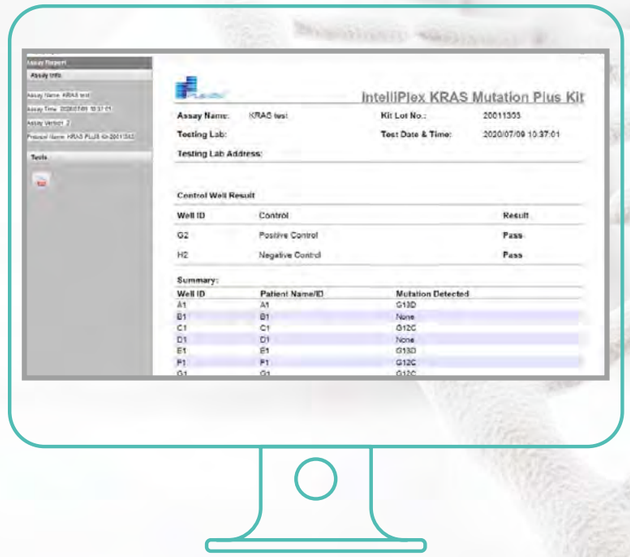
- US9063044B2 (Magnetic aggregating and washing)
- US10436776B2 (Methods and systems for selection of detection area)
- US10019815B2 (Methods and systems for image differentiated multiplex assays)



Automated Reporting Fully Data Traceability

DeXipher Network Configuration





Specifications	
Model	IP 5000
Operation Temperature	15° C~32° C
Storage Conditions	-10° C~70° C/ 10~80% RH non-condensing
Processing Time (Hybridization, Washing, SA-PE Signaling, Detection)	≤ 120min
Dispensing accuracy	Accuracy: 150uL ± 5%
Dispensing uniformity	Precision: CV ≤ 3%
Throughput	96 Samples
Assay Types	96 well Plate
Supported Plate Types	• U-bottom plate • F-bottom plate • PCR plate

PlexBio is Your Best Partner for Precision Medicine

Mutation Panel by IntelliPlex™

Probes are designed to pick up the mutations of the genes known to be associated with cancers. Multiplexing is designed to analyze selected targets in one reaction.

Gene / Cancer type	DNA								RNA			
	KRAS	BRAF	EGFR	NRAS	PIK3CA	HER2	AKT1	MEK1	ALK	ROS1	RET/ NTRK1	MET
Colorectal	V	V	V	V	V							
Lung	V	V	V	V	V	V	V	V	V	V	V	V
Pancreas	V											
Endometrial	V				V		V	V				
Melanoma	V	V										
Thyroid		V										
Breast					V							

IVD approval labeled in red

CAT. 82020

IntelliPlex™ NRAS Mutation Kit

The IntelliPlex™ NRAS Mutation Kit is a qualitative molecular assay for the detection of clinically actionable somatic mutations on exon 2-4 of the NRAS gene. A total of 33 mutations can be analyzed in a single well by using πCode MicroDisc and the SelectAmp PCR Technologies.

Product Highlights

- Single-well multiplex detection
- High sensitivity (0.5-2.9 % LoD)
- Low DNA sample input (10ng)
- <5 hours turnaround time for 96 samples (sample extraction not included)

CAT. 82004

IntelliPlex™ BRAF V600 Mutation Kit

The IntelliPlex™ BRAF Mutation Kit is a qualitative molecular assay for the detection of clinical actionable somatic mutations on exon 15 of the BRAF gene. A total of 7 mutations can be analyzed in a single well by using πCode MicroDisc and SelectAmp PCR Technologies.

Product Highlights

- Single-well multiplex detection
- High sensitivity (0.29-1.57 % LoD)
- Low DNA sample input (10ng)
- <5 hours turnaround time for 96 samples (sample extraction not included)

CAT. 82022

IntelliPlex™ KRAS Mutation Plus Kit

The IntelliPlex™ KRAS Mutation Plus Kit is a qualitative molecular assay for the detection of clinically actionable somatic mutations on exon 2-4 of the KRAS gene. A total of 27 mutations can be analyzedd in a single well by using πCode MicroDisc and the SelectAmp PCR Technologies.

Product Highlights

- Single-well multiplex detection
- High sensitivity (0.36-1.83 % LoD)
- Low DNA sample input (10ng)
- <5 hours turnaround time for 96 samples (sample extraction not included)

CAT. 82023

IntelliPlex™ ALK Rearrangement Kit

The IntelliPlex™ ALK Rearrangement Kit is a qualitative molecular assay for the aberrant gene fusions detection on EML4-ALK, KIF5B-ALK, and TFG-ALK transcripts. The kit utilizes one-step RT-PCR and PlexBio's core πCode technology which enables 24 ALK variants to be identified in a single well using RNA samples extracted from formalin-fixed paraffin-embedded tissues (FFPET).

Product Highlights

- Detect 24 ALK fusion variants in one well test
- High sensitivity (5~1209 copies LoD)
- Only ≥50ng RNA sample required
- <5 hours turnaround time for 96 samples (sample extraction not included)

CAT. 82024

IntelliPlex™ ROS1 Rearrangement Kit

The IntelliPlex™ ROS1 Rearrangement Kit is a qualitative molecular assay for the aberrant gene fusions detection on ROS1 gene. The kit utilizes one-step RT-PCR and PlexBio' s core πCode technology which enables 14 ROS1 fusion variants to be identified in a single well using RNA samples extracted from formalin-fixed paraffin-embedded tissues (FFPET).

Product Highlights

- Detect 14 ROS1 fusion variants in one well test
- High sensitivity (≤ 5~120 copies LoD)
- Only ≥50ng RNA sample required
- <5 hours turnaround time for 96 samples (sample extraction not included)

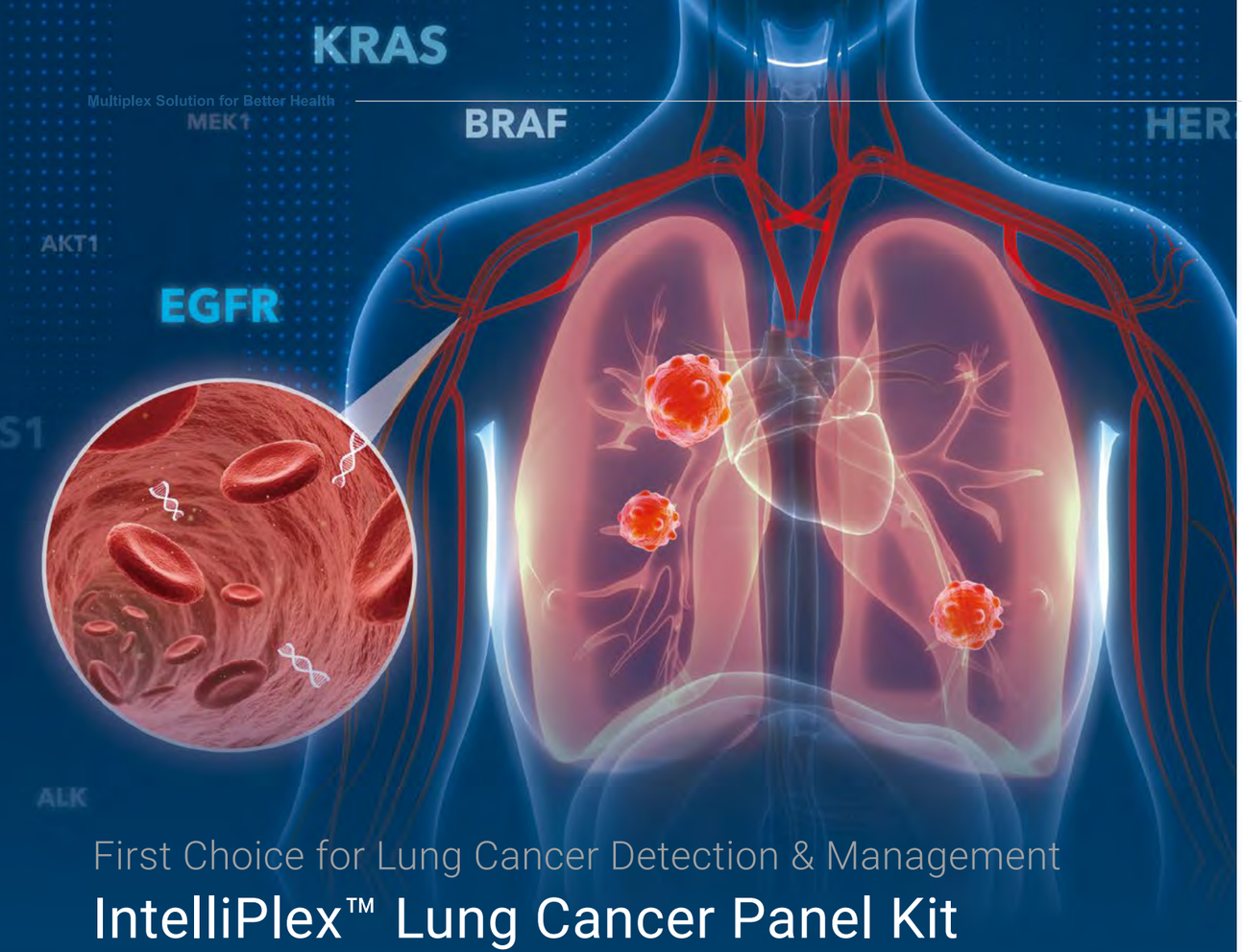
CAT. 82025

IntelliPlex™ RET/NTRK1 Rearrangement Kit

The IntelliPlex™ RET/NTRK1 Rearrangement Kit is a qualitative molecular assay for the aberrant gene fusions detection on RET and NTRK1 genes. The kit utilizes one-step RT-PCR and PlexBio's core πCode technology which enables 14 RET and NTRK1 fusion variants to be identified in a single well using RNA samples extracted from formalin-fixed paraffin-embedded tissues (FFPET).

Product Highlights

- Detect 14 RET and NTRK1 fusion variants in one well test
- High sensitivity (12~486 copies LoD)
- Only ≥50ng RNA sample required
- <5 hours turnaround time for 96 samples (sample extraction not included)



First Choice for Lung Cancer Detection & Management

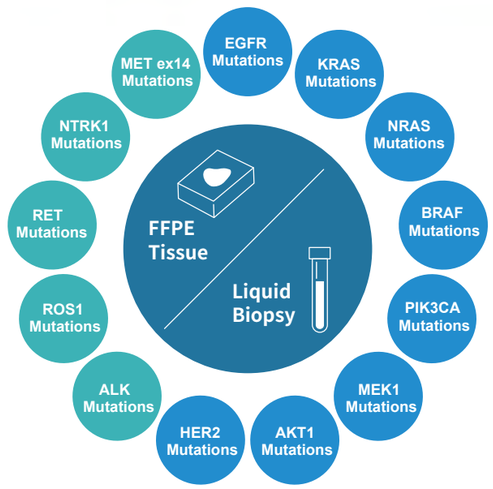
IntelliPlex™ Lung Cancer Panel Kit

+ Comprehensive Coverage

74 mutations of KRAS, NRAS, PIK3CA,
BRAF, EGFR, HER2, MEK1 and AKT1 genes
28 gene fusions of ALK, ROS1, RET, NTRK1
and MET genes

+ High Sensitivity

cfDNA : 0.1~2.32 % LoD
cfRNA : 10~89 copies LoD
FFPE DNA : 1~2.5 % LoD
FFPE RNA : 10~89 copies LoD



+ Low Sample Input

DNA : ≥10ng
RNA : ≥50ng

+ Quick Turnaround

From sample to report
in less than 5 hours

PLEXBIO™

CAT. 82030

IntelliPlex™ Lung Cancer Panel-cfDNA

CAT. 82032

IntelliPlex™ Lung Cancer Panel-DNA

The IntelliPlex™ Lung Cancer Panel is a qualitative molecular assay for the detection of mutations that are clinically actionable for targeted therapy for non-small cell lung cancer (NSCLC). The assay detects 74 DNA mutations in the KRAS, NRAS, PIK3CA, BRAF, EGFR, HER2, AKT1, MEK1 genes derived from plasma or FFPE of patients with NSCLC.

Comprehensive Coverage

+ 74 mutations of KRAS,NRAS, PIK3CA, BRAF, EGFR, HER2, MEK1 and AKT1 genes

High Sensitivity

+ cfDNA: 0.1-2.32% LoD
FFPE DNA: 1~2.5 % LoD

Low Sample Input

+ DNA: ≥10ng

Quick Turnaround

+ From sample to report in less than 5 hours

CAT. 82031

IntelliPlex™ Lung Cancer Panel-cfRNA

CAT. 82033

IntelliPlex™ Lung Cancer Panel-RNA

The IntelliPlex™ Lung Cancer Panel is a qualitative molecular assay for the detection of variants that are clinically actionable for targeted therapy selection in non-small cell lung cancer (NSCLC). The assay detects 28 variants of the ALK, ROS1, RET, NTRK1 and MET genes using cell-free RNA derived from plasma or FFPE of patients with NSCLC.

Comprehensive Coverage

✚ 28 gene fusions of ALK, ROS1, RET, NTRK1 and MET genes

High Sensitivity

✚ cfRNA: 10-89 copies LoD
FFPE RNA: 10-89 copies LoD

Low Sample Input

✚ RNA: ≥50 ng

Quick Turnaround

✚ From sample to report in less than 5 hours

PlexBio Product Portfolio

Item	Cat. NO.	Product Name
Single Gene Mutation Kits	82004	IntelliPlex™ BRAF V600 Mutation Kit
	82006	IntelliPlex™ EGFR Mutation Kit
	82020	IntelliPlex™ NRAS Mutation Kit
	82021	IntelliPlex™ PIK3CA Mutation Plus Kit
	82022	IntelliPlex™ KRAS Mutation Plus Kit
	82023	IntelliPlex™ ALK Rearrangement Kit
	82024	IntelliPlex™ ROS1 Rearrangement Kit
	82025	IntelliPlex™ RET/NTRK1 Rearrangement Kit
Lung Cancer Panel Kits	82030	IntelliPlex™ Lung Cancer Panel-cfDNA
	82031	IntelliPlex™ Lung Cancer Panel-cfRNA
	82032	IntelliPlex™ Lung Cancer Panel-DNA
	82033	IntelliPlex™ Lung Cancer Panel-RNA
Infectious Disease Kits	82303	IntelliPlex SARS-CoV-2 Detection Kit
	82304	IntelliPlex™ SARS-CoV-2/Flu Kit
	82306	IntelliPlex™ SARS-CoV-2 Detection Test Kit
	82307	IntelliPlex™ SARS-CoV-2 Variant Analysis Kit
	82302	IntelliPlex™ HPV Genotyping Kit

PLEXBIO™

Multiplex Solution for Better Health

We are committed to the delivery of safe, high quality products and services to yield improved healthcare options for our customers and their patients.

RUO

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Statement