

Making a Healthier Future  
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## **BIONEER's MDx in LMIC**

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# Chapter 01

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## Company Profile of BIONEER



## Mission

**Bioneer, an innovative biotech company since 1992**

**Makes healthier future for humanity with genomic technology**

The company is positioned to fully-integrate its capability to develop next generation technologies in the post-genome era through the invention of new biochemistry and instrument.

Bioneer will provide the finest value-priced products for the global Healthcare market by application of state-of-art technologies bringing life-saving treatments as well as diagnostics to the largest number of people.

# Company Profile

Location	Daejeon, South Korea
KOSDAQ Listed /Established	1992.08 / 2005.12
Revenue	USD 39,414,870 (2019)
Employees	390 (as of 2020.01)
Webpage	www.bioneer.com

## Han-Oh Park, President & CEO



- B.S. Chemistry, Seoul National University (84')
- Ph.D. Biochemistry, KAIST (92')
- Vice President, Korea Biotechnology Industry Organization
- Adjunct Professor, KAIST
- Committee Member, Presidential Advisory Council on Science & Technology

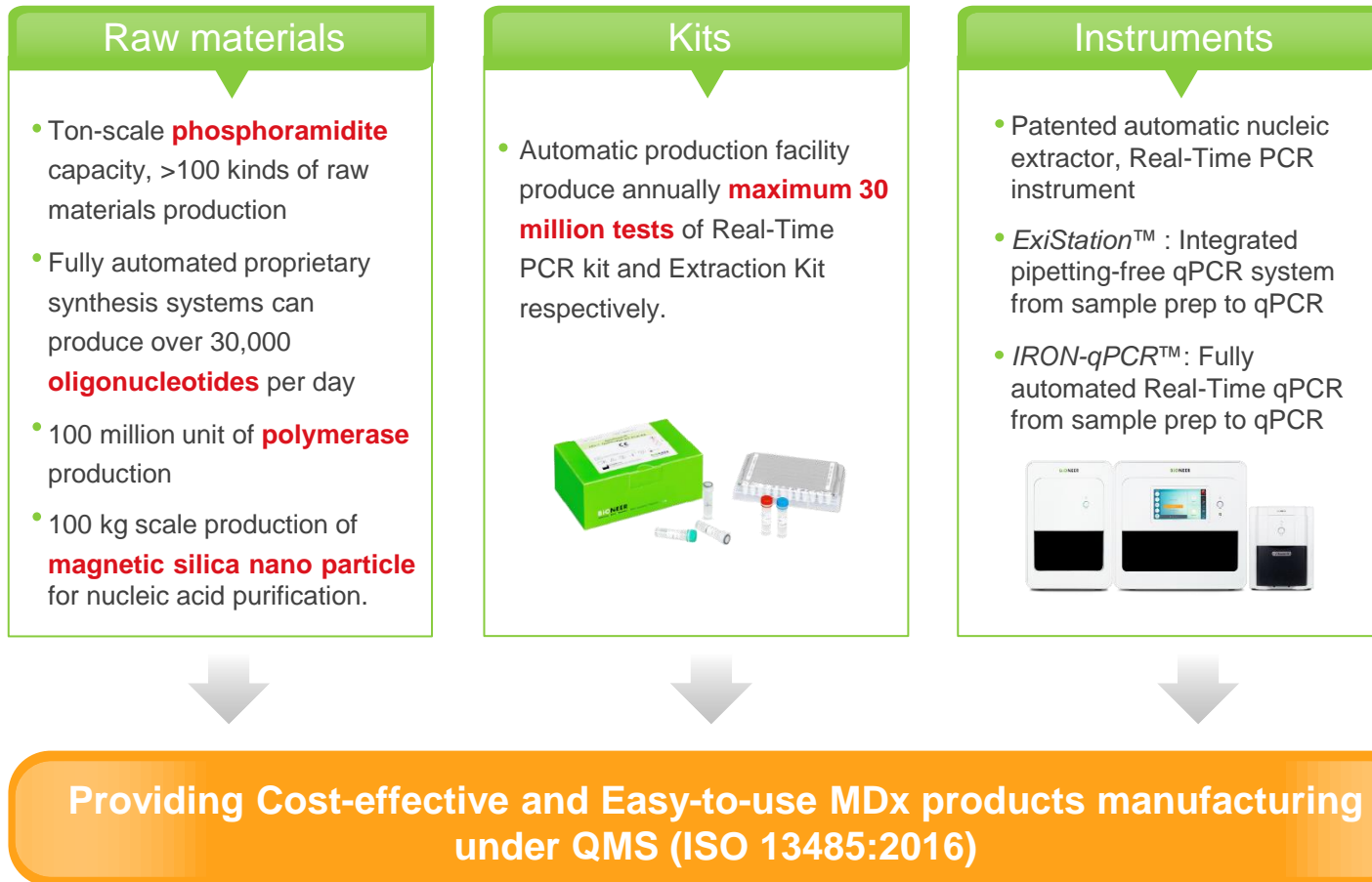
## Synergy in Business

- The key technology of each division is organically integrated.
- Create and maximize synergy by Bioneer strategy.



# BIONEER Provide Total Solution of MDx

BIONEER has developed from raw materials, kits to instruments since 1992



# Intellectual Properties Warrant MDx Technology

## Reagents and Kits (total 60)

No	Application no.	Patent no.	Title	Registered	Pending
1	10-1999-004361	KR 0292883	Hot start PCR Mixture Comprising Pyrophosphate and Pyrophosphatase	KR	
2	10-2007-109055	KR 1098764	Dried Composition for hot-start PCR with Long-Term Stability	KR, US, BR, IN, CN	
3	10-2011-0011639	KR 1818126	Reverse transcriptase having improved thermostability	KR(3), US, EP(GB, FR, DE), JP, CN	
4	10-2013-0025119		Compositions for hot start reverse transcription reaction or hot start reverse transcription polymerase chain reaction	EP(GB, DE, FR, CH), JP, AU, RU	KR, US, CN, CA, IN, BR
5	10-2013-0091821	KR 1717953	New azo compound, use thereof, and process for preparing of the same	JP	EP, US, CN

## Amplification system (total 91)

No	Application no.	Patent no.	Title	Registered	Pending
1	10-2005-7018766	KR 0794703	Real-time monitoring apparatus for biochemical reaction	KR, US, JP, CN	EP
2	10-2007-064558	KR 1089045	Real-time PCR monitoring apparatus	KR, US, JP, CN, EP (GB, DE, FR, IT)	
3	10-2010-0021532	KR 1423936	Universal automatic apparatus for real time monitoring products of nucleic acid amplification reaction and method thereof	KR, RU, JP, AU, ID	US, EP, CA, IN, BR, , TH, TR, CL
4	10-2010-0105630	KR 1420094	Automatic Real-time PCR system for the various analysis of biological sample	KR, US, JP, CN, RU	EP, IN

## Purification system (total 45)

No	Application no.	Patent no.	Title	Registered	Pending
1	10-2011-0041126	KR 1443727	Automatic purification apparatus with magnetic field applying part for biological samples preparation and isolation method of target material from biological samples, and protein expression and purification method	KR, US, RU, ID	EP, IN, BR, TH, TR
2	10-2012-0138335	KR 155534	Automatic cell-free protein production instrument	KR	
3	13858370.3		Automatic cell-free protein production instrument and protein production method using the same	JP, RU, AU	EP, US, CN, IN
4	10-2014-0174256		Magnetic particle separation device and method for separating and purifying nucleic acid or protein		KR, US, EP, CN, JP

# BIONEER protect public human health from epidemic



- SARS Diagnostic Solution : ABADIS Mobile PCR Lab in China



- Swine Flu (H1N1) Diagnostic Kit : About 2 million cases were tested



- Ebola Virus Diagnostic Kit : development with Nigeria Government

2003

2009

2014



- Development of Novel Coronavirus assay
- HBV viral load test kit : CE List A approval

2020



- HIV-1 viral load test kit : CE List A approval

2018



2016

- Zika Multiplex Diagnostic Kit: 1st multiplex kit on WHO EUAL



2020 ~



- WHO PQ – HIV, HCV
- FIND – Tuberculosis (with RIGHT FUND)
- Under EUA by KCDC – Novel Coronavirus



2019

- Listing of HIV (CE) on the Global Fund
- HCV viral load test kit : CE List A approval

BIONEER consistently seeks to provide affordable

“State-of-the-Art Molecular Diagnostics” for Global Human Health .





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## Chapter **02**

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**Suitable  
MDx in LMIC**



# Why **BIONEER's MDx** is suitable to do **LMIC**?

- Highest accuracy by aerosol protection
- Flexible configuration with 2 types of MDx system
- Easy operation system
- Affordable prices

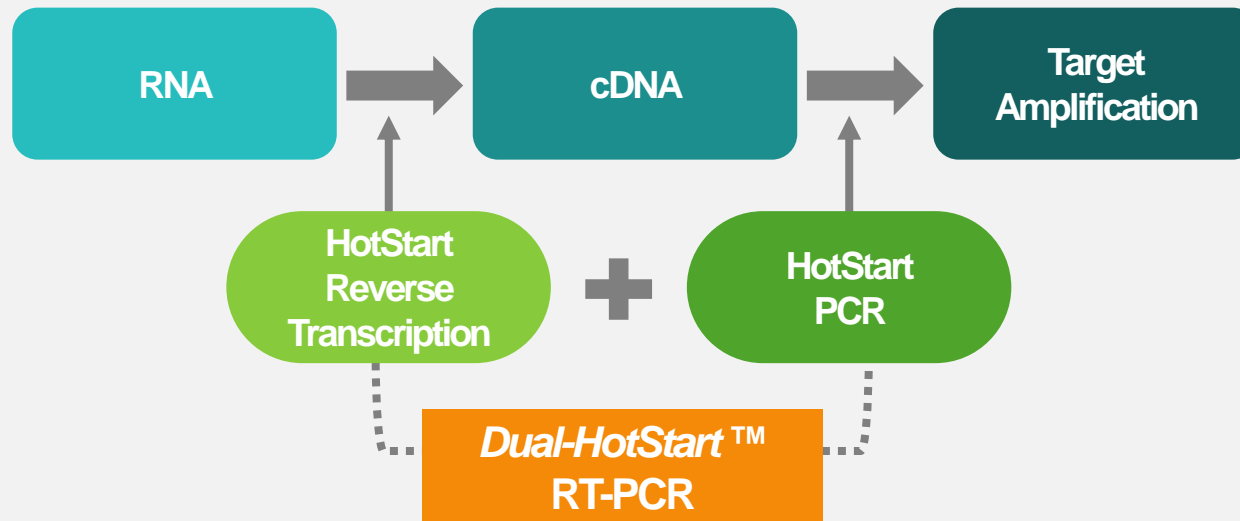
# How could get more sensitive & specific results?

- Unique Dual Hot Start PCR technology.
- Prevent non-specific amplification caused by aerosol contamination

BIONEER's MDx products  
include **various patents & innate system**

Why BIONEER's MDx solution for LMIC?

## What is *Dual-HotStart*<sup>™</sup> technology ?



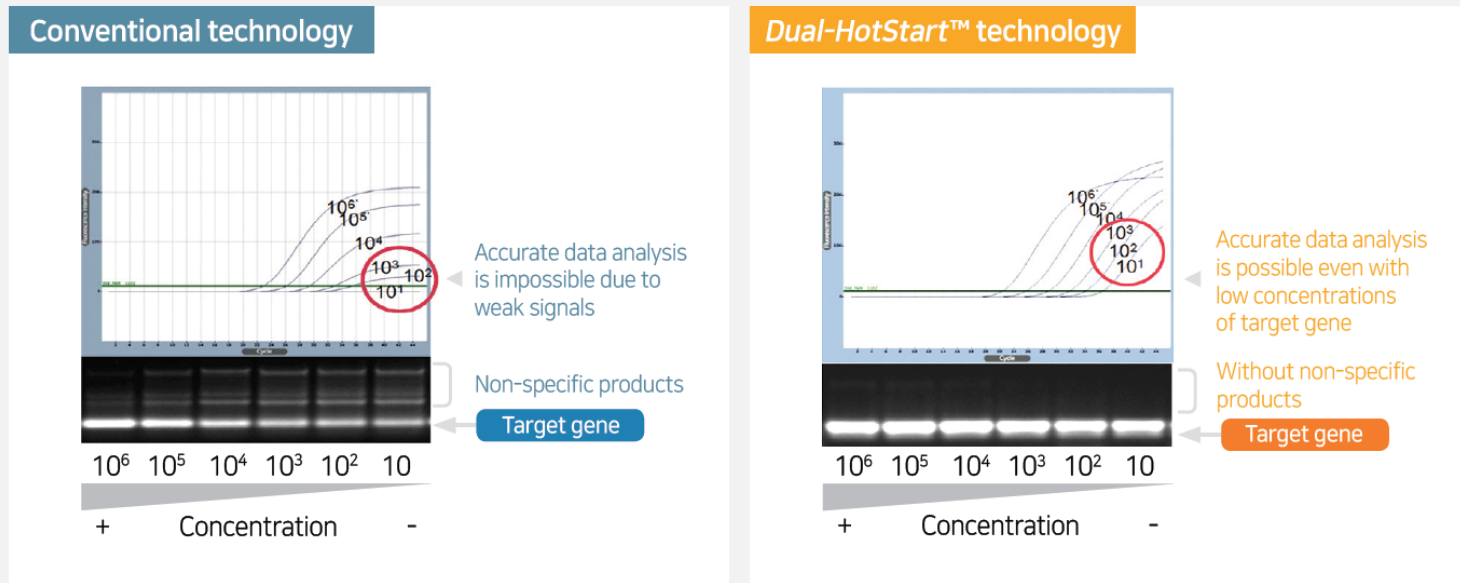
- **More sensitive diagnosis using *Dual-HotStart*<sup>™</sup> technology**

- : Able to diagnose low copies of RNA by eliminating non-specific cDNA synthesis and non-specific DNA amplification

- : Increased specificity by preventing non-specific zero-cycle product formation

# Why BIONEER's MDx solution for LMIC?

## *Dual-HotStart*<sup>TM</sup> technology



- **More sensitive diagnosis using *Dual-HotStart*<sup>TM</sup> technology**

- : Able to diagnose low copies of RNA by eliminating non-specific cDNA synthesis and non-specific DNA amplification

- : Increased specificity by preventing non-specific zero-cycle product formation

# Why BIONEER's MDx solution for LMIC? Keep test accuracy from contamination – *ExiStation*<sup>TM</sup>

## *ExiStation*<sup>TM</sup> System



- **Adapted the 3 layer contamination protecting system to keep the accuracy of test**  
Aerosol generation shield shut down the air flow between in and exterior of instrument.  
Droplet contamination shield block the cross contamination among specimens

Why BIONEER's MDx solution for LMIC?

Keep test accuracy from contamination – *ExiStation*<sup>TM</sup>

## *ExiStation*<sup>TM</sup> System

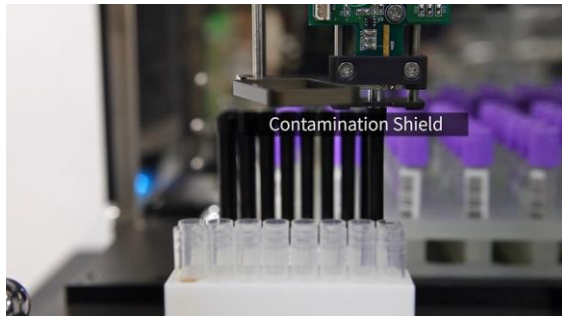


- UV irradiation lamp
  - : Eliminate residual contamination source after running template extraction from biological specimens

Why BIONEER's MDx solution for LMIC?

# Eliminate source of cross contamination – *ExiStation*™ 48A

## *ExiStation*™ 48A System



Contamination Shield



Aerosol Shutter



Aerosol Protection Cover



Why BIONEER's MDx solution for LMIC?

## Pipetting Free, Using Primary Tube – *ExiStation*<sup>™</sup> 48A

### *ExiStation*<sup>™</sup> 48A System



- **ExiLT allow to safe operation without any chance to exposure infection source**  
: Place the capped primary tube in ExiLT  
All process to handle the liquid specimens, Decapping, Transfer tube , dispensing reagent and Recapping are automatic process.

# Excellent performance

**BIONEER provides the lowest LOD with the less sample volume**

**BIONEER's viral load tests allow sensitive analysis using only 400ul sample, but Roche's kit using 1000ul sample.**

System		BIONEER	Roche	Abbott
Analytical sensitivity	HIV-1	33.1 IU/ml *sample vol; 400 µL	33.4 IU/ml *sample vol; 1000 µL	68 IU/ml *sample vol; 600 µL
	HBV	6.02 IU/ml *sample vol; 400 µL	9 IU/ml *sample vol; 650 µL	10 IU/ml *sample vol; 500 µL
	HCV	10.7 IU/ml *sample vol; 400 µL	9.3 IU/ml *sample vol; 650 µL	12 IU/ml *sample vol; 500 µL

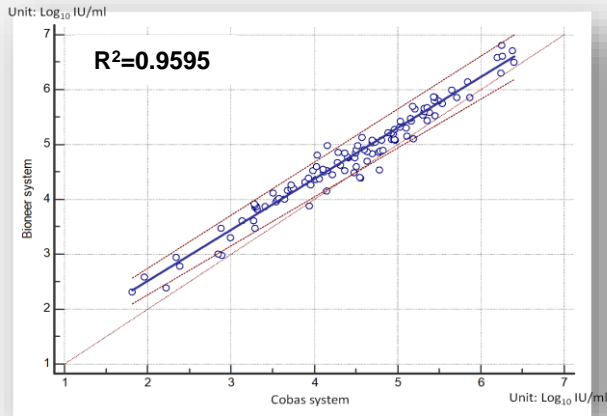
Why BIONEER's MDx solution for LMIC?

# AccuPower® HIV-1 Quantitative RT-PCR Kit

## Features

- **CE List A approved HIV-1 VL test kit**
- Quantification of HIV-1 viral load
- Specimens : EDTA-plasma
- Target & Analytical sensitivity
  - Sensitive detection of various subtype of HIV-1 (group M, N and O)
  - **The LoD is 33.1 IU/ml (Subtype B)**
  - **The LoQ is 50 IU/ml**

The Result of Clinical Comparison with cobas® 8800 system



		Roche cobas® 8800 system (n=254)	
		Positive (n=133)	Negative (n=121)
ExiStation™ system (n=254)	Positive (n=129)	129	0
	Negative (n=125)	4	121

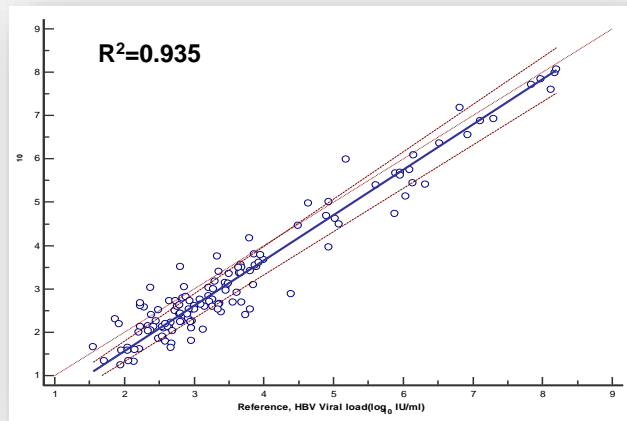
Why BIONEER's MDx solution for LMIC?

# AccuPower® HBV Quantitative PCR Kit

## Features

- **CE List A approved HBV VL test kit**
- Quantification of HBV viral load
- Specimens : Serum, EDTA-plasma
- Target & Analytical sensitivity
  - Sensitive detection of various genotype of HBV (genotype A to G)
  - **The LoD is 6.02 IU/ml (Genotype A2)**
  - **The LoQ is 15 IU/ml**

The Result of Clinical Comparison with cobas® 8800 System



		Roche cobas® 8800 System (n=244)	
		Positive (n=133)	Negative (n=111)
ExiStation™ system (n=244)	Positive (n=133)	133	0
	Negative (n=111)	0	111

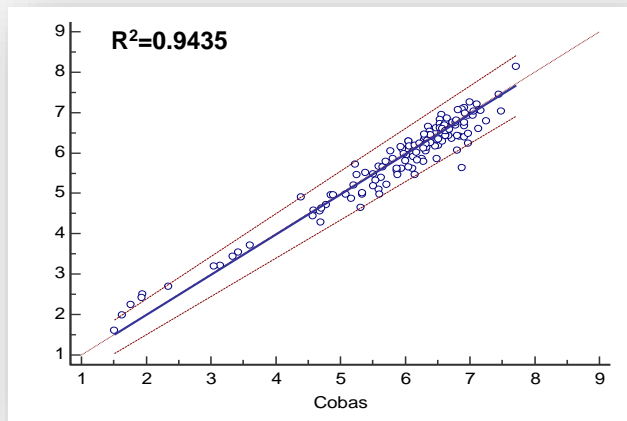
Why BIONEER's MDx solution for LMIC?

# AccuPower® HCV Quantitative RT-PCR Kit

## Features

- **CE List A approved HCV VL test kit**
- Quantification of HCV viral load
- Specimens : Serum, EDTA-plasma
- Target & Analytical sensitivity
  - Sensitive detection of various genotype of HCV (genotype 1 to 6)
  - **The LoD is 10.7 IU/ml (genotype 1a)**
  - **The LoQ is 15 IU/ml**

The Result of Clinical Comparison with cobas® 8800 System



		Roche cobas® 8800 System (n=250)	
		Positive (n=136)	Negative (n=114)
ExiStation™ system (n=250)	Positive (n=136)	135	1
	Negative (n=114)	1	113

## Need MDx system for LMIC?

- Flexible option to choose suitable system according to lab condition
- Various applications applied in a system

BIONEER's unique MDx system provide  
**optimized diagnostic environment**

## Why BIONEER's MDx solution for LMIC?

# ExiStation™ Composed of Prep and PCR Cycler



ExiStation™



ExiStation™ 48A

### Through-put

Configuration	Max. No. of test/a day (8-hour workday)	Hands on time (for Extraction)	Extraction	Hands on time (for PCR)	PCR Analysis
ExiStation™ (with 1 Exiprep™ 16 Dx)	48 tests	15min	1hr 30min	15min	1hr 20min
ExiStation™ (with 2 Exiprep™ 16 Dx)	96 tests	30min	1hr 30min	15min	1hr 20min
ExiStation™ (with 3 Exiprep™ 16 Dx)	144 tests	45min	1hr 30min	15min	1hr 20min
ExiStation™ 48A	144 tests	5min	1hr 40min*	15min	1hr 20min

\*Including automatic sample preparation by ExiLT

Hands on time could vary depending on the user.

## Why BIONEER's MDx solution for LMIC?

# ExiStation™ , Flexibility of Throughput



### 16DX Molecular Diagnostic System

- Flexible usage due to simultaneous diagnosis regardless of sample types and targets.
  - Simultaneous test of HIV, HBV and HCV
- Flexible sample numbers: 1 to 14 samples/run
- Flexible configuration according to sample number
- Continuous workflow from sample to result, within the shortest time of 3.5 hours for 42 tests.
- 3 way protection system against false positive contamination

### Through-put

Configuration	Max. No. of test/a day (8-hour workday)	Hands on time* (for Extraction)	Extraction	Hands on time* (for PCR)	PCR Analysis
<i>ExiStation™</i> (with 1 <i>Exiprep™</i> 16 Dx)	48 tests	15min	1hr 30min	15min	1hr 20min
<i>ExiStation™</i> (with 2 <i>Exiprep™</i> 16 Dx)	96 tests	30min	1hr 30min	15min	1hr 20min
<i>ExiStation™</i> (with 3 <i>Exiprep™</i> 16 Dx)	144 tests	45min	1hr 30min	15min	1hr 20min



Why BIONEER's MDx solution for LMIC?

# Safe, Easy and Fast operation with 48A automatic system



## ExiStation™ 48A System

- Pipetting free  
: Eliminate exposure chance of operator from contamination source
- **Use primary tube directly**  
: decapping/recapping of sample tube and sample transfer motions are all automated.
- **Sample information is inputted automatically using built-in barcoding system**
- Flexibility in sample numbers: 8 to 48 samples / run
- First result is delivered within 3.5 hr and next result is delivered every 1.5 hr.

## Through-put

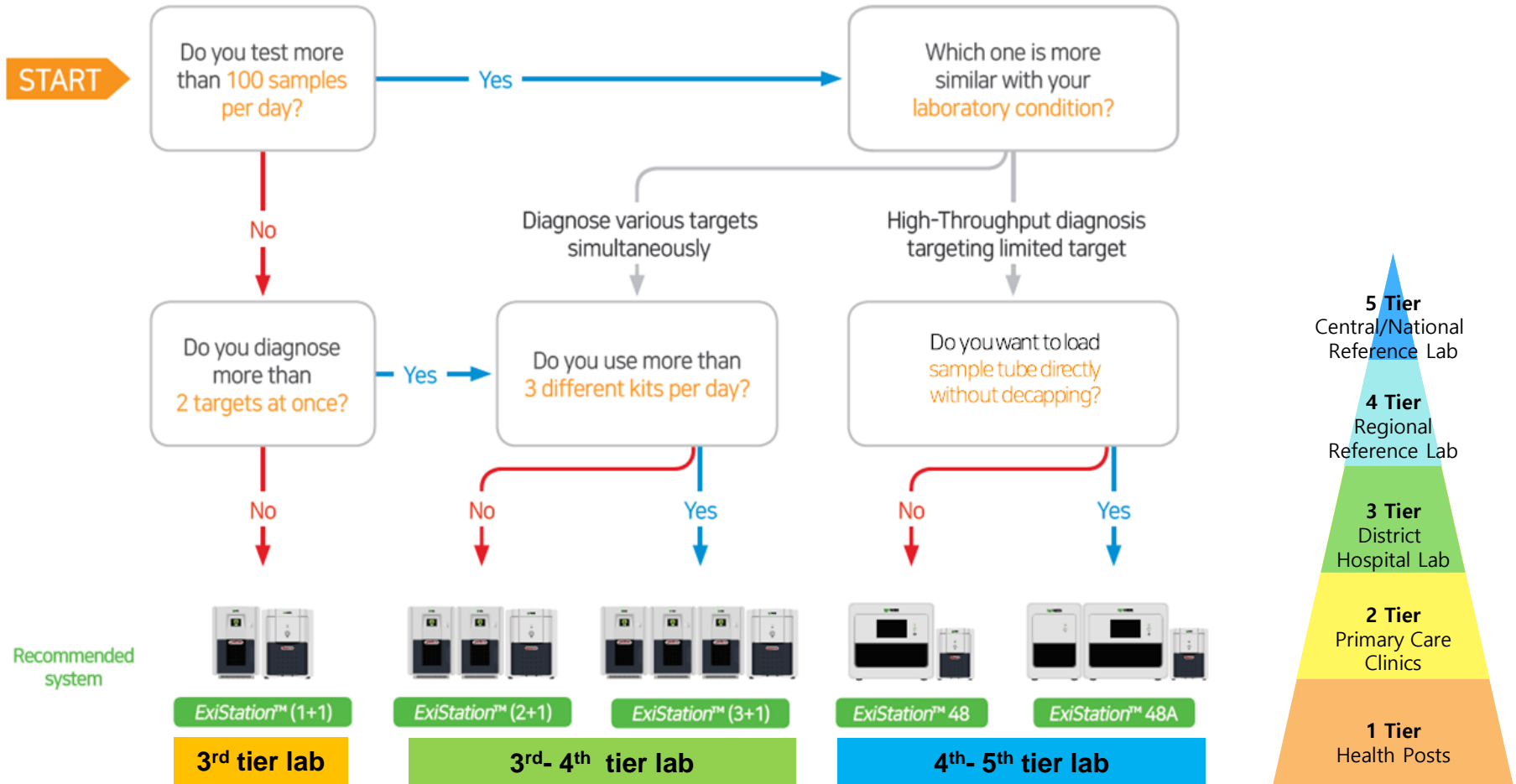
Configuration	Max. No. of test / a day (9-hour workday)	Hands on time (for Extraction)	Extraction	Hands on time (for PCR)	PCR Analysis
ExiStation™ 48A	144 tests	5min	1hr 40min*	15min	1hr 20min

\*Including automatic sample preparation by ExiLT

# Why BIONEER's MDx solution for LMIC?

## Design to cover from 3<sup>rd</sup> and 5<sup>th</sup> Tire Lab

Various configurations of system allow that **optimized setting** for each lab is available.



# Space Efficient Design



Optimized lab setting is available



Company	System	Size (W x H x D, cm)	
		Extractor	Real-Time PCR
Bioneer	ExiStation™ 1+1	32 x 50 x 53	35.5 x 47 x 54
	ExiStation™ 2+1	64 x 50 x 53	35.5 x 47 x 54
	ExiStation™ 3+1	96 x 50 x 53	35.5 x 47 x 54
Abbott	m2000	145 x 178 x 79	34 x 49 x 45
Roche	Cobas 4800	166 x 90 x 101	57 x 50 x 59

# Why BIONEER's MDx solution for LMIC?

## Space Efficient Design – MobileLab

Compact size of *ExiStation™* allows to place in Mobile Lab



	Install Instruments	Qty
1	<i>Exicycler™</i> 96	1
2	<i>ExiPrep™</i> 16 Dx	3
3	<i>ExiSpin™</i> (basic + vortex)	2
4	Centrifuge(2ml tube)	1
5	Bio-safety Cabinet class II A2	1
6	Control Computer	1
7	Refrigerator	2
8	clinical centrifuge	1
9	Thermo shaker	1
10	Vortex	1
11	Bio-safety Cabinet Class I	1
12	Mini Cabinet	1
13	printer	1
14	label printer	1

- **Expected test number: 630 clinical samples**
  - 126 clinical samples x 5 days for each mobile lab
- **Provide modern MDx lab.**
  - Separated space for Laboratory and Preparation
  - Installation of UV lamps and individual air conditional in each room

# Diverse Applications in a single system

The only system compatible with 30 types of applications

		ExiStation™	Cobas4800	m2000
Targets	HIV	O	O	O
	HBV	O	O	O
	HCV	O	O	O
	MDR-TB	O	X	X
	MTB&NTM	O	O	O
	Zika, Dengue, Chikungunya	O	X	△ (Only Zika)
	STI Multiplex	O (Total 12 targets)	△ (Total 4 targets)	△ (Total 2 targets)
	CMV	O	O	O
	EBV	O	X	X
	BKV	O	X	X
	HPV	O	O	X
	Influenza A, New influenza A	O	X	X
	C. pneumonia	O	X	X
	M. pneumonia	O	X	X
	Norovirus	O	X	X
	Enterovirus	O	X	X

# Current & Future CE certified parameters

BIONEER provides the **BEST POLYVALENT** MDx System in the world

## Now (30 types)

### Hepatitis & HIV VL Test

- HBV Kit
- HCV Kit
- HIV-1 Kit

### Tuberculosis

- MTB Kit
- MTB & NTM Kit
- TB & MDR Kit
- TB & XDR Kit

### STIs

- STI 8A Kit  
(CT, NG, UU, MG)
- STI 8B Kit  
(TV, MH, HSV1, HSV2)
- STI 4C Kit  
(TP, UP, CA, GV)

### Transplantation-related virus

- CMV Kit
- EBV Kit
- BKV Kit

### Genotyping Kits

### Human Papillomavirus

- HPV 16&18 Kit
- HPV Genotyping Kit

### Gastrointestinal Diseases

- Norovirus Kit
- Enterovirus Kit

### Respiratory Diseases

- InfA Kit
- New InfA Kit
- CP Kit
- MP Kit
- MERS-CoV Kit

### Mosquito-borne Diseases

- ZIKV multiplex Kit  
(ZIKV, DENV, CHIKV)

## Near Future (35 types)

### Hepatitis & HIV VL Test

- HBV Kit
- HCV Kit
- HIV-1 Kit

### Tuberculosis

- MTB Kit
- MTB & NTM Kit
- TB & MDR Kit
- TB & XDR Kit

### STIs

- STI 8A Kit  
(CT, NG, UU, MG)
- STI 8B Kit  
(TV, MH, HSV1, HSV2)
- STI 4C Kit  
(TP, UP, CA, GV)

### Transplantation-related virus

- CMV Kit
- EBV Kit
- BKV Kit

### Genotyping Kits

### Human Papillomavirus

- HPV 16&18 Kit
- HPV Genotyping Kit
- HPV-HR screening Kit

### Gastrointestinal Diseases

- Norovirus Kit
- Enterovirus Kit
- Diarrhea Virus Kit

### Respiratory Diseases

- InfA Kit
- New InfA Kit
- CP Kit
- MP Kit
- MERS-CoV Kit
- Pneumonia multiplex Kit

### Mosquito-borne Diseases

- ZIKV multiplex Kit  
(ZIKV, DENV, CHIKV)
- DENV Serotyping Kit

### AMR Diagnostics

- AMR Screening & ID Kit

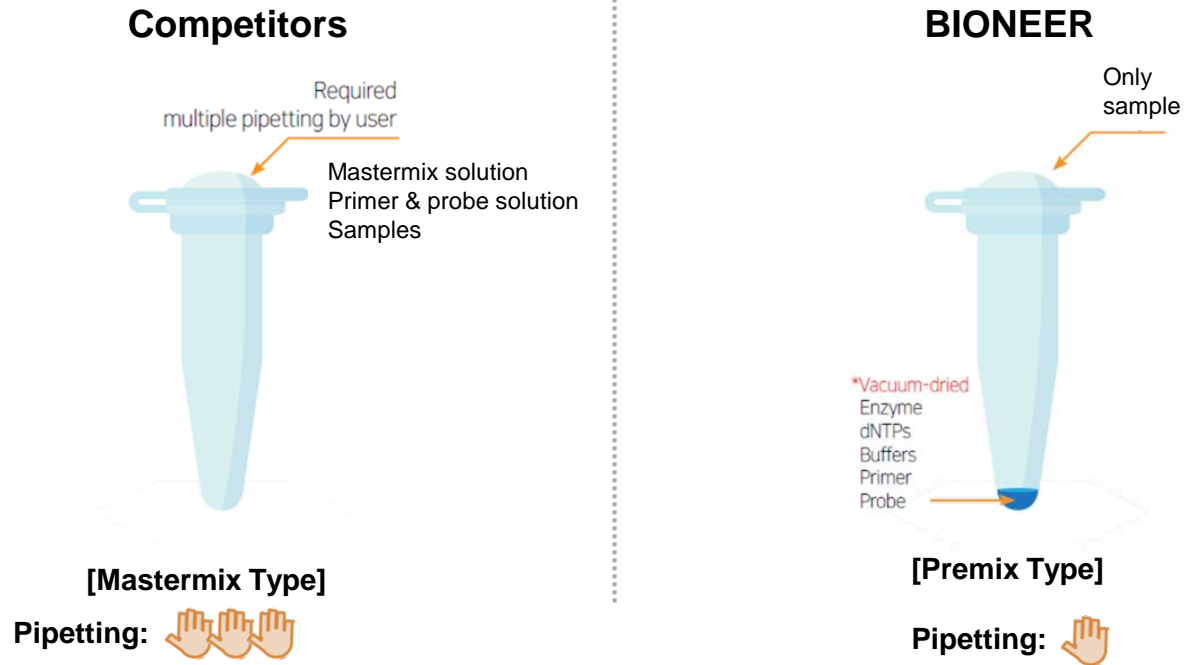


# **How to solve deficiency of skilled human resource in LMIC?**

**One day training make a specialist for Existation operation**

# Why BIONEER's MDx solution for LMIC? Easy to Use

## Minimized hands on step by premix type kit



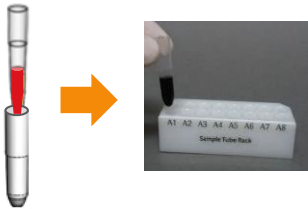
Premix type MDx kits **eliminate volumetric variations** and **enhance user convenience** by minimizing pipetting



# Easy , Fast and comfortable Operation using 16 DX

## *ExiStation™ System*

### Bio Safety bench



Sample preparation

### *ExiPrep™ 16 Dx*



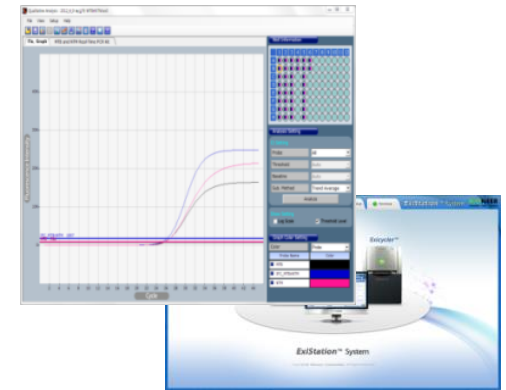
Template Extraction

### *Exicycler™ 96*



Real-Time PCR  
Amplify template RNA

### *ExiStation™ S/W*

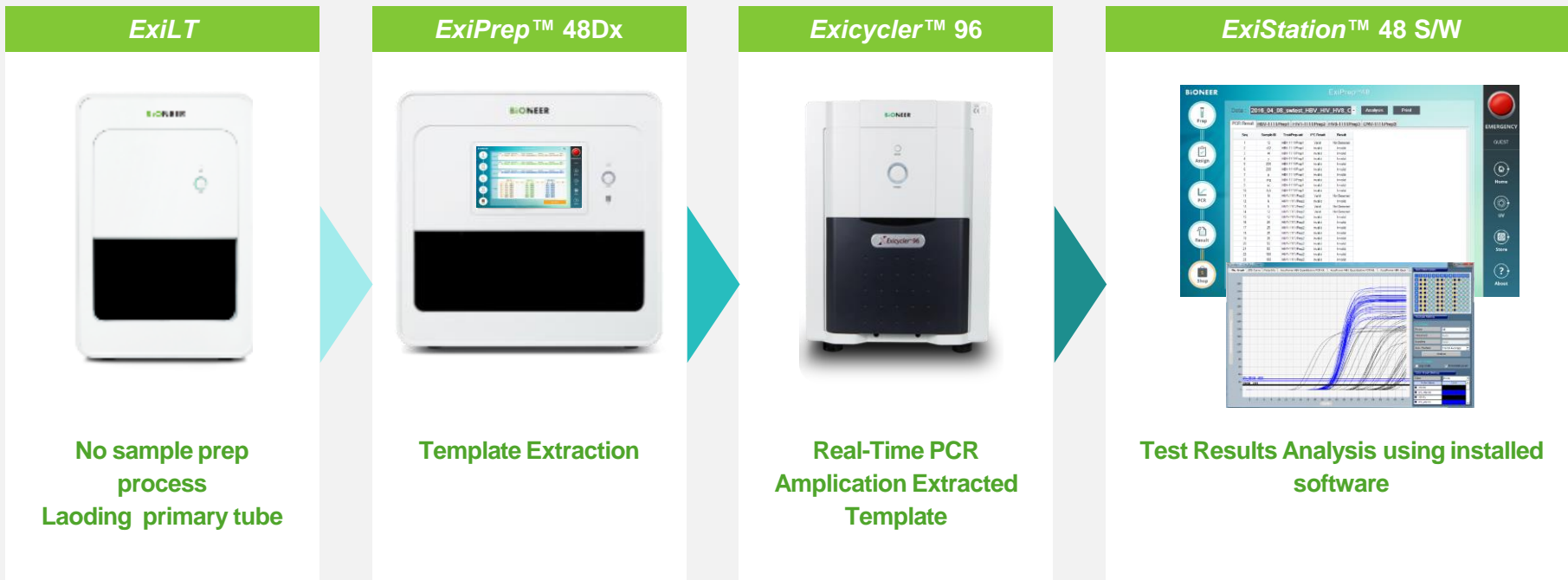


Test Results Analysis using installed  
software

- **Efficient Test using *ExiStation™ System***
  - : No pipetting process after sample loading
  - : Acquire test results with in 3.5 hours
  - : Flexible system configuration depending on throughput

# Safe, Easy and Fast operation with 48A automatic system

## ExiStation™ 48A System

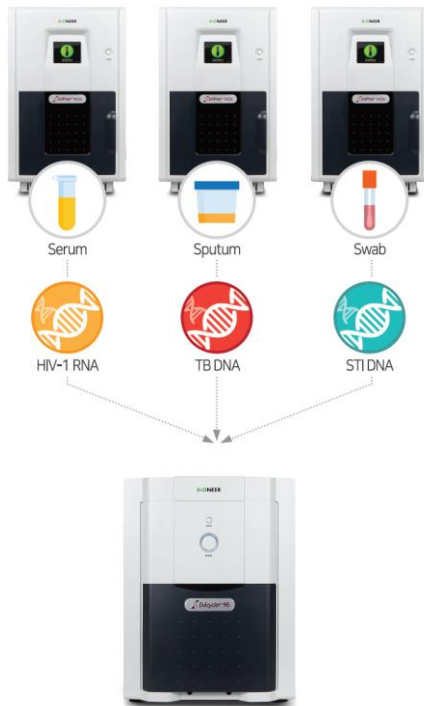


- **Full automatic process from Loading to Extraction with ExiStation™ 48A System**
  - : **Pipetting "0"**, warrant operator safety from infectious source
  - : Require minimum labor resource
  - : First result is delivered within 3.5 hr and next result is delivered every 1.5 hr.

# Why BIONEER's MDx solution for LMIC?

## Easy to Use

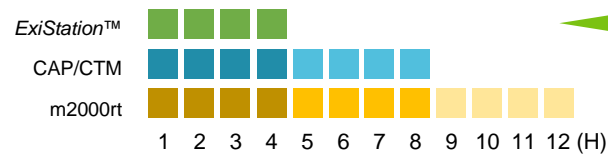
### Easy & Efficient simultaneous diagnosis



- Flexible usage due to simultaneous diagnosis regardless of sample types and targets.
  - Simultaneous diagnosis allows earlier detection of superinfection, such as HIV and TB.
  - Simultaneous test of **HIV-1, HBV, HCV viral load**

#### [TIME TABLE<sup>1</sup>]

Time comparison in the case of diagnosis of 3 targets



Based on diagnosis of 3 targets,  
**2-3 Times faster**  
than competitors due to  
Random-access system!

1- It is for the simultaneous diagnosis of 16 samples (including controls) of HIV-1, HBV and HCV VL tests. *ExiStation™* system is proper to small-mid laboratory. Similar throughput is expected in case of other target combination like above figure.

# Why BIONEER's MDx solution for LMIC?

## Easy to Use

Easy operation allows one-day training!



- Just “ONE-DAY” training to operate *ExiStation*™
- Using various training materials such as video, quick guide, SOP and etc.

# Who will be in charge of customer claims

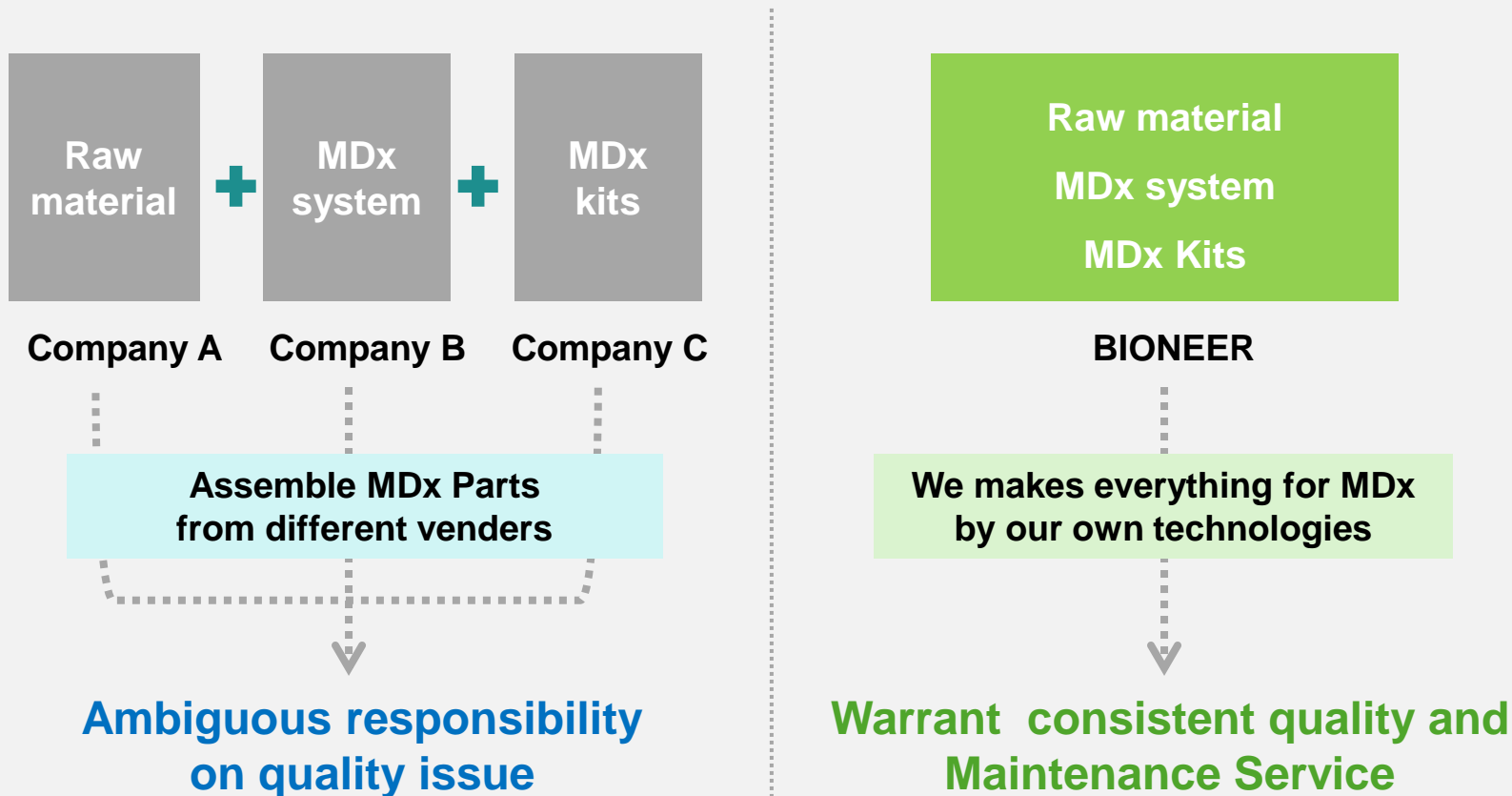
BIONEER provide total solution from raw materials to instruments  
**using our own technologies**

# Why BIONEER's MDx solution for LMIC?

## High Quality with Affordable Price

BIONEER provides MDx products with integrated quality

### Vender Consortium VS Total Solution





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## Chapter **03**

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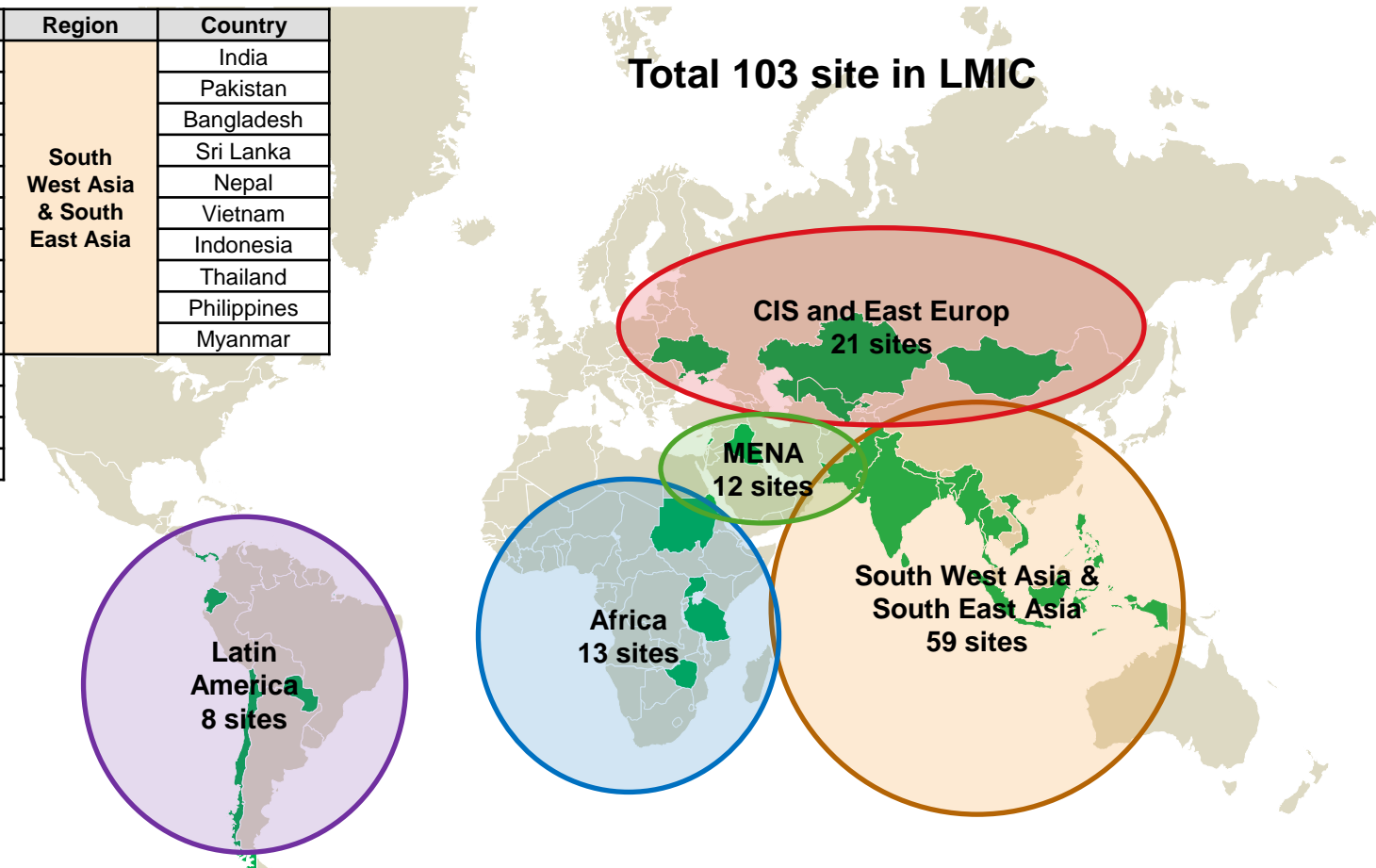
### Existation in LMIC

# Existation Installation Status in LMIC

**ExiStation™ series are used in 24 LMIC countries.**

Targets : HIV, HBV, HCV, TB, ZIKV and others

Region	Country	Region	Country
Africa	Sudan	South West Asia & South East Asia	India
	Uganda		Pakistan
	Zimbabwe		Bangladesh
	Tanzania		Sri Lanka
C. I. S	Kazakhstan		Nepal
	Uzbekistan		Vietnam
	Ukraine		Indonesia
	Mongolia		Thailand
Latin America	Panama		Philippines
	Chile		Myanmar
	Paraguay		
MENA	Lebanon		
	Iraq		
	U.A.E		





# Evaluation Study in Field

Year	Country	Tested Items	Institute
2016	Tanzania	ZIKA, HIV, Dengue	National Institute For Medical Research(NIMR)
2016	Cameroon	HCV, HBV Viral Load	CPC (Centre Pasteur Du Cameroun)
2016	France	HIV, HBV, HCV (CE IVD certification)	Cerba Specimen Service, Paris
2016	Tanzania	ZIKA, HBV, HCV, TB&MDR, HIV	NHLQATC(National Health Laboratory Quality Assurance and Training Center)
2017	Kazakhstan	MTB/XDR	National Scientific Center of Physic pulmonology
2018	Kenya	HIV, HBV, HCV, HPV	KNBTS (Kenya National Blood Transfusion Services )
2018	Uganda	BCI combo kit ( HIV, HBV, HCV)	UBTS (Uganda Blood Transfusion Services)
2019	Indonesia	HIV	National Institute of Allergy and Infectious Disease
Present	South Africa	HIV (WHO PQ)	National Health Laboratory Service Tygerberg

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