Making

da Healthier Future

for Humanity

with BIONEER’s MDx
Who is BIONEER?

Based on integrated molecular technology,
We delivers **TOTAL SOLUTION** for MDx

- Established 1992
- 1st Bio-venture in Korea
- Invest 35% of the annual revenues
- Various MDx products using own technologies

Features of BIONEER’s MDx
BIONEER provides total solution of MDx by integrated technologies

- MDx System
- Various Diagnostic Kits
- In-house Raw Material Production

We guarantee of FULL RESPONSIBILITY for MDx
Features of BIONEER’s MDx

**BIONEER’s MDx**

- **Raw material**
- **MDx system**
- **MDx kits**

Company A + Company B + Company C

Each different company makes products for MDx

Expensive!

Raw material

MDx system

MDx Kits

BIONEER

We makes everything for MDx by our own technologies

High cost effectiveness!
Status of Global Business - Network

Diagnostic Distributor: about 30 counties
Branch: USA, China
Status of Global Business - Partners

BIONEER makes global business by cooperating with many of business partners!
History of BIONEER’s MDx Product

- **2003**: SARS Diagnostic Solution: ABADIS Mobile PCR Lab in China
- **2009**: Swine Flu (H1N1) Diagnostic Kit: about 2 million cases were tested
- **2014**: Ebola Virus Diagnostic Kit: development with Nigeria Government
- **2016**: Zika Multiplex Diagnostic Kit: 1st multiplex kit on WHO EUAL

**Features of BIONEER’s MDx**

- **6 types of ExiPrep™ Dx Kit**
- **TB&MDR Real-Time PCR Kit**
- **TV Real-Time PCR Kit**
- **UU Real-Time PCR Kit**
- **Exicycler™ 96 V4**
- **5 types of AccuPower® Real-Time PCR Kit**
- **ExiStation™**
- **ExiPrep™ 16 Dx**
- **14 types of AccuPower® Real-Time PCR Kit** (including MTB&NTM, EBV, InfA and etc.)
- **15 types of AccuPower® Real-Time PCR Kit** (including HPV 16&18 kit, STI multiplex kit and etc.)
- **AccuPower® STI8A-Plex Real-Time PCR Kit**
- **AccuPower® CT&NG Real-Time PCR Kit**
- **CE List A of HBV, HCV, HIV-1 diagnostic kit**
- **XDR-TB Launching**

* This history is based on the year of achievement of CE mark.
### Key Patents

#### Reagents and Kits (total 60)

<table>
<thead>
<tr>
<th>No</th>
<th>Application no.</th>
<th>Patent no.</th>
<th>Title</th>
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<tr>
<td>1</td>
<td>10-1999-004361</td>
<td>KR 0292883</td>
<td>Hot start PCR Mixture Comprising Pyrophosphate and Pyrophosphatase</td>
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<td>4</td>
<td>10-2013-0025119</td>
<td>KR 1717953</td>
<td>Compositions for hot start reverse transcription reaction or hot start reverse transcription polymerase chain reaction</td>
<td>EP(GB, DE, FR, CH), JP, AU, RU</td>
<td>KR, US, CN, CA, IN, BR</td>
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<td>5</td>
<td>10-2013-0091821</td>
<td>KR 1717953</td>
<td>New azo compound, use thereof, and process for preparing of the same</td>
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#### Amplification system (total 91)

<table>
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<th>Patent no.</th>
<th>Title</th>
<th>Registered</th>
<th>Pending</th>
</tr>
</thead>
</table>

#### Purification system (total 45)

<table>
<thead>
<tr>
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<th>Application no.</th>
<th>Patent no.</th>
<th>Title</th>
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<th>Pending</th>
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<tr>
<td>1</td>
<td>10-2011-0041126</td>
<td>KR 1443727</td>
<td>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</td>
<td>KR, US, RU, ID</td>
<td>EP, IN, BR, TH, TR</td>
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<td>2</td>
<td>10-2012-0138335</td>
<td>KR 155534</td>
<td>Automatic cell-free protein production instrument</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>13858370.3</td>
<td>KR 155534</td>
<td>Automatic cell-free protein production instrument and protein production method using the same</td>
<td>JP, RU, AU</td>
<td>EP, US, CN, IN</td>
</tr>
</tbody>
</table>
### MDx System - *ExiStation™* Series

#### Through-put

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Max. No. of test / a day (9-hour workday)</th>
<th>Hands on time (for Extraction)</th>
<th>Extraction</th>
<th>Hands on time (for PCR)</th>
<th>PCR Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>ExiStation™</em> (with 1 <em>Exiprep™</em> 16 Dx)</td>
<td>48 tests</td>
<td>15min</td>
<td>1hr 30min</td>
<td>15min</td>
<td>1hr 20min</td>
</tr>
<tr>
<td><em>ExiStation™</em> (with 2 <em>Exiprep™</em> 16 Dx)</td>
<td>96 tests</td>
<td>30min</td>
<td>1hr 30min</td>
<td>15min</td>
<td>1hr 20min</td>
</tr>
<tr>
<td><em>ExiStation™</em> (with 3 <em>Exiprep™</em> 16 Dx)</td>
<td>144 tests</td>
<td>45min</td>
<td>1hr 30min</td>
<td>15min</td>
<td>1hr 20min</td>
</tr>
<tr>
<td><em>ExiStation™</em> 48</td>
<td>144 tests</td>
<td>35min</td>
<td>1hr</td>
<td>15min</td>
<td>1hr 20min</td>
</tr>
<tr>
<td><em>ExiStation™</em> 48A</td>
<td>192 tests</td>
<td>5min</td>
<td>1hr 20min*</td>
<td>15min</td>
<td>1hr 20min</td>
</tr>
</tbody>
</table>

*Including automatic sample preparation by *ExiLT*
MDx System - *ExiStation™ 48A*

**Ultimate Molecular Diagnostic System with Full Automation**

- **Pipetting free**: Use primary tube directly. Decapping/capping 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.
Features of BIONEER’s MDx

MDx System - *ExiStation™*

Simultaneous diagnosis: Random-access

- **Flexible sample numbers:** 1 to 16 samples/run
- **Flexible system configuration** according to sample number
- **Simultaneous diagnosis** allows earlier detection of superinfection, such as HIV and TB.
  → Thus, saving more people.
- **Easy and efficient control of sample information** by scanning barcode only once.
- **Continuous workflow** from sample to result, **within the shortest time of 3.5 hours for 48 tests.**

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**Enter Information using Barcode Scanner**

**Whole Blood, Serum, plasma**
- HIV
- Hepatitis
- ZIKV, DENV, CHIKV

**Sputum**
- MDR-TB, TB/NTM
- Pneumonia

**Urine, Swabs**
- STIs
- HPV
- RV

**Sample Prep**

**ExiPrep™ 16 Dx**

**Exicycler™ 96**

**Analyze, Save results & Report**
Pipeline of MDx System - POC-qPCR

**Features**

- 2 types of instrument; for 2-cartridge & 4-cartridge
- All process complete within 30min
  - Automatic process from sample preparation to Real-Time PCR
  - No pre-treatment before sample preparation

* Specifications & features of product can be changed.*
Applications

- Potential to Polyvalent assays
  - RV16 (Respiratory viruses)
  - AMR (Antimicrobial resistance)
  - TB-MDR (Tuberculosis-Multi drug resistance) & XDR (Extended Drug Resistance)
  - HIV-1 / HBV / HCV viral load
  - STI (Sexually Transmitted infections)

* Specifications & features of product can be changed.
<table>
<thead>
<tr>
<th>Features of BIONEER’s MDx</th>
<th>List of BIONEER’s MDx Kits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis &amp; HIV</td>
<td>• HBV Kit</td>
</tr>
<tr>
<td></td>
<td>• HCV Kit</td>
</tr>
<tr>
<td></td>
<td>• HIV-1 Kit</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>• MTB Kit</td>
</tr>
<tr>
<td></td>
<td>• MTB &amp; NTM Kit</td>
</tr>
<tr>
<td></td>
<td>• TB &amp; MDR Kit</td>
</tr>
<tr>
<td>Sexually Transmitted</td>
<td>• STI 8A Kit (CT, NG, UU, MG)</td>
</tr>
<tr>
<td>Disease</td>
<td>• STI 8B Kit (TV, MH, HSV1, HSV2)</td>
</tr>
<tr>
<td>Respiratory Disease</td>
<td>• InfA Kit</td>
</tr>
<tr>
<td></td>
<td>• New InfA Kit</td>
</tr>
<tr>
<td></td>
<td>• CP Kit</td>
</tr>
<tr>
<td></td>
<td>• MP Kit</td>
</tr>
<tr>
<td></td>
<td>• MERS-CoV Kit</td>
</tr>
<tr>
<td>Transplantation-related</td>
<td>• CMV Kit</td>
</tr>
<tr>
<td>Disease</td>
<td>• EBV Kit</td>
</tr>
<tr>
<td></td>
<td>• BKV Kit</td>
</tr>
<tr>
<td>Gastro-intestinal Disease</td>
<td>• Norovirus Kit</td>
</tr>
<tr>
<td></td>
<td>• Enterovirus Kit</td>
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<tr>
<td>Mosquito-borne Disease</td>
<td>• ZIKV multiplex Kit (ZIKV, DENV, CHIKV)</td>
</tr>
<tr>
<td>Genotyping</td>
<td>• HPV 16&amp;18 Kit</td>
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<tr>
<td></td>
<td>• HPV Genotyping Kit</td>
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<tr>
<td></td>
<td>• MTHFR Kit</td>
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<tr>
<td></td>
<td>• JAK2 V617F Kit</td>
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<tr>
<td></td>
<td>• Factor V Leiden Kit</td>
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<td>• ApoE Kit</td>
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<td>• Warfarin Kit</td>
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<td></td>
<td>• HLA-B27 Kit</td>
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<td>• TPMT Kit</td>
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<td>• MTHFR Kit</td>
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<td>• JAK2 V617F Kit</td>
</tr>
<tr>
<td></td>
<td>• Factor V Leiden Kit</td>
</tr>
</tbody>
</table>
Features of BIONEER’s MDx

MDx Kit - HIV-1

Features

• 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® 6800 at Cerba Center in Paris

<table>
<thead>
<tr>
<th></th>
<th>Roche cobas® 6800 (n=224)</th>
<th>ExiStation™ system (n=224)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Positive (n=111)</td>
<td>Positive (n=111)</td>
</tr>
<tr>
<td></td>
<td>Negative (n=113)</td>
<td>Negative (n=113)</td>
</tr>
</tbody>
</table>

R² = 0.9713
MDx Kit - Hepatitis B (HBV)

Features

- 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® 6800 at Cerba Center in Paris
MDx Kit - Hepatitis C (HCV)

Features

• 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® 6800 at Cerba Center in Paris

<table>
<thead>
<tr>
<th></th>
<th>Roche cobas® 6800 (n=230)</th>
<th>ExiStation™ system (n=230)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive (n=116)</td>
<td>115</td>
<td>115</td>
</tr>
<tr>
<td>Negative (n=114)</td>
<td>1</td>
<td>113</td>
</tr>
</tbody>
</table>

R² = 0.9508
MDx Kit - Tuberculosis

TB/NTM related kits enable accurate diagnosis

• AccuPower® MTB&NTM Real-Time PCR Kit
• AccuPower® TB&MDR Real-Time PCR Kit
• AccuPower® XDR-TB Real-Time PCR Kit (In the development)

Take samples from TB suspected patients (Sputum, BAL, Urine)

Nucleic acid extraction

ExiPrep™ 16 Dx

1st diagnosis

• AccuPower® TB&MDR kit
  - TB : Positive MDR resistance
  - TB : Positive MDR sensitivity

2nd diagnosis

• AccuPower® TB&XDR kit
  - XDR Resistance
  - XDR Sensitivity

• AccuPower® MTB&NTM kit
  - NTM: Positive
  - NTM: Negative

XDR-TB
MDR-TB
Tuberculosis
NTM
Not infected
MDx Kit - Tuberculosis

Features of MDR-TB diagnostic Kit

- Simultaneous diagnosis of TB and MDR-TB
- Specimens: Sputum, BAL, CSF, tissue, culture specimen
  - Simple pretreatment of sputum samples by using EZ-Solution
- Target
  - MTB: IS6110
  - RIF: rpoB (10 mutant sites, 29 mutations)
  - INH: inhA, katG (3 mutant sites, 7 mutations)
- Analytical Sensitivity
  - MTB: 21.88 copies/test
  - RIF: 3.98 copies/test
  - INH: 179.8 copies/test
Features of XDR-TB diagnostic Kit

• Simultaneous diagnosis of TB and XDR-TB
• Specimens: Sputum, BAL, CSF, tissue, culture specimen
  › Simple pretreatment of sputum samples by using EZ-Solution
• Target
  › gyrA: Codon 90~94 (Fluoroquionolone)
  › rpsL: Codon 43, 88 (Aminoglycosides (Amikacin, Capreomycin, Kanamycin)
  › rrs: Nucleotide 513~517, 1401, 1402, 1484 (Streptomycin)
  › embB: Codon 306 (Ethambutol)
MDx Kit - Human Papilloma Virus (HPV)

Features

• Simultaneous diagnosis of HPV 16 & HPV 18
• Specimens: Cervical swab
• Analytical Sensitivity
  › HPV 16: 13.18 copies/test
  › HPV 18: 10.18 copies/test

Correlation with Reference Method

• Comparison study with reference method
• Using total 22 clinical samples

<table>
<thead>
<tr>
<th></th>
<th>SeeGene Seeplex®</th>
<th>AccuPower® HPV 16&amp;18 Real-Time PCR Kit</th>
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</thead>
<tbody>
<tr>
<td>Positive</td>
<td>12</td>
<td>Positive</td>
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<tr>
<td>Negative</td>
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</table>

* Those results agreed 100% with those from direct sequencing results.
BIONEER provides affordable MDx for the world!

- Full responsibility of QMS by the integration of in-house developed systems and kits including raw materials.

- Multi-valent system up to 16 multiplex assay

- Outstanding sensitivity & reproducibility

- Easy to operate; one-day training is enough

- High cost effectiveness
Thank you

www.bioneer.com