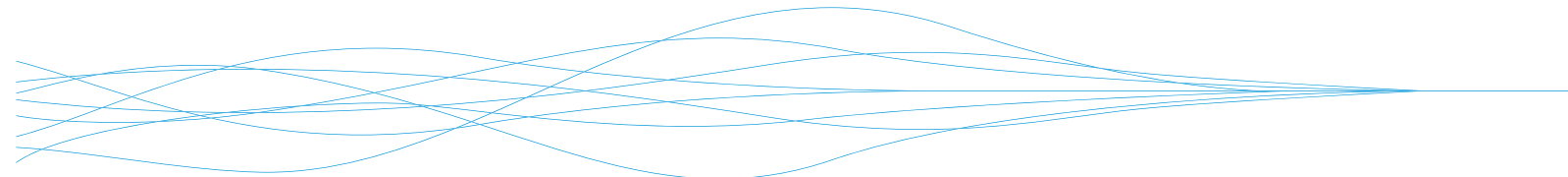
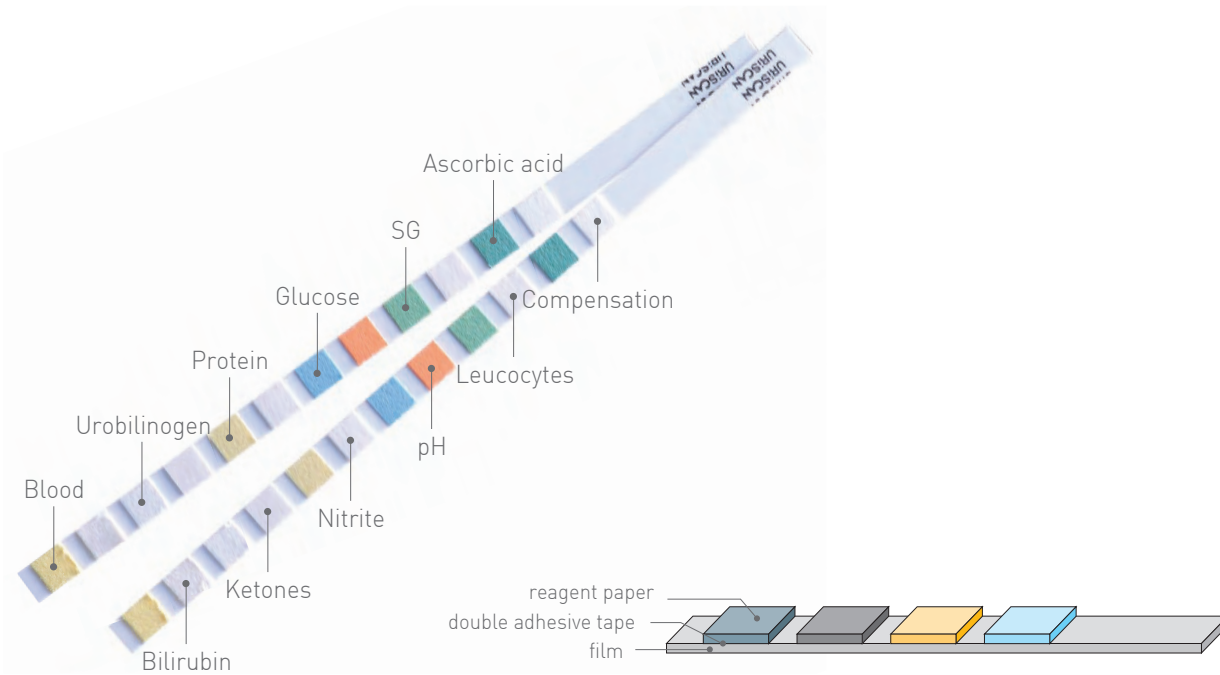


Most reliable & accurate Urine test strip.

URiSCAN® Strip

Most reliable & accurate Urine test strip.



Feature

- ✦ **Convenient to use for both of visual and analyzer**
 - Long handling part and easy bending for small sample volume.
- ✦ **Satisfy user's needs with 14 different items**
 - Well designed test position from Blood to Ascorbic Acid.
- ✦ **Accuracy, precision, reproducibility and stability**
 - With more than 40 years experience proved by world wide customers over 116 countries
- ✦ **Ascorbic Acid Warning System**
 - Free from false report caused by Ascorbic Acid
 - Ascorbic Acid pad indicate concentration of Vitamin-C in urine.
- ✦ **Compensate urine color with Compensation Area.**
 - Unusual color of urine can be reported and compensated.
- ✦ **CE marked and FDA approved for professional use and self-test**

* Optimized for URiSCAN Reader

Product line

Item No.	Test Portion		Blood	Bilirubin	Urobilinogen	Ketones	Protein	Nitrite	Glucose	pH	S.G	Leucocytes	Ascorbic Acid
	Product name	Package size (Tests)											
U11	1 Protein strip	50/100					■						
* U12	4 Hemo GPH strip	100	■				■		■	■			
U15	1 Ketones strip	50/100				■							
U19	1 Glucose strip	50/100						■					
U20	2 GP strip	100					■		■				
U21	3 GPH strip	100					■		■	■			
* U22	5 Hemoketo GPH strip	100	■				■		■	■			
U24	2 Gluketo strip	50/100				■		■	■				
* U25	6 L strip	100	■				■		■	■		■	
* U26	8 strip	100	■	■	■	■	■	■	■	■			
* U27	7 strip	100	■	■	■	■	■	■	■	■			
* U37	9 SG strip	100	■	■	■	■	■	■	■	■	■		
* U39	10 SGL strip	100	■	■	■	■	■	■	■	■	■	■	
* U41	11 strip	100	■	■	■	■	■	■	■	■	■	■	■



URiSCAN[®] *Optima*

Most compact & full featured
urine chemistry analyzer



URISCAN[®] Optima

Most compact & full featured
urine chemistry analyzer



Easy access to review test results
(printout data selectable)



4.3" Touch Screen TFT LCD
Software available in English, German,
Spanish, Italian, Polish, French,
Chinese and Russian



Interface for the external
barcode reader,
PC and lab network system
Easy connect by 2 USB port



Memory capacity :
2,000 test results
Simple calibration
Easy data management & various
data printing format
Workable with 4-11 parameter strips

Reflection photometer : CCD color
image sensor (Image capture) and
3 LED for light source
Color and clarity reading available



Support two different test modes :
36 or 300 tests per hour
Can be changed to Rapid test Cartridge
(Applicable by the Version)

Technical Specifications

Operation mode	Semi-automatic urine analyzer
Materials	ABS resin
Dimension	210mm[W] x 240mm[D] x 90mm[H]
Weight	970g(2.13lb)
Rated voltage	100 - 240V
Rated frequency	50/60Hz
Rated power	42W
Operating conditions	Temperature : 10°C 40°C (50°F 104°F) Humidity : 10% 70%
Storage conditions	Temperature : 0°C 40°C (32°F 104°F) Humidity : 10% 85%
Measurement method type	Reflectance photometers
Test capacity	Routine mode : 36 tests/hour Quick mode : 300 tests/hour

Measurement cycle	Routine mode : 100 seconds Quick mode : 6 seconds
Memory capacity	2000 Patient data
Sensor	CCD color image sensor
Light source	LED
Result display	4.3" TFT LCD (480 x 272)
Printer	High speed thermal printer 203dpi(8dots/mm)
Host Communication	Bi directional RS 232C interface for data transfer to HOST
Peripherals	Barcode reader, External printer
Safety standard	EN / IEC 61010 1
EMC standard	Emission EN55011/A1:1997,A2:1996,Group 1, ClassA Immunity EN 61000 4 2/3/4/5/6/11
Approval	CE, FDA

Free voltage

Easy access to review test results (printout data selectable)

Possible to connect to the PC or to the lab network system.

Highest throughput: 720 tests per hour

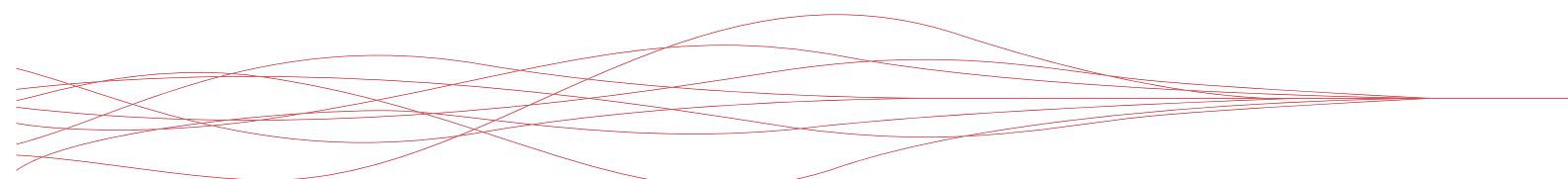
Software available in English, German, Spanish, Italian, Polish, Chinese and Russian

**Memory capacity : 1,000 test and 300 control data
Simple Calibration
Easy Data management & various data printing format
Workable with 4-11 parameter strips**

**Reflection photometer :CCD Color image sensor and LED for light source
Color and Clarity reading available**

URiSCAN[®] PRO II

World's Fastest Urine Chemistry Analyzer



Technical Specifications

Operating Mode	Semi-automatic urine analyzer
Dimension	465mm(W) X 440mm(D) X 246mm(H)
Weight	6Kg (13.50 lb)
Electrical Input Rated Voltage	110 - 240V
Rated Frequency	50/60Hz
Rated Power	75W
Operating Conditions	Temperature : 10°C - 40°C (50°F - 104°F) Humidity : 10% - 70%
Storage Conditions	Temperature : 0°C - 40°C (32°F - 104°F) Humidity : 10% - 85%

Measurement Method Type	Reflectance photometers
Test Capacity	720 tests per hour
Measurement cycle	5 seconds
Memory Capacity	1000 tests Patient data, 300 tests Control data
Sensor	CCD color image sensor
Light Source	LED
Result Display	LCD (8 lines, 4 char/line)
Printer	High speed thermal-printer 203dpi (8dots/mm)
Host- Communication	Bi-directional RS 232C interface for data transfer to HOST
Peripherals	Barcode reader, External Printer
EMC Standard	Emmission EN55011/A1:1997, A2:1996, Group1, Class A Immunity EN61000-4-2/3/4/5/6/11

URISCAN[®] Super +
 High-end Fully Automated Urine Chemistry Analyzer

Technical Specifications	
Dimension	536mm(W) x 686mm(D) x 535mm(H)
Weight	70Kg
Voltage	110V - 240V (50~60Hz), free voltage
Measurement Method	Test Type: CCD image scanner Throughput : 200 tests per hour Test parameters : Blood, Bilirubin, Creatinine, Urobilinogen, Ketones, Protein, Nitrite, Microalbumin, Glucose, pH, Leukocytes, Ascorbic acid, Color S.G(By Refractometer), Clarity(By Turbidimeter) Sensor : CCD image scanner Memory capacity : more than 1,000,000 patient test results, 500 control results Light source: LED
Display	8.4" LCD touch screen
Reagent Volume	400 samples at once
Sample Volume	Min 1.5 ~2.0ml
Sample Rack	Standard 10-position rack
Sample Loading	100 samples at one time
STAT sample	Handling 1 stat in the rack
Operating Condition	Temperature: 15~30°C, Humidity: 20~80%
Approval	CE



“ Take advantage !! ”
MicroAlbumin / Creatinine test

Touch screen LCD

Menu driven 8.4" large color touch LCD for convenient operation
Display the real view of the test strip image during operation



Cassette room

Double-sealed Super Strip Cassette for extended on-board stability
New Strip delivery System : Elevator system for strip loading



Interface

Various interfaces such as 4 USB, RS232C, serial interface, 2 PS/2, parallel, Ethernet
Easy integration into the lab and hospital network system

Single probe

Detect liquid level and aspirate together

Sample loading

Capable of loading up to 100 samples at once



Refractometer&Turbidimeter with CCD Image Scanner

Built in refractometer for S.G and Turbidimeter for turbidity
Accurate result by CCD Image Scanner



Syringe pump

Adoption of high performance 5ml syringe pump for precise sample treatment



Integrated barcode reader for sample ID

Apply advanced barcode reader(300 scans/sec)

Waste pump

Built-in waste pump for effective discharge of waste liquid

STAT Position

Enable to test urgent sample during normal operation



Able to test Microalbumin and Creatinine in 13 parameter Super+ strip Cassette

- Test parameters : Blood, Bilirubin, Creatinine, Urobilinogen, Ketones, Protein, Nitrite, Microalbumin, Glucose, pH, Leukocytes, Ascorbic acid, Color S.G(By Refractometer), Clarity(By Turbidimeter)
- Accurate and reliable performance by using proven URISCAN test strips
- Load 400 tests at one time using ready-to-use Super+ Strip Cassette
- Double-sealed Super Strip Cassette for extended on-board stability

Unique cassette type reagent supply system simplifies loading and operation

- Load the maximum of 400 tests at once for optimized reagent replacement time
- Cassette type reagent format minimizes reagent handling time

Easily integrates into the lab and hospital network system via Ethernet.

Using standard 10-Position rack ensures easy lab integration

Color LCD touch screen with friendly GUI makes the analyzer ease of use, quick and convenient

EASYPREP®

Fully Automated Liquid Based Cytology System



EASYPREP®

Fully Automated Liquid Based Cytology System



Slide Plate Module :
Slide smear module consist with Plate, Slide, Slide Chamber
Minimum 8 ,Maximum64 Slides



Touch Screen Monitor :
17" TFT LCD
Manage option and sequence
Display the process

Tip Jig module

Suction & Reagent module :
Remove Supernatant by
Suction control & Density
gradient solution

Clamp module



Sample Holder :
Set 32 vials in one time



Reagent container :
Set 4 Reagent (Gradient Density Reagent,
Fixative Solution, Suspension Buffer, Rinse Solution)
Waste Box



Centrifuge Module :
Auto-Position control System
Max 3000 rpm



Gynecological Preservative



Non-Gynecological Liquid



Non-Gynecological Mucous



Non-Gynecological Punctuation

Technical Specifications

✕ Dimension	1,431mm[W] × 1,129mm[D] × 1,230mm[H]
✕ Weight	450 Kg
✕ Rated voltage	AC 200 – 250V (50Hz/60Hz)
✕ Rated power	5 KW
✕ Storage conditions	0 – 40°C
✕ Operation	Full Automation
✕ Cell transfer method	Subsidence

✕ Quickness	64T/H
✕ Sample cell circle	15mm
✕ Certifications	KFDA, CE
✕ Back ground	Remove inflammation cell
✕ Mucus	Partially
✕ HPV test	Possible
✕ Work force(8h/day)	500T/1person

Product Line of Rapid Test

Cardiac marker test

- ✦ ImmunTech Cardiac Triple test

Tumor marker test

- ✦ OcculTech FOB Rapid Test
- ✦ ImmunTech AFP
- ✦ ImmunTech CEA
- ✦ ImmunTech PSA

Fertility test

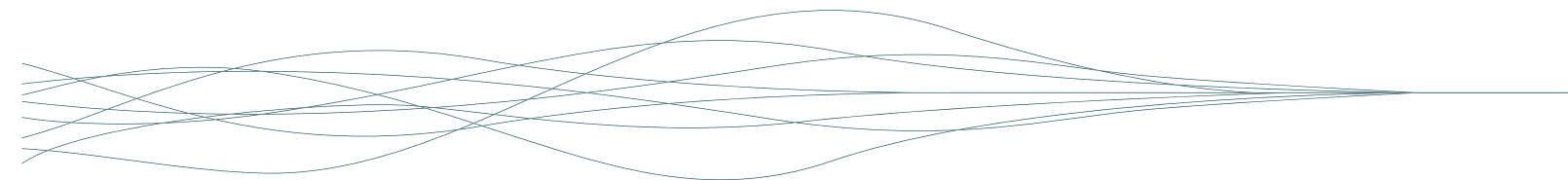
- ✦ PREG-Q Early Pregnancy Test

Infectious disease test

- ✦ HepaScan HBsAg
- ✦ HepaScan Anti-HBs
- ✦ HepaScan HBsAg/HBeAg Combo
- ✦ AIDScan Anti-HIV(1/2)
- ✦ ImmunTech H.pylori

ImmunTech

Immunochromatographic Assay System



Product List

Product Name	Packages	Analytes	Features
INFECTIOUS DISEASE	HepaScan HBsAg (Hepatitis B Virus Test) 100 tests(10 tests X 10/Box) 50 tests-Strip type (25 strips X 2/Box)	HBsAg	<ul style="list-style-type: none"> • Sensitivity: Antigen test - 2ng/mL • Antigen test - 10mIU/mL(Agree with EIA results) • Results within 5-20 minutes • Specimen: Human serum/Plasma
	HepaScan Anti-HBs (Hepatitis B Virus Test)	Anti-HBs	
	HepaScan Anti-HCV (Hepatitis C Virus Test) 30 tests(1 test X 30/Box) 100 tests(10 tests X 10/Box)	Anti-HCV	<ul style="list-style-type: none"> • Results within 5-20 minutes • Simple one-step method • Specimen: Human serum/Plasma/whole blood
	HepaScan HBsAg/HBeAg Combo (Hepatitis B Virus Test) 30 tests(1 test X 30/Box) 100 tests(10 tests X 10/Box)	HBsAg/HBeAg	<ul style="list-style-type: none"> • Detect envelope and surface antigens • Specimen: Human serum/plasma
	AIDScan Anti-HIV(1/2) 30 tests(1 test X 30/Box) 100 tests(10 tests X 10/Box)	Anti-HIV(1/2) type	<ul style="list-style-type: none"> • Detect antibodies of all isotype(IgG, IgM, IgA) specific to HIV-1 and HIV-2 • Results within 5-20 minutes • Simple one - step method • Specimen: Human serum/plasma/whole blood
	ImmunTech H.Pylori 30 tests(1 test X 30/Box) 100 tests(10 tests X 10/Box)	Anti-Helicobacter pylori	<ul style="list-style-type: none"> • Simple one-step method • Specimen: Human serum/plasma • Results within 5-10 minutes
TUMOR MARKER	OcculTech Fecal Occult Blood Rapid Test 20 tests(1 test X 20/Box) 100 tests(10 tests X 10/Box)	Occult blood	<ul style="list-style-type: none"> • Immunochemical method • Results within 5 minutes • Quantitative sample collection • Sensitivity: 50ng/mL Hb in stool • No dietary treatment required before test • Specimen: Human stool
	ImmunTech AFP 30 tests(1 test X 30/Box) 100 tests(10 tests X 10/Box)	α-fetoprotein	<ul style="list-style-type: none"> • Sensitivity: 20ng/mL • Results within 5-10 minutes • Specimen: Human serum/plasma
	ImmunTech CEA 30 tests(1 test X 30/Box)	Carcinoembryonic anitgen	<ul style="list-style-type: none"> • Sensitivity: 5ng/mL • Results within 5-10 minutes • Specimen: Human serum/plasma
	ImmunTech PSA 30 tests(1 test X 30/Box)	Prostate-specific anitgen	<ul style="list-style-type: none"> • Sensitivity: 3ng/mL • Results within 5-10 minutes • Specimen: Human serum/plasma
FERTILITY	PREG-Q (Early Pregnancy Test) 25 tests(25 tests/Box) 250 tests(25 strips X 10/Box)	hCG	<ul style="list-style-type: none"> • Sensitivity: 25mIU/mL • Rapid determination: Less than 5 minutes • No cross - reactivity with LH, FSH, TSH • Specimen: Human urine





OcculTech FOB test

Test Kit for the detection of Fecal Occult Blood

PROVEN QUALITY

Clinical Evaluation Report

- ✦ Clinical Biochemistry(Vol 38(2005) p.395-399, SCI Journal)
- ✦ Kangbuk Samsung Hospital & Sungkyunkwan University School of Medicine

Diagnostic Sensitivity & Specificity

- ✦ Correlation with Endoscopy: 100% in sensitivity & 98.9% in specificity.

Analytical Sensitivity and No - Prozone effect

- ✦ Analytical sensitivity of OcculTech FOB Test is 50 ng/ml and no prozone effect appears upon 2,000 ng/ml. Hemoglobin concentration of 2,000 ng/ml in diluent solution is 2 mg/g feces.



Approval: FDA, CE

INSTRUCTION & SPECIFICATION

Test Procedure



Specification of Product

- ✦ **Test Device**
 - Rapid absorption of specimen: absorbed within 10 seconds after dropping
 - Rapid test time : 45 seconds ~ 5 minutes
 - Detection Limit of Hemoglobin : 50 ng/mL
 - Sensitivity of Product : 10 ~ 20 µg Hb/g Stool (can be detected by 200 mg/g)
- ✦ **Sample Collection Tube**
 - Quantitative specimen collection (removal membrane of excess stool)
 - High reproducibility
 - Easy collection of specimen because of long collecting rod
 - Requires small volume of specimen (ca. 10 mg)
 - Easy handling



ImmuneTech Cardiac Triple Test

Test kit for the detection of cardiac markers for professional use

Features

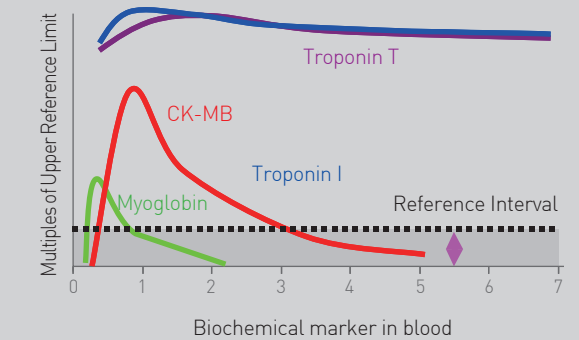
- ✦ **Fast, easy and convenient**
 - Results in 15 minutes
 - Simple and easy to use
 - Requires no instruments and special skills
- ✦ **Whole Blood Test**
 - Either whole blood , serum or plasma can be tested
- ✦ **Long shelf life**
 - 18 months shelf life
 - Store at room temperature

- ✦ **Sensitivity**
 - 0.5ng/mL of cardiac Troponin I
 - 5ng/mL of CK-MB
 - 50ng/mL of Myoglobin
- ✦ **Accuracy**
 - Troponin I : 96.6%
 - CK-MB : 97.8%
 - Myoglobin : 97.1%

Specification and Reference

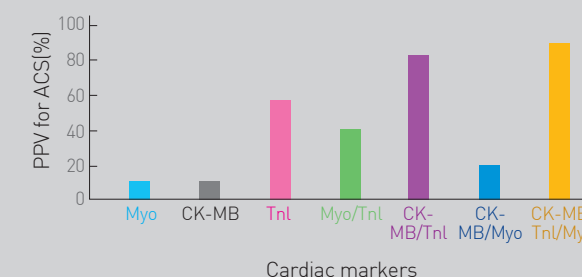
Specification

Product name	Cardiac Triple Test
Cat. No.	IM712-10
Test format	Cassette
Specimen	Serum, plasma, whole blood
Storage Temperature	4~25°C
Shelf life	18 months
Package	10 tests/kit



Reference

Myoglobin is a sensitive early marker elevating within 2 hours. Cardiac Troponin I (cTnI), CK-MB is released within 4~6 hours after the onset of AMI certified specific to myocardium remaining elevated for up to 6~10 days. The Positive Predictive Values(PPVs) for Acute Coronary Syndrome by using three markers (cTnI , CK-MB and Myoglobin) were excellent better than single market used.



	Troponin I	Troponin T
Level in normal blood(ng/ml)	←0.2	←0.02
Cut-off level	0.5ng/ml	0.1ng/ml
Form in blood	free TnI, TnI complexed with one or more Troponin components, or troponin which has been partially degraded and chemically altered.	Free cTnT
Standardization of Calibrator	Lack of standardization between different assay	Good(Due to patent restrictions, assays for TnT are available from only one manufacturer)
Cardiospecificity	Very superiority	Superiority
Positive value for MI	→99%	94%
Positive value for UA	36%	22%
False positive	Rareness	Variety clinical condition

Troponin I Vs Troponin T

Clinical Chemistry Reagent

Product	Item No.	Package	Mixing ratio	Method	Reference Range
AST(GOT)	R201	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2	4:1	IFCC	0-37 U/L
	A301	25mLx10			
ALT(GPT)	R202	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2	4:1	IFCC	0-40 U/L
	A302	25mLx10			
Glucose	R203-T	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2	4:1	Trinder	70-120 mg/dL
	A303-T	25mLx10			
	R203-H	R1 100mLx4, R2 100mLx2			
ALP	R204-D	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2	4:1	Kinetic (DEA)	60-300 U/L (Child < 700)
	A304-D	25mLx10			
Amylase	R205	R1 60mLx4, 100mLx4, R2 20mLx4, 75mLx2	3:1	Gal-G2-CNP	39-115 Unit
A305	25mLx5				
Creatinine	R206	R1 60mLx4, 100mLx4, 250mLx4, R2 60mLx4, 100mLx4, 250mLx4	1:1	Jaffe-Kinetic	0.5-1.4 mg/dL
A306	100mLx2				
Uric Acid	R207	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx4, 100mLx2	2:1	Trinder	M:3.6-8.0 mg/dL F:2.5-6.8 mg/dL
A307	60mLx4				
Cholesterol	R208	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx4, 100mLx2	4:1	Trinder	130-250 mg/dL
	A308	25mLx10			
HDL-Cholesterol	R208-H	R1 60mLx4, 100mLx4, R2 20mLx4, 75mLx2	3:1	Immunological Method	40-70 mg/dL
	A308-H	20mLx5			
LDL-Cholesterol	R208-L	R1 60mLx4, 100mLx4, R2 20mLx4, 75mLx2	3:1	Direct LDL Cholesterol	0-100 mg/dL
	A308-L	20mLx5			
Chloride	R209	60mLx4, 100mLx4	1:1	Hg(SCN) ₂	96-107 mg/dL
	A309	100mLx2			
Calcium	R210	R1 60mLx4, 100mLx4, 250mLx4, R2 60mLx4, 100mLx4, 250mLx4	1:1	OCPC	8.5-10.5 mg/dL
	A310	100mLx2			
	R210-N	100mLx4			
	A310-N	100mLx2			
Bilirubin-Total	R211-T	60mLx4, 100mLx4	1:1	DPD	0.2-1.0 mg/dL
	A311-T	20mLx10			
Bilirubin-Direct	R211-D	60mLx4, 100mLx4	1:1	DPD	0-0.4 mg/dL
	A311-D	20mLx10			
Magnesium	R212	60mLx4, 100mLx4	1:1	Magon	0.74-0.9 mg/dL
T-Protein	R214	60mLx4, 100mLx4, 250mLx4			
Albumin	A314	100mLx2	1:1	Biuret	6.5-8.0 g/dL
	R215	60mLx4, 100mLx4, 250mLx4			
Pi	A315	100mLx2	1:1	UV-Phosphomolybdate	2.5-4.5 mg/dL (Child : 4.0-7.0)
	R217	R1 60mLx4, 100mLx4, R2 60mLx4, 100mLx4			
TG	A317	100mLx2	2:1	Trinder	10-200 mg/dL
	R218	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx4, 100mLx2			
v-GT	A318	60mLx4	4:1	IFCC	M:0-50 U/L F:0-35 U/L
	R219	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2			
BUN	A319	25mLx10	4:1	Kinetic	5-23 mg/dL
	R220	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2			
LDH-P	A320	25mLx10	4:1	UV-Pyruvate	200-400 U/L
	R221	R1 60mLx4, 100mLx4, 250mLx4, R2 30mLx2, 100mLx2			
CK-NAC	R222	R1 60mLx4, 100mLx4, R2 30mLx2, 100mLx2	4:1	SCE	M:40-190 U/L F:30-165 U/L
	A322	25mLx5			
Hemoglobin	H7	500mLx1		Cyanmethemoglobin	13.5-15.6 g/dL

Stain Solution

ITEM NO.	ITEM	PACKAGE
B1	B1-1	Gram Stain Crystal Violet Sol. Lugol Sol. Alcohol Decolorizer Safranin Sol.
	B1-2	
	B1-3	
	B1-4	
H1	H1-2	Wright Stain Wright Stain Wright Buffer
	H1-1	
B2	B2-1	AFB Stain Carbol Fuchsin Acid Alcohol Methylene Blue
	B2-2	
	B2-3	
S2	S2-1	Papanicolau Stain Harris Hematoxylin-I EA-50 Orange G-6 Harris Hematoxylin-II
	S2-2	
	S2-3	
	S2-4	

AceChem

Clinical chemistry reagent & Staining solution



MolecuTech REBA HPV-ID® System

Fully Automated Human Papilloma Virus Diagnostic System



YD's REBA HPV-ID® is a molecular diagnostic kit for identification of 32 Human Papilloma Virus (HPV) genotypes and detection of 80 HPV genotypes, which is a causative pathogen of cervical cancer. It is an available genotyping of 18 high-risk, 1 medium-risk and 13 low-risk HPV genotypes, simultaneously. These HPV genotypes are depending on the induction of uterine cervical cancer. Genetic target of REBA HPV-ID® is a polymorphic L1 gene, which expressed at the late stage of infection cycles in the host cells, and the kit employs one-tube nested PCR and Reverse Blot Hybridization Assay(REBA).



- ◆ Detect to HPV genotype of 18 species of high-risk, 1 species of medium-risk, and 13 species of low risk group at once
 - High risk group : HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69,73
 - Medium risk group : HPV 34
 - Low risk group : HPV 6, 11, 32, 40, 42, 43, 44, 54, 70, 72, 81, 84, 87
- ◆ Specimen : solid and liquid based specimen
- ◆ Rapid test within 2 hours after PCR reaction

REBA HPV-ID® System



- DNA extraction
- PCR amplification



HybREAD 480®



Analysis and Result

◆ HybREAD 480® Specification

Display unit	LED Indicator	Test capacity	1~48 sample
Data Input	PC	Volume of reagent dispensed	0.5 ~ 1.4 ml
Detector	CMOS camera	Dimension	1100 x 650 x 750 (L x W x H)
Sample Dispenser	3axis robot/ADP Pipettor	Running Time	2 hours
Cap. of Reagent containers	6 x 250 ml		

Reference

1. Kim SH, Lee DS, Kim Y, Kim GH, Park SJ, Choi YN, Kim TU, Park KH, Lee HY. Clinical Evaluation of Human Papillomavirus DNA Genotyping Assay to Diagnose Women Cervical Cancer. J. Exp. Biomed. 2012, 18(2):123~130.
2. Kim SH, Lee DS, Park SJ, Kim TU, Jeon BY, Park KH, Lee HY. REBA HPV-ID for Efficient Genotyping of Human Papillomavirus in Clinical Samples From Korean Patients. J. Med. Virology. 2012, 84:1248-1253.
3. Lee DS, Kim SH, Park SJ, Jin HW, Kim TU, Park KH, Lee HY. Human Papillomavirus Prevalence in Gangwon Province Using Reverse Blot Hybridization Assay. Korean J. Pathology. 2011, 45:348-353.

MolecuTech

**Molecular
Diagnostic
System**



173 Seo-Ri, Yidong-Myun
Choin-Gu, Yongin-Shi
Kyunggi-Do 449-834
Republic Of Korea
T 82-31-329-2000
F 82-31-329-2002
www.yd-diagnostics.com
admin@yd-diagnostics.com

MOLECULAR DIAGNOSTIC PRODUCTS

	Product name (Cat. No.)	INFORMATION	Test quantity/kit
TB	Polymerase Chain Reaction (PCR)		
	TB-Tag Two® (M01)	Two-tube Nested PCR-based Assay System for Detection of only MTB among MTBcomplex	50 T/kit
	MTB-ID®v3 (M02)	PCR-based Assay System for Simultaneous Detection of MTB and Other Mycobacteria	100 T/kit
TB	Real-time PCR		
	Real TB-Tag® (M03)	Real-time PCR-based Assay System for Detection of only MTB among MTBcomplex	100 T/kit
	Real MTB-ID® (M14)	Real-time PCR-based Assay System for Simultaneous Detection of MTB and Other Mycobacteria	100 T/kit
TB	PCR-RFLP Assay (PRA)		
	PRA Myco-ID® (M04)	PCR-RFLP Assay System for Identification of Mycobacterial Species Including MTB	100 T/kit
TB	Reverse Blot Hybridization Assay (REBA) (Each product, strip type and membrane type also)		
	REBA Myco-ID® (M06)	Reverse Blot Hybridization Assay System for Identification of Mycobacterial Species Including MTB	50 T/kit 56 T/kit
	REBA MTB-MDR® (M11)	Reverse Blot Hybridization Assay System for Determination of Rifampin and Isoniazid Susceptibility of MTB	20 T/kit
	REBA MTB-FQ® (M09)	Reverse Blot Hybridization Assay System for Determination of Fluoroquinolone Susceptibility of MTB	20 T/kit
	REBA MTB-KM® (M10)	Reverse Blot Hybridization Assay System for Determination of Kanamycin Susceptibility of MTB	20 T/kit
	REBA MTB-XDR® (M12)	Reverse Blot Hybridization Assay System for Determination of Fluoroquinolone, Kanamycin and Streptomycin Susceptibility of MTB	20 T/kit
HPV	REBA (Each product, strip type and membrane type also)		
	REBA HPV-ID® (M13)	Reverse Blot Hybridization Assay System for Identification of Human Papilloma Virus (HPV) Genotypes	50 T/kit 200 T/kit
REBA Devices			
	REBA Processor	Automated Washing & Hybridization Steps of Strip-based Assay	
	REBASCAN	Automatic Scanning of Strips for Interpretation	

TB

OVERVIEW

There are over 70 species of mycobacteria

Of these, two are major pathogens: *Mycobacterium tuberculosis* (Koch, 1882)

Mycobacterium leprae (Hansen, 1874)

The remaining mycobacteria are environmental organisms-collectively known as NTM (Nontuberculous mycobacteria)

NTM organisms are responsible for opportunistic infections, especially in people with AIDS

TUBERCULOSIS, A GLOBAL THREAT

Caused by *Mycobacterium tuberculosis* (MTB)

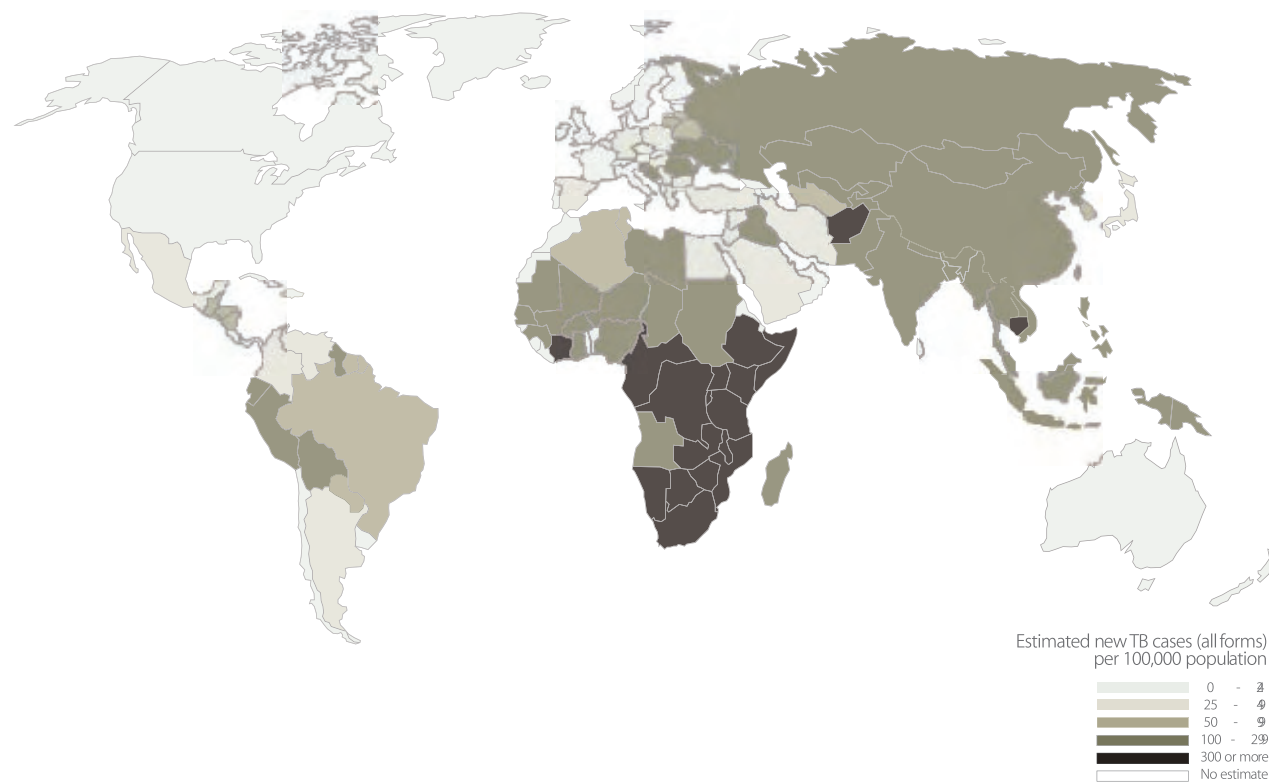
Over 2 billions infected

Around 8 million new cases per year

Over 2 million deaths per year

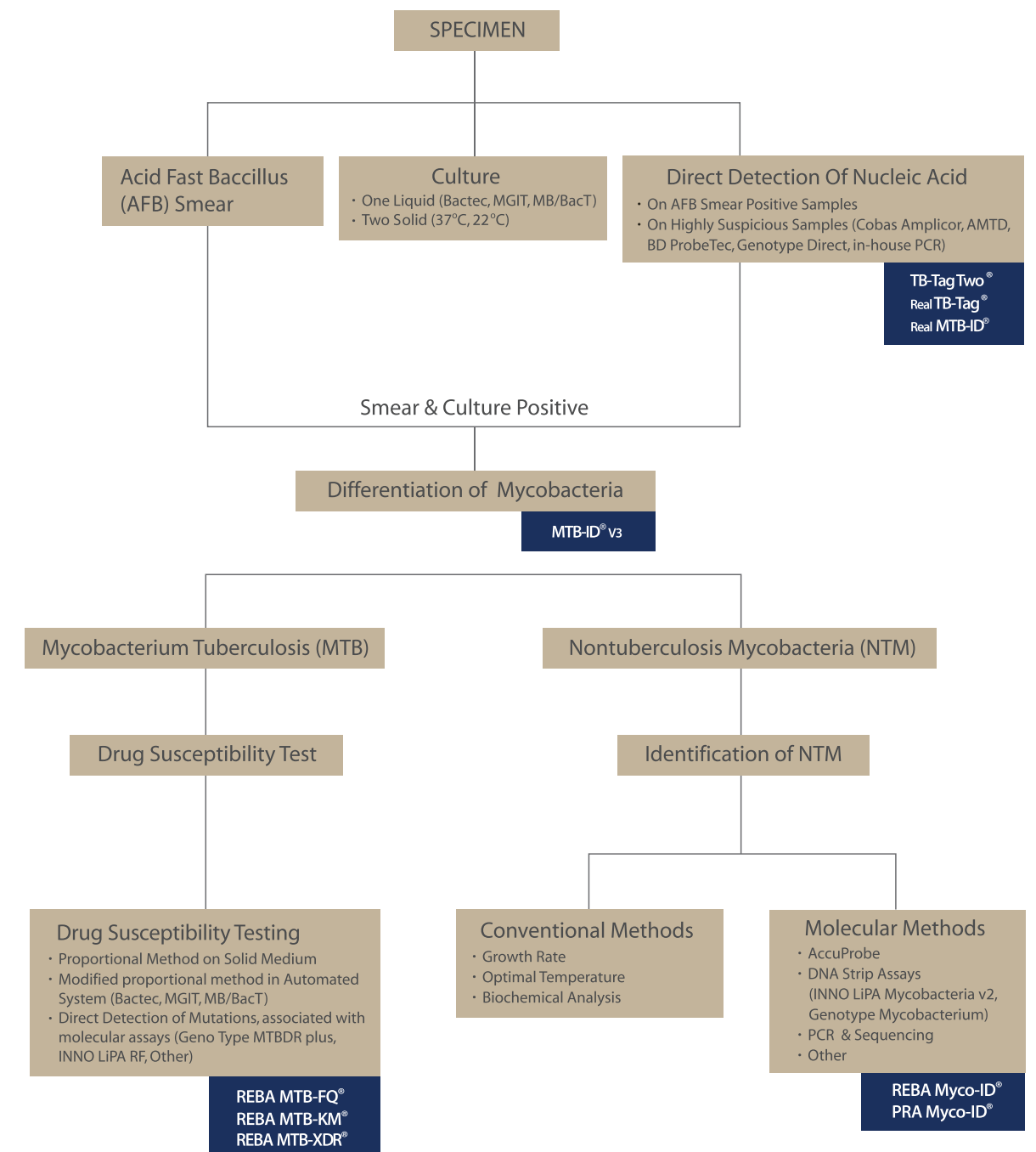
Around 11 millions TB/HIV co-infected

Over 50 millions infected with MDR-TB



Estimated TB incidence rates, 2004 © WHO 2005. All rights reserved

ALGORITHM FOR THE HANDLING OF MYCOBACTERIAL SPECIMEN



- Kit contents**
- First PCR premix (50 tests)
 - Second PCR premix (50 tests)
 - PCR DNA size marker
 - Internal control DNA
 - DNA extraction solution
 - 8 - MOP
 - 2% TBE agarose gel(17 lanes/gel)
 - 5X TBE gel electrophoresis buffer

YD's TB-Tag Two® is a molecular diagnostic kit for unique detection only Mycobacterium tuberculosis (MTB) among MTB complex (M. bovis, M. africanum, M. canetti, M. microti). YD's TB-Tag Two® employs two-tube nested PCR for MTB specific target region. The region which is only present in the MTB for detecting only MTB and no other NTM including MTB complex (M. A. Behr et al. Science 284, 1999)

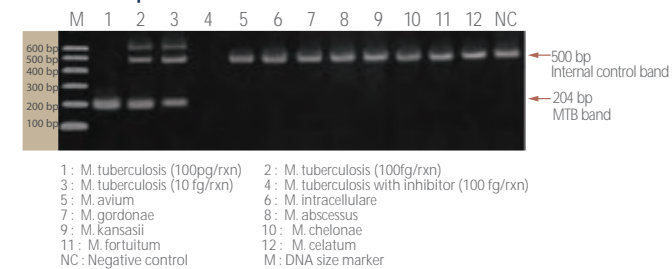
Features

- Rapid and accurate detection only MTB among MTB complex
- Specimen : sputum, bronchial washed solution, body fluid, tissue, and cultured specimen
- High specificity and sensitivity with two-tube nested PCR
- All in one system : from DNA extraction to agarose gel electrophoresis of PCR product
- Internal control is included, determining existence of PCR inhibitor within specimens

Sensitivity and Specificity

- Sensitivity : detect up to 2 ~20 bacilli
- Specificity : detect specific target region for only MTB

Data Interpretation



Band size (bp)	Result interpretation	
	MTB	Note
204	Positive	In case of excessive existence of MTB DNA, internal band may be faint
204, 500	Positive	
500	Negative	
No band	Invalid	PCR error (require re-test)

YD's MTB-ID® V3 is a molecular diagnostic kit designed to simultaneously detects and differentiates both MTB (Mycobacterium tuberculosis) and NTM (Nontuberculous mycobacteria) by amplify MTB specific region (M. A. Behr et al. Science 284, 1999) and high polymorphic region of rpoB (RNA polymerase β-subunit, patent). MTB target region exists specially in MTB and rpoB genetic region commonly exists in all mycobacterium including MTB.

Features

- Rapid and accurate detection and differentiates MTB and NTM at DNA level simultaneously
- Specimen : DNA of culture isolate
- High specificity and sensitivity by application multiplex and one-tube nested PCR
- All in one system : from DNA extraction to agarose gel electrophoresis of PCR product
- Internal control is included, determining existence of PCR inhibitor within specimens

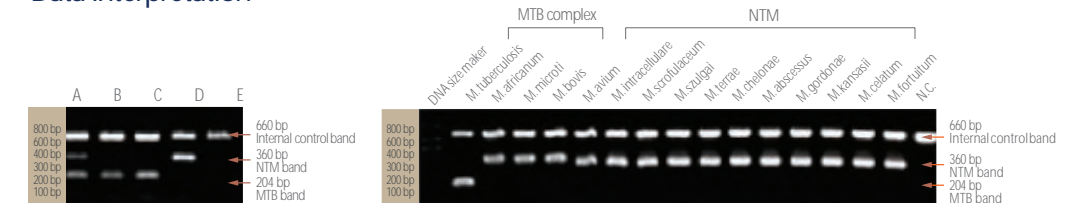
Sensitivity and Specificity

- Sensitivity for MTB : detect up to 2~20 bacilli
- Sensitivity for NTM : detect up to 200 bacilli
- Specificity : no cross-reactivity between MTB and NTM

- Kit contents**
- 2X PCR premix (100 tests)
 - Primer mixture
 - PCR DNA size marker
 - DNA extraction solution
 - 8 - MOP
 - 2% TBE agarose gel (17 lanes/gel)
 - 5 X TBE gel electrophoresis buffer



Data Interpretation



Band size (bp)	Result interpretation		
	MTB	NTM	Note
A	204, 360, 660	Positive	In case of excessive existence of MTB DNA, internal band may be faint
B	204, 660	Positive	
C	360, 660	Negative	Positive
D	660	Mycobacteria negative	
E	No band	Invalid	PCR error (require re-test)

- Kit contents**
- 2 X Real-Time PCR premix (100 tests)
 - MTB probe & Primer mixture
 - Internal control probe & Primer mixture
 - PCR internal control DNA
 - MTB positive control DNA
 - DNA extraction solution



YD's Real TB-Tag® is a molecular diagnostic kit for unique detection only Mycobacterium tuberculosis (MTB) among MTB complex (*M. bovis*, *M. africanum*, *M. canettii*, *M. microti*). YD's TB-Tag Two® employs real-time PCR for MTB specific target region using Taqman probe with two kinds of wave length. The region which is only present in the MTB for detecting only MTB and no other NTM including MTB complex (M. A. Behret al. Science284, 1999).

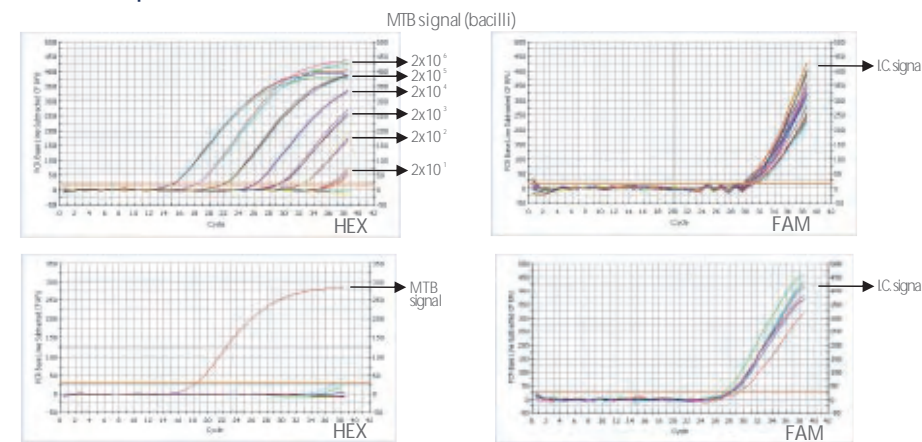
Features

- Rapid and accurate detection
- Diverse clinical specimen: sputum, bronchial washed solution, body fluid, tissue, and cultured specimen
- High specificity and sensitivity
- Simple procedure and closed system
 - Not required gel electrophoresis
 - Minimized to cross or carry-over contamination in process
- DNA extraction solution included

Sensitivity and Specificity

- Sensitivity: detect up to 2 ~20 bacilli
- Specificity: detect specific target region for only MTB

Data Interpretation



Sample	Fluorescence dye		Result interpretation
	FAM	HEX	
Positive control DNA	-	+	Valid
Internal control DNA (IC)	+	-	Valid
Clinical sample	+	+	MTB positive
	+	-	MTB negative
	-	-	PCR error (require re-test)

YD's Real MTB-ID® is a molecular diagnostic kit designed to simultaneously detects and differentiates both MTB (*Mycobacterium tuberculosis*) and NTM (Nontuberculous mycobacteria) by amplify MTB specific region (*M. A. Behr et al. Science 284, 1999*) and high polymorphic region of *rpoB* (RNA polymerase β -subunit, patent). MTB target region exists specifically in MTB and *rpoB* genetic region commonly exists in all mycobacterium including MTB.

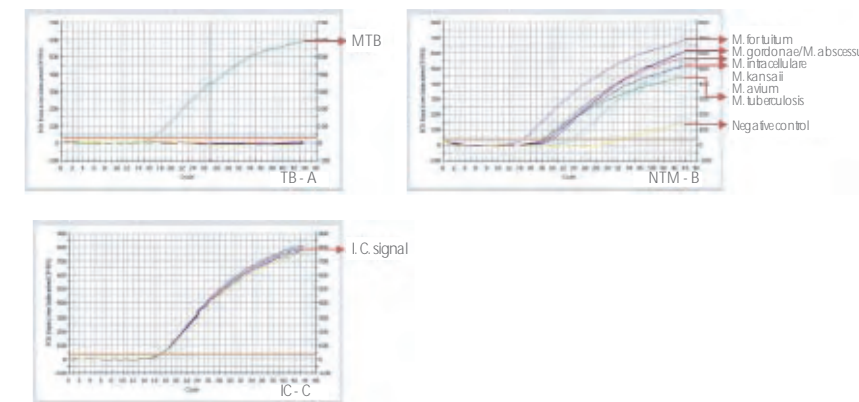
Features

- Rapid and accurate detection
- Diverse clinical specimen: sputum, bronchial washed solution, body fluid, tissue, and cultured specimen
- High specificity and sensitivity
- Simple procedure and closed system
 - Not required gel electrophoresis
 - Minimized to cross or carry-over contamination in process
- DNA extraction solution included

Sensitivity and Specificity

- Sensitivity for MTB: detect up to 2~20 bacilli
- Sensitivity for NTM: detect up to 200 bacilli
- Specificity: no cross-reactivity between MTB and NTM

Data Interpretation



Sample	Fluorescence dye			Result interpretation
	A	B	C	
Positive control DNA	+	-	+	Valid
Internal control DNA (IC)	-	-	+	Valid
Clinical sample	+	-	+	MTB positive
	+	+	+	MTB positive
	-	+	+	NTM positive
	-	-	+	Mycobacteria negative
	-	-	-	PCR error (require re-test)

Kit contents

- 2 X Real-Time PCR premix (100 tests)
- MTB probe & Primer mixture
- NTM probe & Primer mixture
- Internal control probe & Primer mixture
- PCR internal control DNA
- MTB positive control DNA
- DNA extraction solution



- Kit contents**
- 2 X PCR premix (100 tests)
 - PCR positive control DNA
 - PCR size marker
 - PRA size marker
 - Msp I (10 U/μl)
 - 10 X Msp I buffer
 - Hae III (10 U/μl)
 - 10 X Hae III buffer
 - Primer I
 - Primer II
 - DNA extraction solution
 - 8 - MOP
 - 4% Metaphor TBE agarose gel (12 lanes/gel)
 - 2% TBE agarose gel (17 lanes/gel)
 - 5 X TBE gel electrophoresis buffer

YD's PRA Myco-ID® utilizes the property that high polymorphism exists in rpoB gene (J. Clin Microbiol. 38, 2000 : patent registered by M&D, Inc.) which encode RNA polymerase β-subunit of mycobacterium species. Through PCR Restriction Fragment Length Polymorphism Analysis (PRA) of rpoB gene, can identify MTB (*Mycobacterium tuberculosis*), 105 species of NTM (Nontuberculous mycobacteria), *Rhodococcus* and *Nocardia* accurately. Acquired PCR product by amplifying with specific primer of the rpoB gene (registered patent) digested with restriction enzyme Msp I or Hae III, the DNA fragments of different sizes of 3~4 are produced depending on the mycobacterium species. Following the metaphor gel electrophoresis, exactly, mycobacterial species can be identified by comparing and analyzing the size of DNA fragments with 『Algorithm for Mycobacteria and Nocardia identification』 of after electrophoresis.

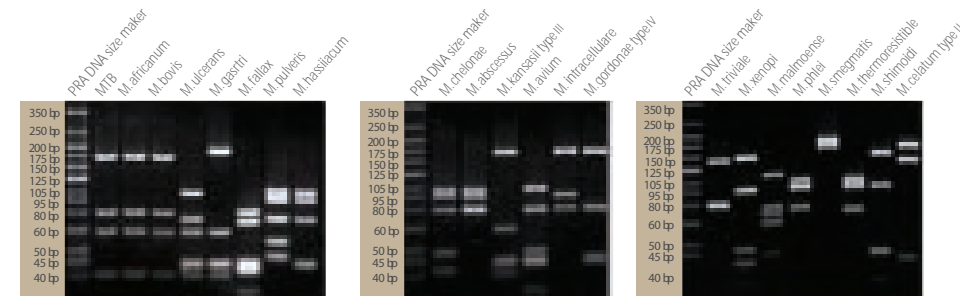
Features

- Identification of NTM of 105 species *Rhodococcus* and *Nocardia* at DNA level
- Specimen : DNA of culture isolate
- YD's target region of rpoB gene is an appropriate for identification of mycobacteria. (Patent and FDA registered)
- All in one system

Sensitivity and Specificity

- Sensitivity for NTM : detect up to 200 bacilli
- Specificity : identify 105 species of NTM (*Nontuberculous mycobacteria*) *Rhodococcus* and *Nocardia*

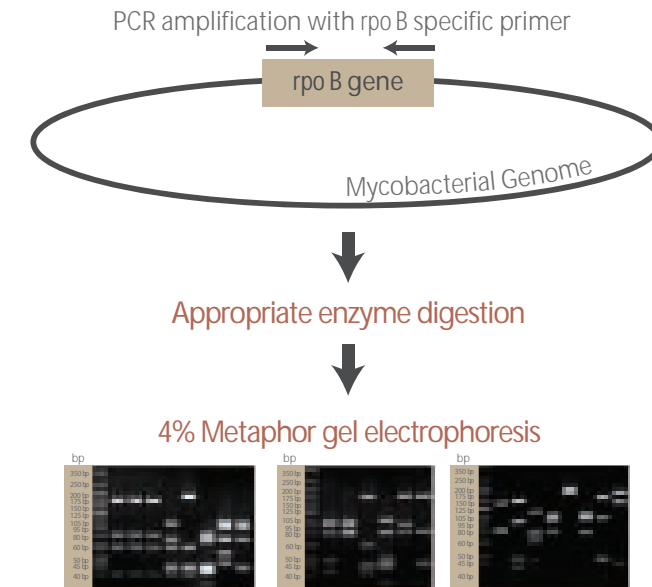
Data Interpretation



To identification of mycobacterium, refer to 『Algorithm for Mycobacteria and Nocardia identification (supplied)』

- Not identify DNA fragment of under 40 bp and excepted in the algorithm
- If the result of restriction digestion by Msp I is the same, re-digestion used to Hae III need. (We offered Hae III, 10 × Hae III buffer)

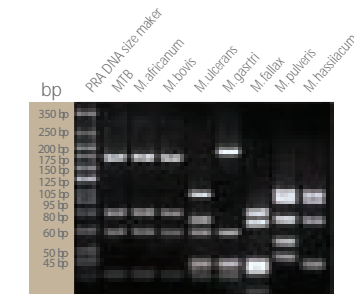
Principle of PRA Myco-ID®



Algorithm for NTM

Species	Fragment 1 (bp)	Fragment 2 (bp)	Fragment 3 (bp)	Fragment 4 (bp)
M. tuberculosis	350	250	200	175
M. africanum	350	250	200	175
M. bovis	350	250	200	175
M. lifecans	350	250	200	175
M. goodii	350	250	200	175
M. fortuitum	350	250	200	175
M. neoaurum	350	250	200	175
M. chelonae	350	250	200	175
M. abscessus	350	250	200	175
M. kansasii type III	350	250	200	175
M. indicus pranii	350	250	200	175
M. intracellulare	350	250	200	175
M. goodii type II	350	250	200	175
M. trivale	350	250	200	175
M. neoaurum	350	250	200	175
M. malmoense	350	250	200	175
M. phlei	350	250	200	175
M. smegmatis	350	250	200	175
M. thermoresistibile	350	250	200	175
M. chimedi	350	250	200	175
M. calatum type II	350	250	200	175

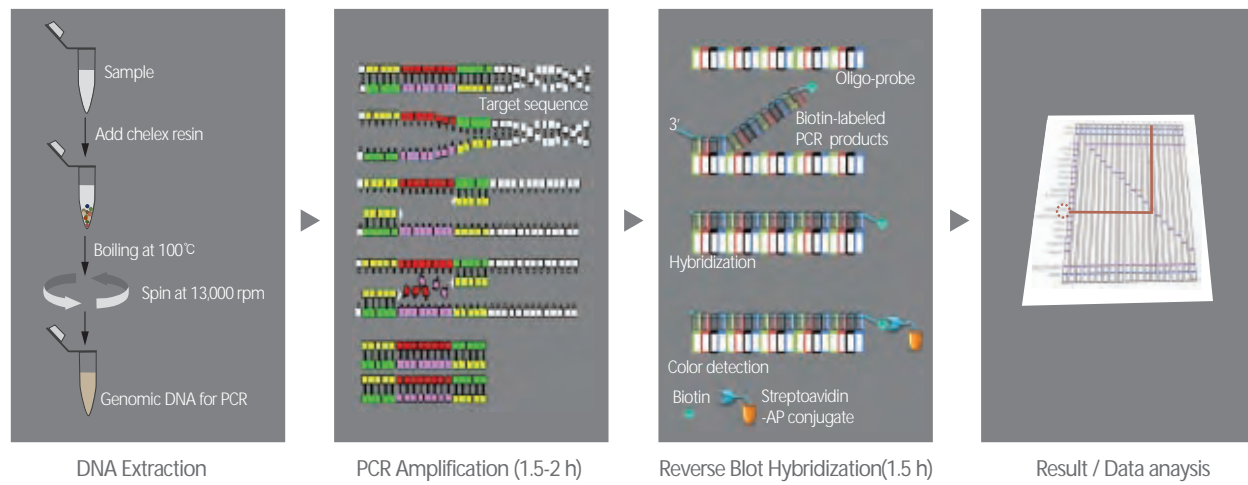
Data interpretation



REBA (REverse Blot Hybridization Assay) Product

- Target gene specific probe bind to nylon membrane strip
- PCR product hybrid to probe bounded membrane strip
- Color detection by chromogenic reaction
- Simultaneously detection and identification for multi-infection

Principle



REBA Myco-ID®

REBA MTB-MDR®

REBA MTB-FQ®

REBA MTB-KM®

REBA MTB-XDR®

REBA HPV-ID®

Kit contents

- 2X PCR premix (50 & 56 tests) (strip & membrane type)
- PCR positive control DNA
- DNA extraction solution
- 8-MOP
- REBA Myco-ID® primer I
- REBA Myco-ID® primer II
- REBA Myco-ID® Membrane
- REBA Myco-ID® REBA positive control
- Denaturation Solution (DS)
- Hybridization Solution (HS)
- Washing Solution (WS)
- AP conjugate
- Conjugate Dilution Solution (CDS)
- NBT/BCIP stock solution
- Staining Solution (SS)
- Blotting Tray

YD's REBA Myco-ID® is a molecular diagnostic kit designed to identify MTB (*Mycobacterium tuberculosis*) and 19 species of NTM (Nontuberculous mycobacteria) and detect to over 100 species of NTM with Reverse Blot Hybridization Assay (REBA) by binding the amplifying *rpoB* gene product to species specific probe (J. Clin. Microbiol. 41). YD's target region of *rpoB* gene is an appropriate for identification of mycobacteria. (Patent and FDA registered)

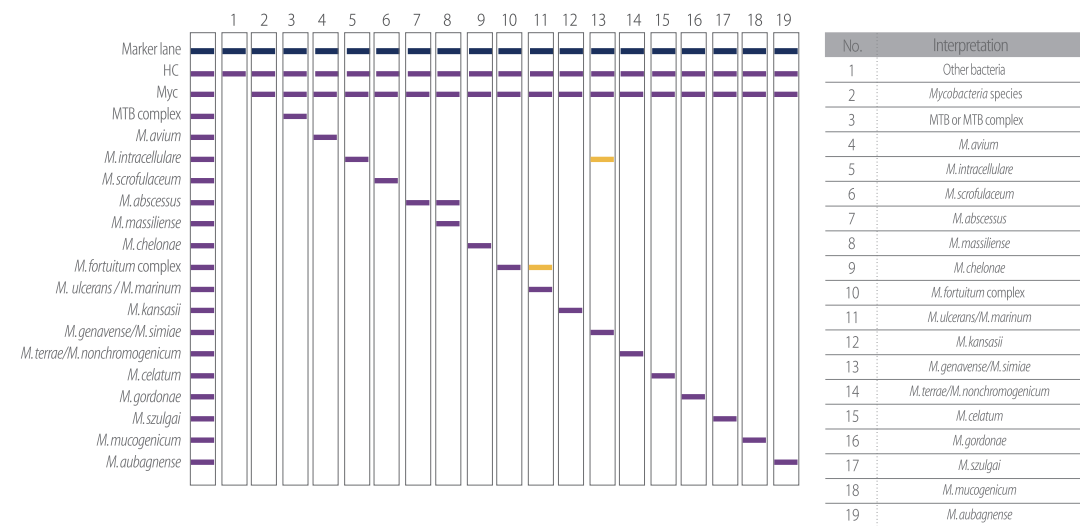
Features

- Identification of 19 species of NTM (*M. avium*/*M. intracellulare*/*M. scrofulaceum*/*M. abscessus*/*M. massiliense*/*M. chelonae*/*M. fortuitum* complex/*M. ulcerans*/*M. marinum*/*M. kansasii*/*M. genavense*/*M. simiae*/*M. terrae*/*M. nonchromogenicum*/*M. celatum*/*M. gordonae*/*M. szulgai*/*M. mucogenicum*/*M. aubagnense* (the most frequently isolated bacterial species in clinical test room, Nontuberculous mycobacterium pulmonary disease, 2006)
- Diverse clinical specimen : sputum, bronchial washed solution, body fluid, tissue, and cultured specimen
- High sensitivity and specificity by binding to species specific probe
- Rapid test within 2 hours after PCR reaction
- Useful for mixed or multiple infection of mycobacteria

Sensitivity and Specificity

- Sensitivity for NTM : detect up to 20 bacilli
- Specificity : identify MTB and 19 species of NTM (detect to over 100 species NTM)

Data Interpretation



YD's REBA MTB-MDR® is a molecular diagnostic kit that can determine drug susceptibility for rifampin and isoniazid of MTB simultaneously using PCR and Reverse Blot Hybridization Assay (REBA). As more MTB that are resistance to drugs are discovered, tuberculosis is becoming threatening disease worldwide and multi-drug resistant bacteria are resistant to rifampin and isoniazid at least. Rifampin resistance of MTB caused by mutation appearance in some region of *rpoB* gene encoded β -subunit of RNA polymerase. Isoniazid resistance of MTB caused by mutation of target gene such as *katG* (50- 95%), *inhA* (20-35%), and *ahpC* intergenic (10-15%) .

Features

- Rapid and accurate detection of rifampin and isoniazid resistance of MTB
- Diverse clinical specimen : sputum, bronchial washed solution, body fluid, tissue, and cultured specimen (not required culture)
- High sensitivity and specificity by binding to target gene specific probe
 - Rifampin target : *rpoB*
 - Isoniazid target : *katG*, *inhA*, and *ahpC* intergenic region
- Rapid test within 2 hours after PCR reaction

Sensitivity and Specificity

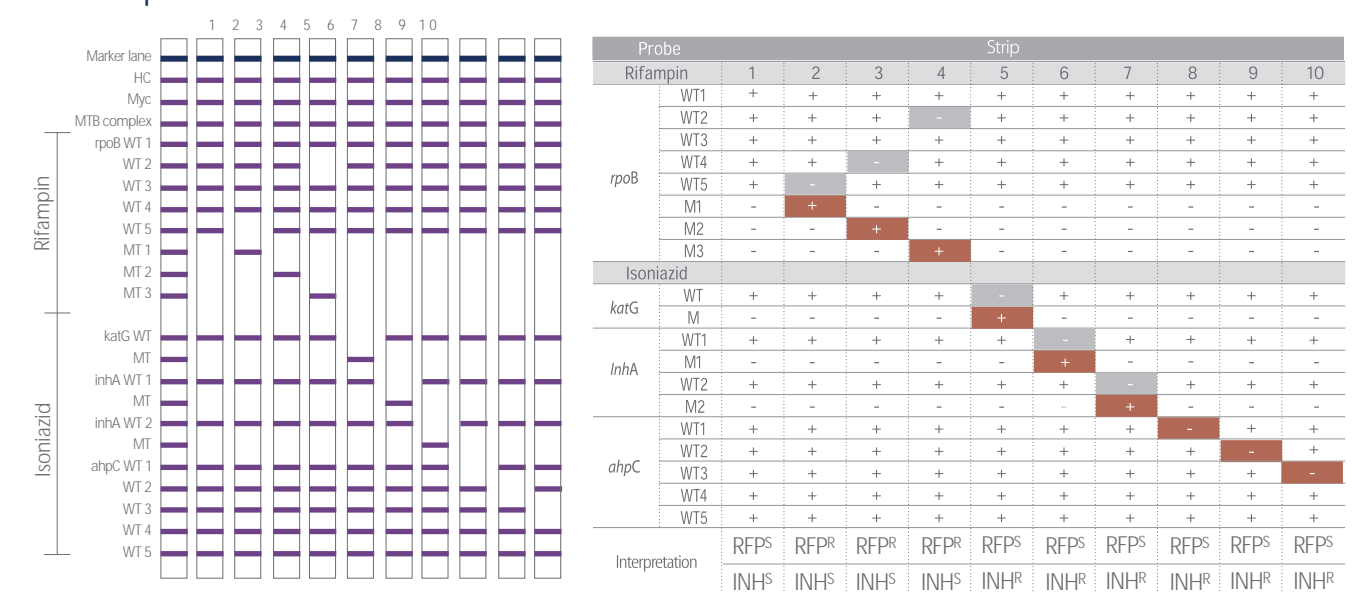
- Sensitivity : detect up to 20 bacilli
- Specificity : detect drug susceptibility for rifampin and isoniazid of MTB

Kit contents

- 2X PCR premix (20 tests)
- PCR positive control DNA
- DNA extraction solution
- 8-MOP
- REBA MTB-MDR® primer mixture
- REBA MTB-MDR® Membrane
- REBA MTB-MDR® REBA positive control
- Denaturation Solution (DS)
- Hybridization Solution (HS)
- Washing Solution (WS)
- AP conjugate
- Conjugate Dilution Solution (CDS)
- NBT/BCIP stock solution
- Staining Solution (SS)
- Blotting Tray



Data Interpretation



Kit contents

- 2 X PCR premix (20 tests)
- PCR positive control DNA
- DNA extraction solution
- 8-MOP
- REBA MTB-FQ® primer mixture
- REBA MTB-FQ® Membrane
- REBA MTB-FQ® REBA positive control
- Denaturation Solution (DS)
- Hybridization Solution (HS)
- Washing Solution (WS)
- AP conjugate
- Conjugate Dilution Solution (CDS)
- NBT/BCIP stock solution
- Staining Solution (SS)
- Blotting Tray

YD's REBA MTB-FQ® is a molecular diagnostic kit that can determine fluoroquinolone susceptibility of MTB using PCR-Reverse Blot Hybridization Assay (REBA). As more MTB that are resistance to drugs are discovered, tuberculosis is becoming threatening disease worldwide and extensively drug resistant Mycobacteria tuberculosis (XDR-MTB) are not only resistant to rifampin and isoniazid but also resistant to fluoroquinolones (FQ) and second-line injectable agents (SLI).

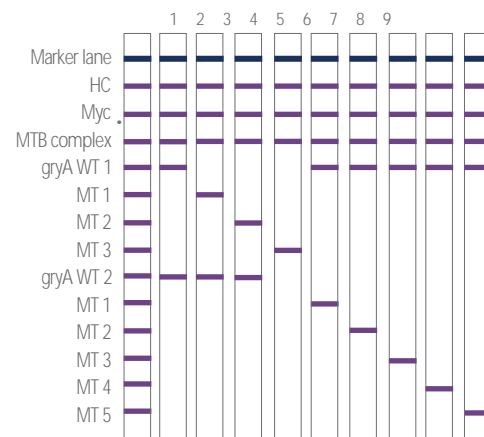
Features

- Rapid and accurate detection of fluoroquinolone resistance of MTB
- Diverse clinical specimen : sputum, bronchial washed solution, body fluid, tissue, and cultured specimen (not required culture)
- High sensitivity and specificity by binding to target gene specific probe
 - Detect mutations in the quinolone resistance-determining region (QRDR) of *gyrA*
- Rapid test within 2 hours after PCR reaction

Sensitivity and Specificity

- Sensitivity for NTM : detect up to 20 bacilli
- Specificity : detect drug susceptibility for fluoroquinolone of MTB

Data Interpretation



Probe	Strip								
	1	2	3	4	5	6	7	8	9
<i>gyrA</i> WT 1	+	-	-	-	+	+	+	+	+
M1	-	+	-	-	-	-	-	-	-
M2	-	-	+	-	-	-	-	-	-
M3	-	-	-	+	-	-	-	-	-
<i>gyrA</i> WT 2	+	+	+	+	-	-	-	-	-
M1	-	-	-	-	+	-	-	-	-
M2	-	-	-	-	-	+	-	-	-
M3	-	-	-	-	-	-	+	-	-
M4	-	-	-	-	-	-	-	+	-
M5	-	-	-	-	-	-	-	-	+
Interpretation	FQ ^S	FQ ^R	FQ ^R	FQ ^R	FQ ^R	FQ ^R	FQ ^R	FQ ^R	FQ ^R

YD's REBA MTB-KM® is a molecular diagnostic kit that can determine second-line injectable drug susceptibility such as kanamycin, capreomycin, and amikacin of MTB using PCR-Reverse Blot Hybridization Assay (REBA). Kanamycin (KM) is a second-line drug regimens used together with first-line drug regimens (rifampin, isoniazid, ethambutol, streptomycin, pyrazinamide) used in the treatment of tuberculosis.

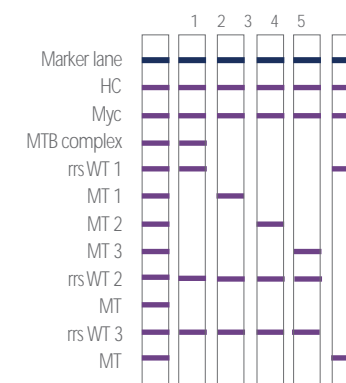
Features

- Rapid and accurate detection of kanamycin resistance of MTB
- Diverse clinical specimen : sputum, bronchial washed solution, body fluid, tissue, and cultured specimen (not required culture)
- High sensitivity and specificity by binding to target gene specific probe
- Detect mutations in the 16S rRNA
- Rapid test within 2 hours after PCR reaction

Sensitivity and Specificity

- Sensitivity : detect up to 20 bacilli
- Specificity : detect drug susceptibility for kanamycin of MTB

Data Interpretation



Probe	Strip				
	1	2	3	4	5
<i>rrs</i> WT 1	+	-	-	-	+
M1	-	+	-	-	-
M2	-	-	+	-	-
M3	-	-	-	+	-
<i>rrs</i> WT 2	+	+	+	+	-
MT	-	-	-	-	-
<i>rrs</i> WT 3	+	+	+	+	-
MT	-	-	-	-	+
Interpretation	KM ^S	KM ^R	KM ^R	KM ^R	KM ^R

Kit contents

- 2X PCR premix (20 tests)
- PCR positive control DNA
- DNA extraction solution
- 8-MOP
- REBA MTB-KM® primer mixture
- REBA MTB-KM® Membrane
- REBA MTB-KM® REBA positive control
- Denaturation Solution (DS)
- Hybridization Solution (HS)
- Washing Solution (WS)
- AP conjugate
- Conjugate Dilution Solution (CDS)
- NBT/BCIP stock solution
- Staining Solution (SS)
- Blotting Tray



Kit contents

- 2X PCR premix (20 test)
- PCR positive control DNA
- DNA extraction solution
- 8-MOP
- REBA MTB-XDR® primer mixture
- REBA MTB-XDR® Membrane
- REBA MTB-XDR® REBA positive control
- Denaturation Solution (DS)
- Hybridization Solution (HS)
- Washing Solution (WS)
- AP conjugate
- Conjugate Dilution Solution (CD)
- NBT/BCIP stock solution
- Staining Solution (SS)
- Blotting Tray



YD's REBA MTB-XDR® is a molecular diagnostic kit that can determine drug susceptibility for second-injectable agents (fluoroquinolone and kanamycin) and streptomycin and of MTB strain in clinical specimen using PCR-Reverse Blot Hybridization Assay (REBA), simultaneously. The REBA MTB-XDR® detects mutations located in *gyrA*, and *rsr* genes in a single assay; these genes are responsible for resistance to fluoroquinolones, streptomycin, and second-line injectable agents (kanamycin, capreomycin, amikacin), respectively.

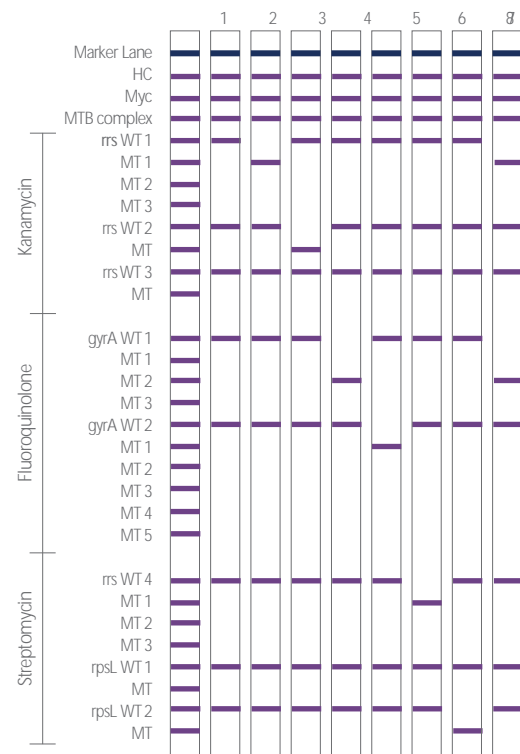
Features

- Rapid and accurate detection extensively drug-resistance (XDR) of MTB
- Diverse clinical specimen : sputum, bronchial washed solution, body fluid, tissue, and cultured specimen (not required culture)
- High sensitivity and specificity by binding to target gene specific probe
- Rapid test within 2 hours after PCR reaction

Sensitivity and Specificity

- Sensitivity for NTM : detect up to 20 bacilli
- Specificity : detect drug susceptibility for kanamycin, fluoroquinolone and streptomycin of MTB

Data Interpretation



Probe	Strip							
	1	2	3	4	5	6	7	8
Kanamycin								
WT 1	+	-	+	+	+	+	+	-
M1	-	+	-	-	-	-	-	+
M2	-	-	-	-	-	-	-	-
M3	-	-	-	-	-	-	-	-
Ofloxacin								
WT 1	+	+	+	-	+	+	+	-
MT1	-	-	-	-	-	-	-	-
MT2	-	-	-	+	-	-	-	+
MT3	-	-	-	-	-	-	-	-
gyrA								
WT 2	+	+	+	+	-	+	+	+
MT1	-	-	-	-	+	-	-	-
MT2	-	-	-	-	-	-	-	-
MT3	-	-	-	-	-	-	-	-
MT4	-	-	-	-	-	-	-	-
MT5	-	-	-	-	-	-	-	-
Streptomycin								
WT4	+	+	+	+	+	-	+	+
MT1	-	-	-	-	-	+	-	-
MT2	-	-	-	-	-	-	-	-
MT3	-	-	-	-	-	-	-	-
rsr								
WT1	+	+	+	+	+	+	+	+
MT	-	-	-	-	-	-	-	-
rpsL								
WT2	+	+	+	+	+	+	-	+
MT	-	-	-	-	-	-	+	-
Interpretation								
	KM ^R	KM ^R	KM ^R	KM ^R	KM ^R	KM ^R	KM ^R	KM ^R
	FO ^R	FO ^R	FO ^R	FO ^R	FO ^R	FO ^R	FO ^R	FO ^R
	SM ^R	SM ^R	SM ^R	SM ^R	SM ^R	SM ^R	SM ^R	SM ^R

Human Cervical Cancer

- The second most common cancer among women cancer world wide
- diagnosed 500,000 women, usually in their 30s or 40s, are stricken by the disease annually (Central America, Africa, Asia)
- Occurance age : 20 ~ 70
- A periodic inspection : each 6 month ~ 1 year

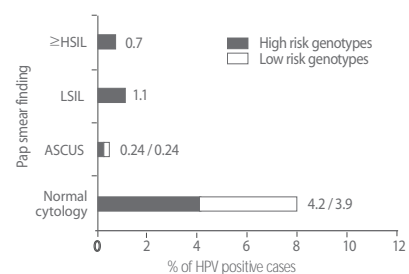


Figure 1.

Prevalence of HPV types by cytological findings in women in Busan, Korea, 1999-2001 (N=863) (ShinHRetal). Overall, 90 women were positive for HPV DNA. HPV prevalence was 8.5% among cytologically normal women, 22.2% among those with ASCUS, 52.9% among those with LSIL and 100 among 7 women with HSIL or worse.

J. Gynecol. Oncol. Vol. 20 No. 1:1-7, March 2009

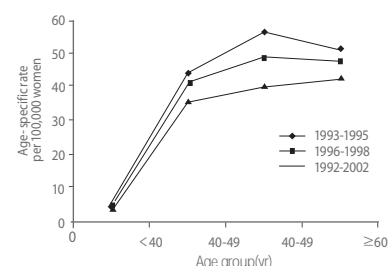
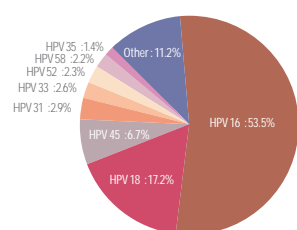


Figure 2.

Age-specific incidence of invasive cervical cancer in Korea (1993-2002). Adapted from the National Cancer Incidence Database by the Korean Central Cancer Registry (ChungH-Hetal).

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- The overall HPV prevalence of subgroups stratified by disease severity and the type-specific HPV prevalence

Table 1 Disease severity of type-specific HPV prevalence

Disease severity	Number of studies	Number of cases	Crude HPV prevalence (%)	Adjusted HPV prevalence (%)	95% CI (%)
Subgroup 1 (Normal cytology)	16	9579	20.4	23.9	23.8 - 24.1
Subgroup 2 (Low-grade lesion*)	15	2620	63.2	60.0	59.5 - 60.2
Subgroup 3 (High-grade lesion†)	14	1027	85.6	85.8	85.2 - 86.5
Subgroup 4 (Invasive cervical cancer)	10	616	88.3	95.8	95.4 - 96.2

*Those including ASCUS, LSIL and CIN I.

†Those including HSIL, CIN 2,3 and CIS.

CI : confidence interval

	Number of cases (%)			
	Subgroup 4* (n=616)	Subgroup 3† (n=1027)	Subgroup 2‡ (n=2620)	Subgroup 1§ (n=9579)
HPV any	88.3%	85.6%	63.2%	20.4%
High-risk HPV	84.6%	83.7%	56.3%	16.7%
HPV 16	53.2%	40.6%	20.0%	6.0%
HPV 18	11.9%	7.2%	4.0%	1.0%
HPV 58	8.6%	14.1%	7.4%	2.3%
HPV 33	3.7%	4.9%	2.7%	0.4%
HPV 52	3.4%	5.0%	4.1%	0.9%
HPV 35	3.1%	4.1%	2.2%	0.4%
HPV 31	1.9%	3.0%	1.7%	0.4%
HPV 45	1.7%	1.2%	0.6%	0.2%
HPV 56	1.6%	2.7%	2.5%	0.9%
HPV 59	1.2%	0.6%	0.3%	0.2%
Low-risk HPV	4.1%	5.4%	7.5%	3.8%

*Those including invasive cancer.

†Those including ASCUS, LSIL and CIN I.

‡Those including HSIL, CIN 2,3 and CIS.

§Those including normal cytology.

J. Microbiol. Biotechnol. (2008), 18(4), 788-794

The Potential Role of HPV Testing

- Equivocal PAP smear (ASCUS, LSIL, Class II) triage
- Surveillance after CIN, microinvasive cancer cure
- Primary screening of cervical cancer

Prevalence HPV genotypes

HPV Genotype	Prevalence	
	Korea (%)	Other countries (%)
HPV 16	25 ~ 50	25 ~ 51
HPV 18	7 ~ 14	7 ~ 15
HPV 31	1.1 ~ 5	1.1 ~ 6
HPV 33	3 ~ 6	3 ~ 7
HPV 35	1 ~ 5	1 ~ 5
HPV 39	1 ~ 2	1
HPV 45	0.2 ~ 3	10 ~
HPV 51	0.5 ~ 6.3	0.5 ~ 6
HPV 52	3 ~ 6	3 ~ 5
HPV 53	7 ~ 10	
HPV 56	0.05 ~ 8	0.05 ~ 8
HPV 58	11 ~ 14	1 ~ 5
HPV 66	0.04 ~ 4	
HPV 59	0.5 ~ 1	0.5 ~ 1
HPV 68	1.1 ~ 2.1	0.5 ~ 1.4
HPV 6	0.4 ~ 3.2	0.4 ~ 3.3
HPV 11	0.5 ~ 5	0.5 ~ 5
HPV 42	~ 0.3	
HPV 43	~ 0.2	
HPV 44	~ 0.2	
HPV 70	2.3 ~ 7.5	2.3 ~ 7.6
HPV 72	~ 0.5	
HPV 84	~ 0.6	
HPV 81	~ 0.7	
HPV 87	~ 0.8	

The Korean Journal of Pathology, 2009; Int.J.Gynecol Cancer

Comparison of molecular diagnostic method HPV genotyping

	REBA HPV-ID	DNA chip	Hybrid Capture II
Genotyping	Identify	Identify	Distinguish high risk group or low risk group
Sensitivity	10 ² ~ 10 ³ copies	10 ² ~ 10 ³ copies	10 ⁵ copies
Co-infection	distinguish	distinguish	Not distinguish
Processing	automatic	automatic	manual
Reading and interpretation	automatic	automatic	automatic

Kit contents

- 2 X PCR premix (50 test)
- REBA HPV-ID® PCR positive control DNA
 - DNA extraction solution
 - 8-MOP
- REBA HPV-ID® primer mixture
- REBA HPV-ID® Membrane strip
- REBA HPV-ID® β-globin primer mixture
- REBA HPV-ID® REBA positive control
 - Denaturation Solution (DS)
 - Hybridization Solution (HS)
 - Washing Solution (WS)
 - AP conjugate
- Conjugate Dilution Solution (CDS)
 - NBT/BCIP stock solution
 - Staining Solution (SS)
 - Blotting Tray

YD's REBA HPV-ID® is a molecular diagnostic kit for identification of 32 human papilloma virus (HPV) genotypes and detection of 80 HPV genotypes and, which is a causative pathogen of cervical cancer. It is an available genotyping of 18 high-risk, 1 medium-risk and 13 low-risk HPV genotypes, simultaneously. These HPV genotypes are depending on the induction of uterine cervical cancer. Genetic target of REBA HPV-ID® is a polymorphic L1 gene, which expressed at the late stage of infection cycles in the host cells, and the kit employs one-tube nested PCR and Reverse Blot Hybridization Assay (REBA).

Features

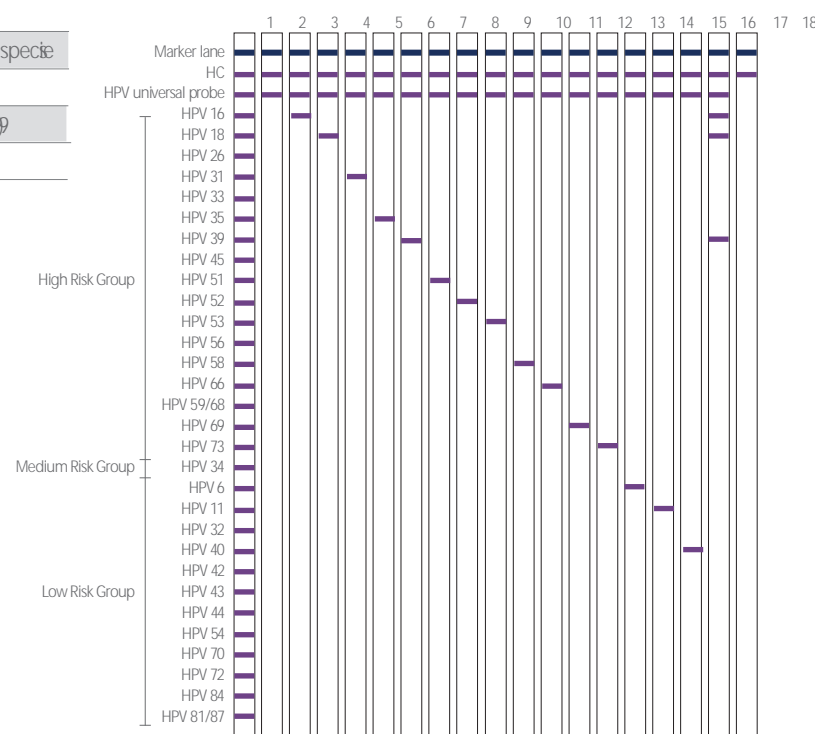
- Detect to HPV genotype of 18 species of high-risk, 1 species of medium-risk, and 13 species of low risk group at one
 - High risk group : HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 66, 59, 68, 69, 73
 - Medium Risk group : HPV 31
 - Low risk group : HPV 6, 11, 32, 40, 42, 43, 44, 54, 70, 72, 81, 84, 87
- Specimen : solid and liquid based specimen
- High sensitivity and specificity
- Rapid test within 2 hours after PCR reaction
- Full automation of REBA procedure and Result analysis
 - REBA Processor : 48 specimen at one
 - REBASCAN : Result interpretation

Sensitivity and Specificity

- Sensitivity : detects up to 100~1000 copies
- Specificity : No cross reactivity other type above this 32 genotypes

Data Interpretation

Lane 1	Other HPV types out of 32 species
Lane 2 -- 16	32 HPV types
Lane 17	Multiple infection (16/18/39)
Lane 18	HPV negative



REBA Devices

REBA Processor

- Automated washing & hybridization steps of strip-based assays
- Easy walk away system
- Quick high throughput
- Reagent pre-heating option
- Reagent save feature
- Fully programmable
- Integral cooling fan
- Reusable trays



Specification

Capacity	48 strips per run
Temperature Control	25°C ~55°C
Temperature Accuracy	+ / -1 degree centigrade
Power	100 - 240 v / 50 - 60 Hz
Dispensing Manifold	6 reagent channels (optional additional 3 channels)
Temperature Controller	PID Control
Dimension	640mm(W) X 620mm(D) X 450mm(H)

REBASCAN

- Automatic scanning of strips for interpretation
- Eliminate critical manual step
- Universal input
- Interface via USB
- Tray orientation sensor
- Comprehensive display for easy operation



Specification

Scan Capacity	48 strips
Tray Detector	Microswitch
Lid Position	Magnetic sensor
Camera Unit	CCD Monochrome unit
Power ON Indicator	Green LED
Scan ON Indicator	Red LED
Instrument Control	PC
Environmental	
Operation	18 °C - 24 °C
Storage	- 10 °C - 70 °C
Relative Humidity	Maximum relative humidity = 80% for temperature up to 31 °C decreasing linearly to 50% relative humidity at 40 °C
Altitude	Up to 2000m
Power Supply	8v DC Universal Input. 100 - 240V AC Main supply voltage fluctuations not to exceed + / - 10% of normal voltage
Dimension	360mm(W) X 630mm(D) X 110mm(H)