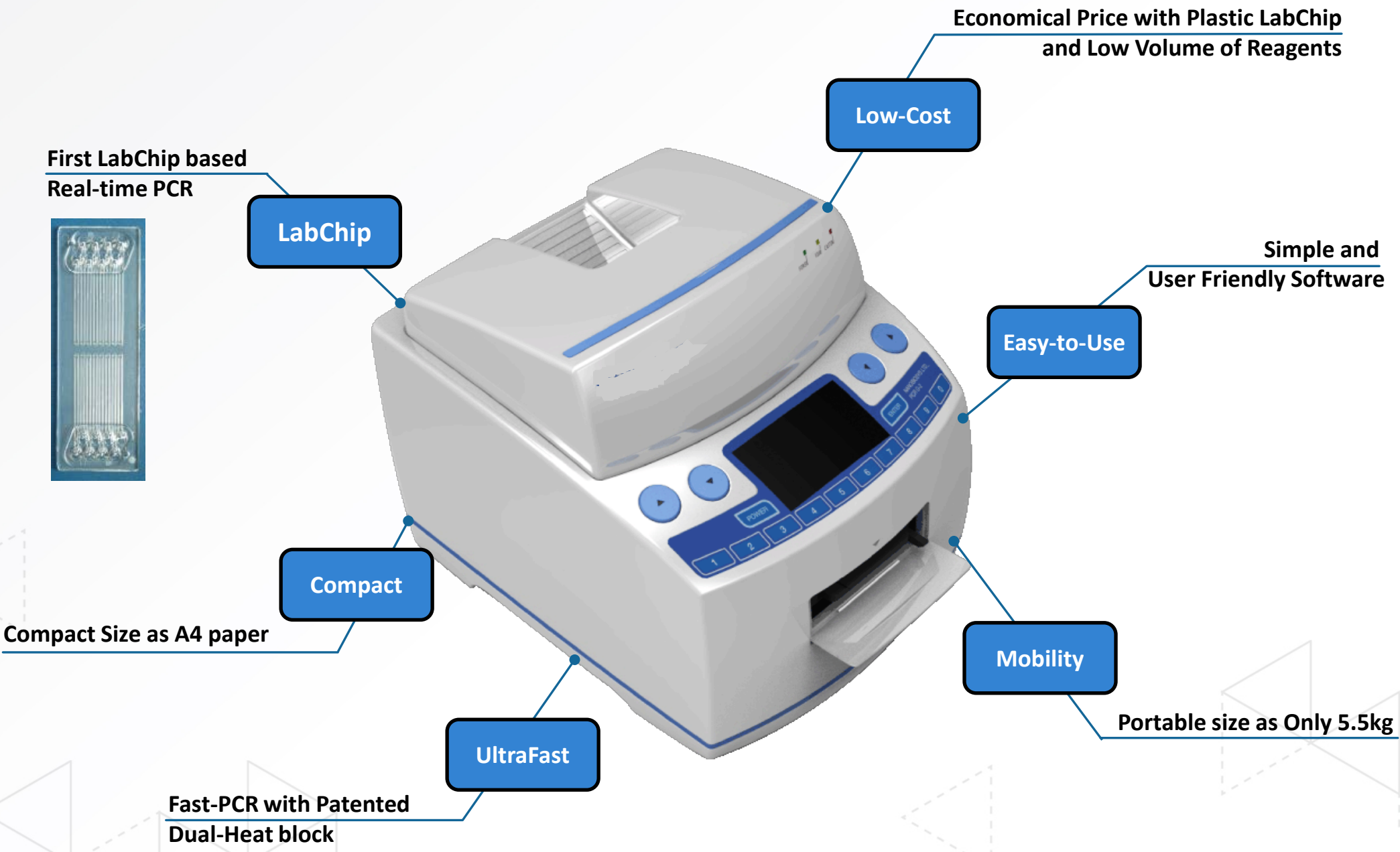
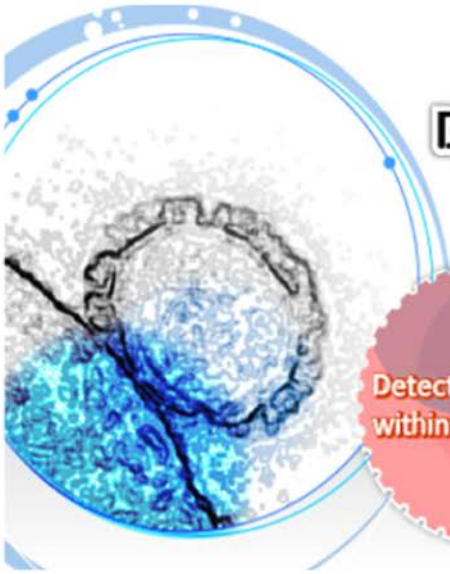


UltraFast LabChip MERS-CoV Detection System







**Development of
MERS-CoV Molecular Diagnostic Kit**

NEW

Detectable virus within 30 minutes

MERS-CoV Detection Kit

- Research-Use Only
- Detectable virus within 30 minutes including RT (Reverse-Transcription) reaction time
- Since it includes 3 kinds of primer set of upE Gene, ORF1a gene and Spike gene, more accurate detection is possible
- Optimization on UltraFast LabChip Real-time PCR G2-4 (Certificate No. 14-1412) manufactured by Nanobiosys Inc.

Declaration of Conformity

MANUFACTURER :

EUROPEAN REPRESENTATIVE : I&L Biosystems GmbH
Königswinter Str. 409a, 53639 Königswinter, Germany.

PRODUCT NAME : UltraFast LabChip Real-time PCR
- MERS-CoV Detection Kit

CATALOG NO. : PBDKC2003

CLASSIFICATION : According to Directive 98/79/EC Annex III :
Declaration of Conformity (Others)
IVD Product Classification Based on EDMA Nomenclature :
15 04 40 19 Coronavirus Detection by NA Reagents

CONFORMITY : IVD Annex III APPLIED
ASSESSMENT ROUTE

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices - CJ L 331 of 7 December 1998

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED : 98/79/EC, EN ISO13485:2012, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 375:2001, EN 980:2008, EN 13612:2002, EN 13640:2002, EN 13641:2002, EN 13975:2003

DATE OF ISSUE : 08 October 2015

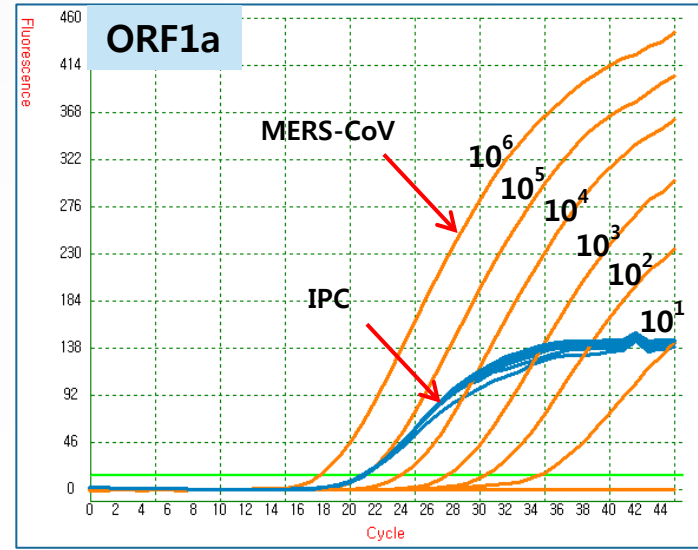
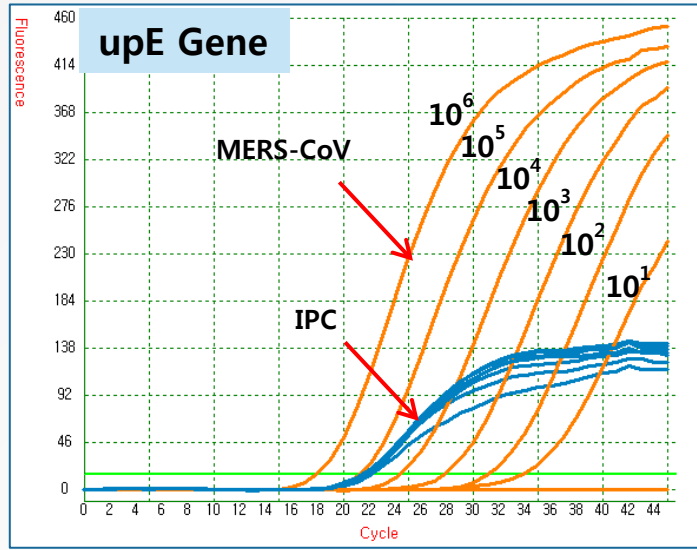
SIGNATURE : 

CE

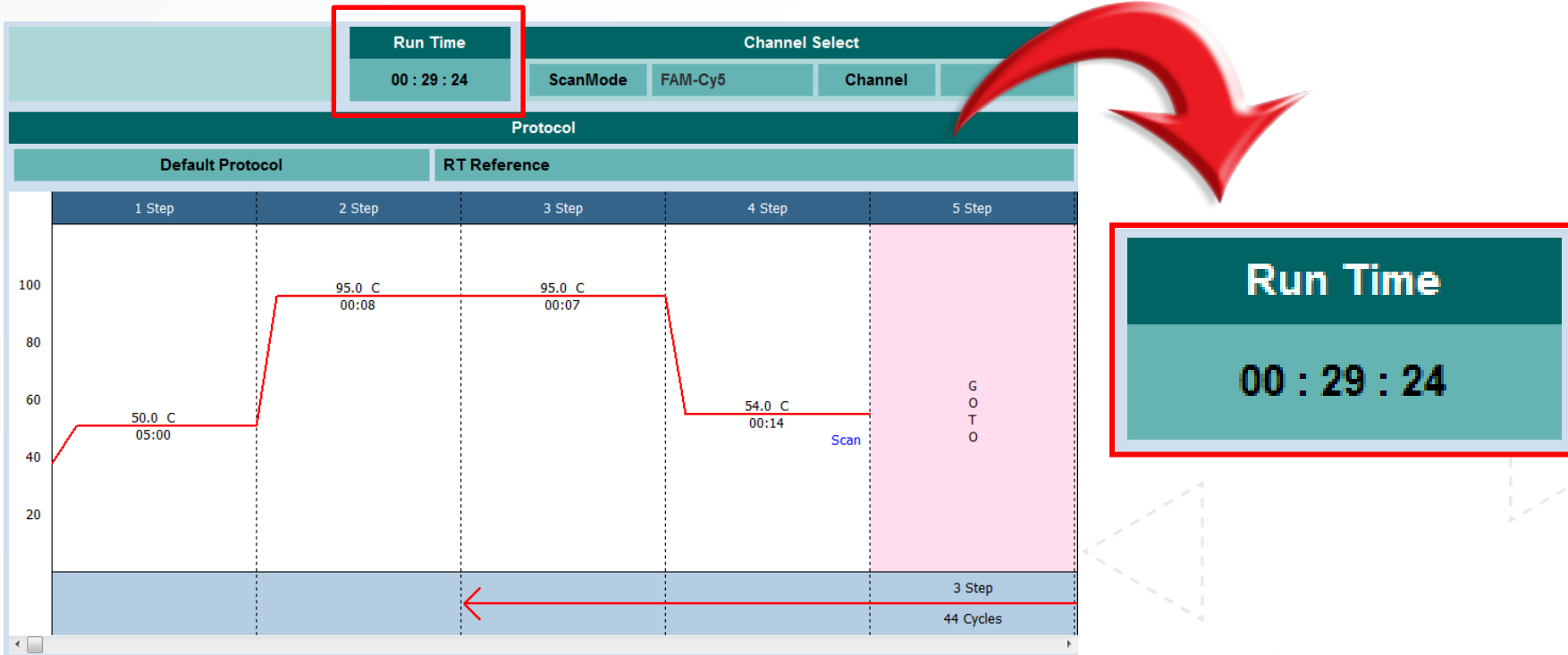
● Specification of real-time PCR Kit

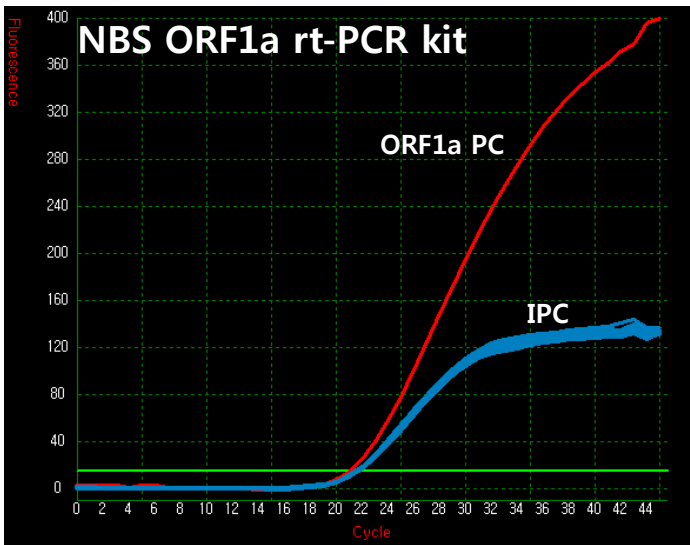
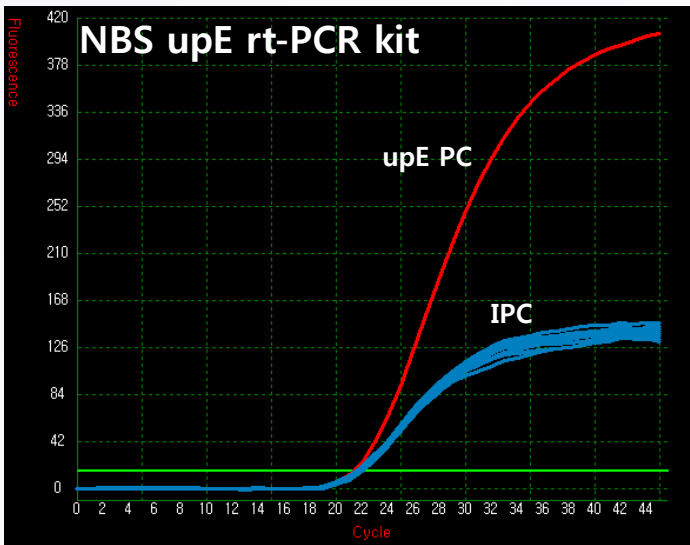
- CE-IVD certified
- Detect within 30 min include One-step RT & Real-time PCR step
- Double confirmation with **upE Gene** and **ORF1a Gene** as KCDC/WHO Guideline
- Optimization on **UltraFast LabChip Real-time PCR G2-4**

Reference Data with MERS-CoV Detection Kit - Sensitivity



Target : FAM
IPC : Cy5

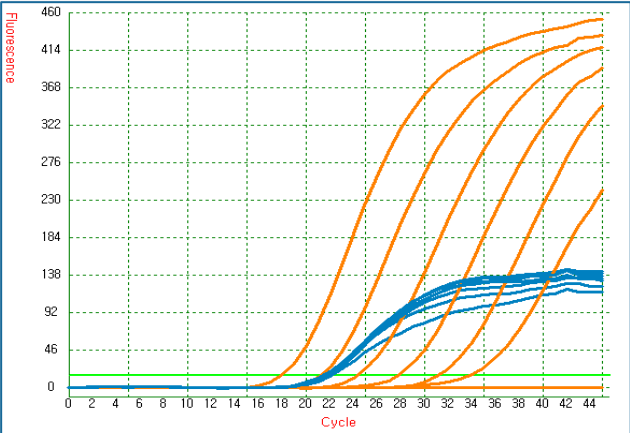




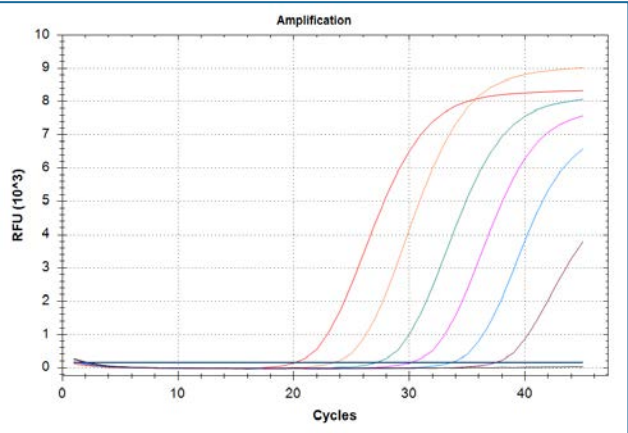
Virus Target	Result	Bacteria Target	Result
Influenza A H1, H3, H1N1/ B	Not Detected	MTB	Not Detected
RSV A/ B	Not Detected	MP	Not Detected
Parainfluenza 1/ 2/ 3	Not Detected	CP	Not Detected
Adenovirus 3	Not Detected		
Enterovirus	Not Detected		
Rhinovirus	Not Detected		
Metapneumovirus	Not Detected		
Coronavirus 229E/ OC43/ SARS	Not Detected		

Comparison Data with MERS-CoV Detection Kit

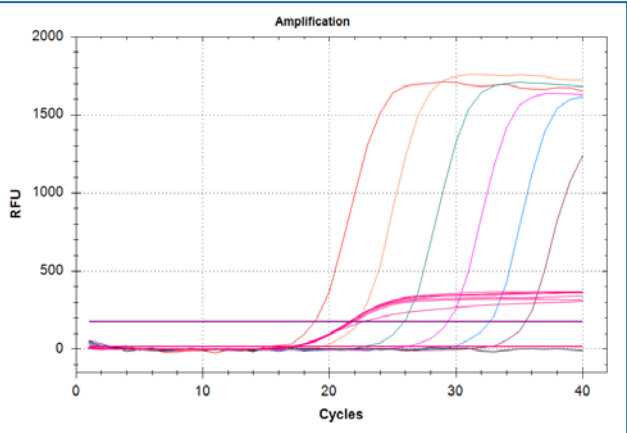
upE
Target Kit



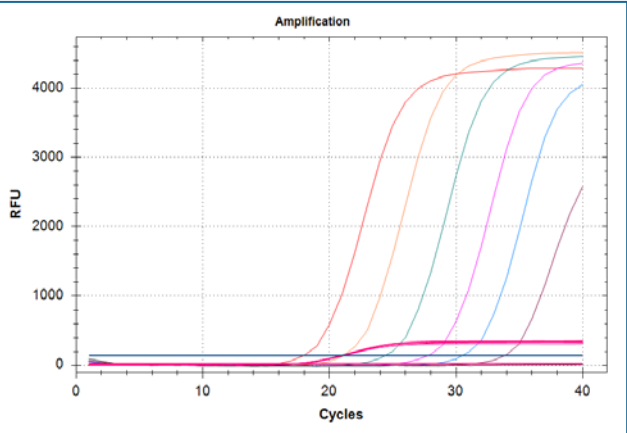
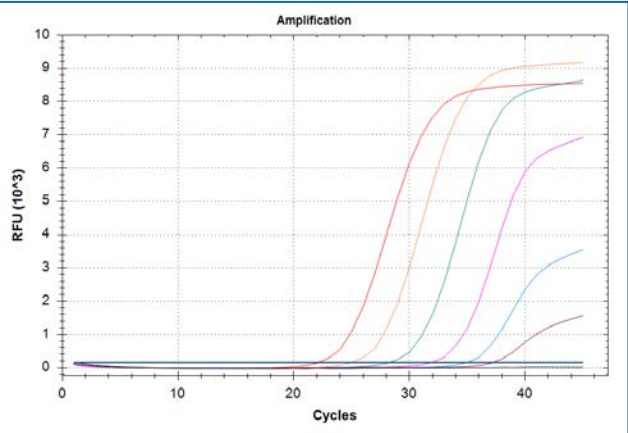
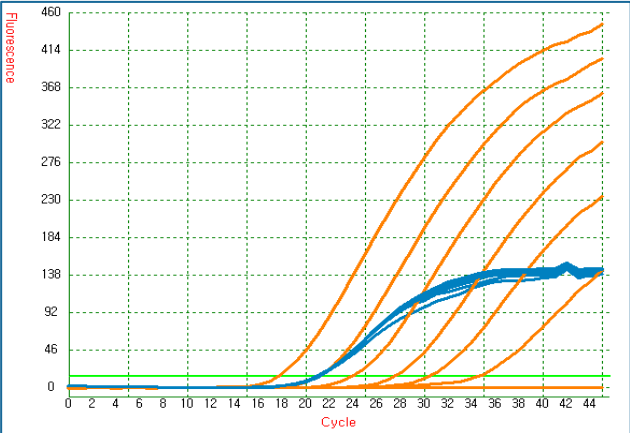
Competitor A (Global R* company)



Competitor B (Korean S* company)



ORF1a
Target Kit



Sensitivity

<10¹ copy/rxn

<10¹ copy/rxn

<10¹ copy/rxn

Run Time

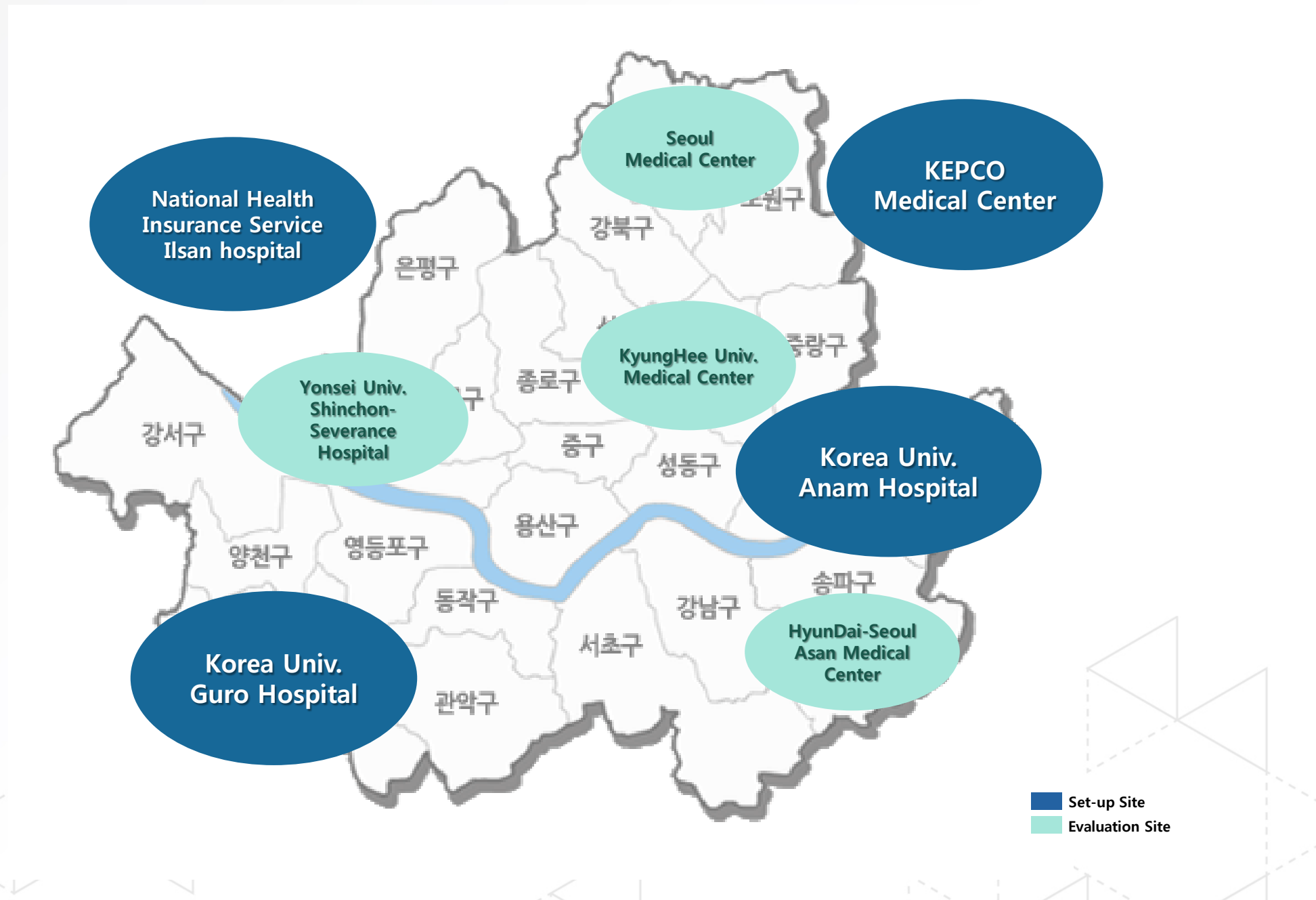
<30 min

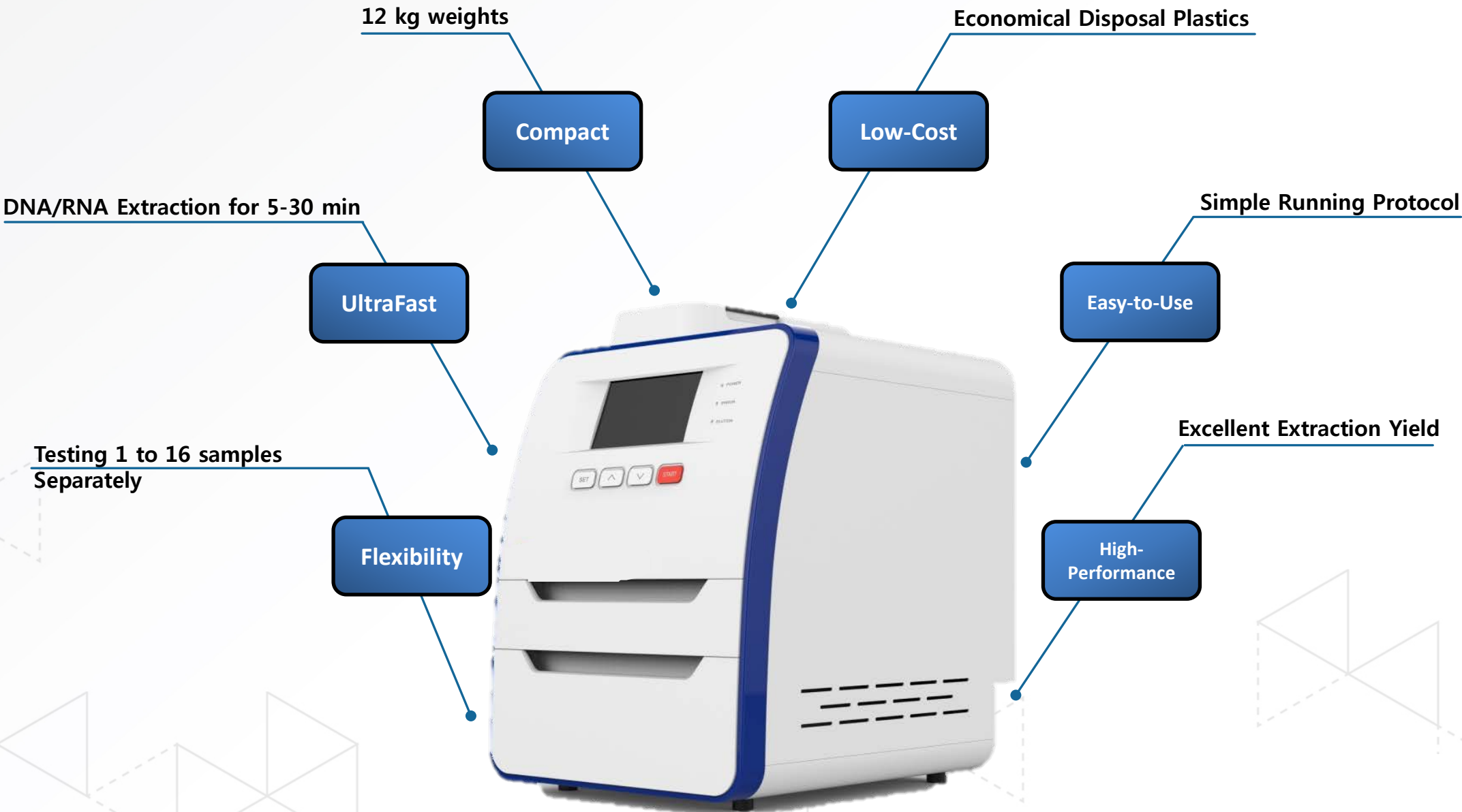
≅ 1 h 30 min

≅ 2 h

Competitor kits were tested with Bio-Rad CFX96 instrument.

Major Hospitals in Capital Area for Clinical Test of NBS MERS-CoV Detection System



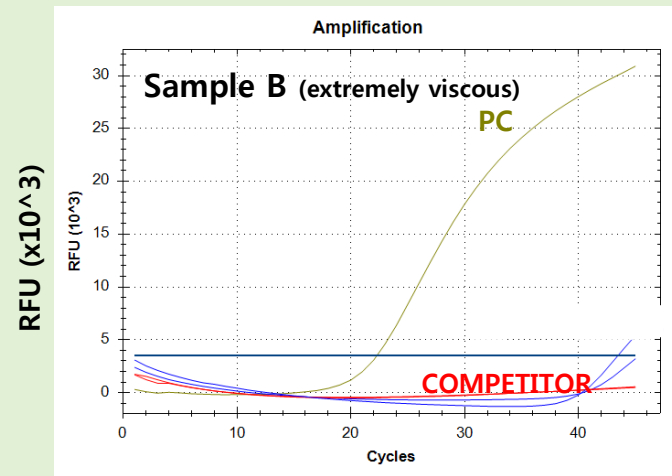
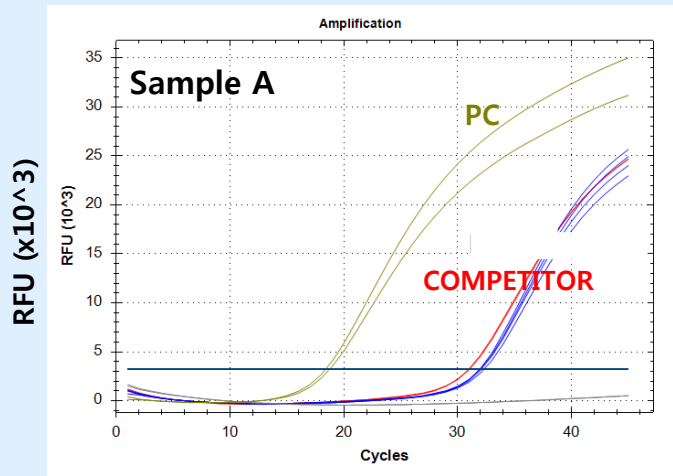


Sample Prep Kits List for G2-16TU

19

Cat No.	Product Description	Size
P-B-SP-16-010	Bacterial gDNA Prep Kit - Cultured bacteria	100 tests
P-B-SP-16-011	Bacterial gDNA Prep Kit - Food	100 tests
P-B-SP-16-020	Bacterial gDNA Prep Kit - Sputum	100 tests
P-B-SP-16-030	Viral DNA/RNA Prep Kit - Swab & Stool	100 tests
P-B-SP-16-031	Viral DNA/RNA Prep Kit - Serum & Plasma	100 tests
P-B-SP-16-032	Viral DNA/RNA Prep Kit - Sputum	100 tests
P-B-SP-16-040	Blood gDNA Prep Kit	100 tests
P-B-SP-16-050	FFPE Tissue DNA Prep Kit	100 tests
P-B-SP-16-060	Sepsis gDNA Prep Kit	100 tests

NBS Sample prep G2-16TU



PCR	Sample prep	Virus-spiked sputum	G2-16TU	Competitor
	BIORAD CFX96	Sample A	Detected (Ct 31.99)	Detected (Ct 31.03)
		Sample B	Detected (Ct 43.38)	-