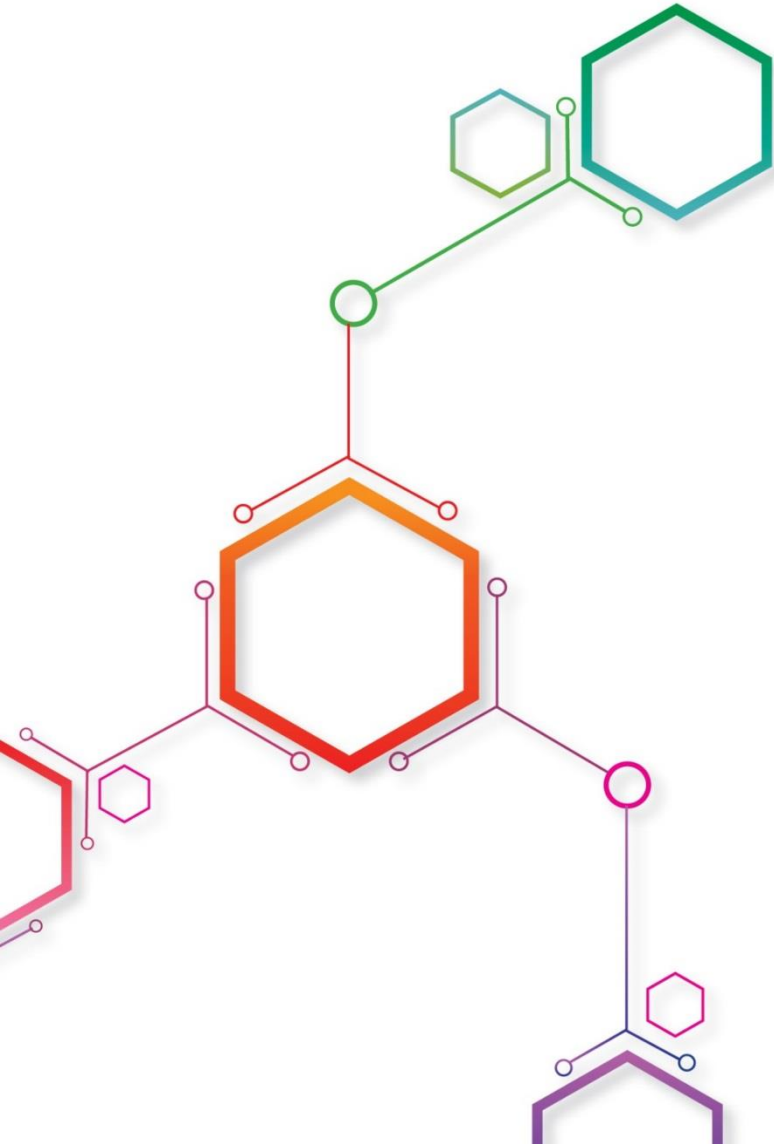




A leading bio company in molecular diagnostics



MDx Collaboration Proposal



LabGenomics

CEO
Sung Hyun Chin

CEO & President, LabGenomics
Former Director, Medipost Clinical Laboratories



Company LabGenomics Co.,Ltd

CEO Sunghyun Chin

Established March 2002

Employee 260 (As of 2019)

Main Biz. IVD / PGS / NGS
IVD Products

KOSDAQ Listed on Korea Stock
Market(Since 2014)

KOSDAQ
LISTED COMPANY

Healthcare company specialized in MDx



Quality of healthcare enhanced through innovation of MDx technology in a more accurate and efficient way



Robust Business & Medical Network



Research collaboration with global healthcare companies and major hospitals in Korea

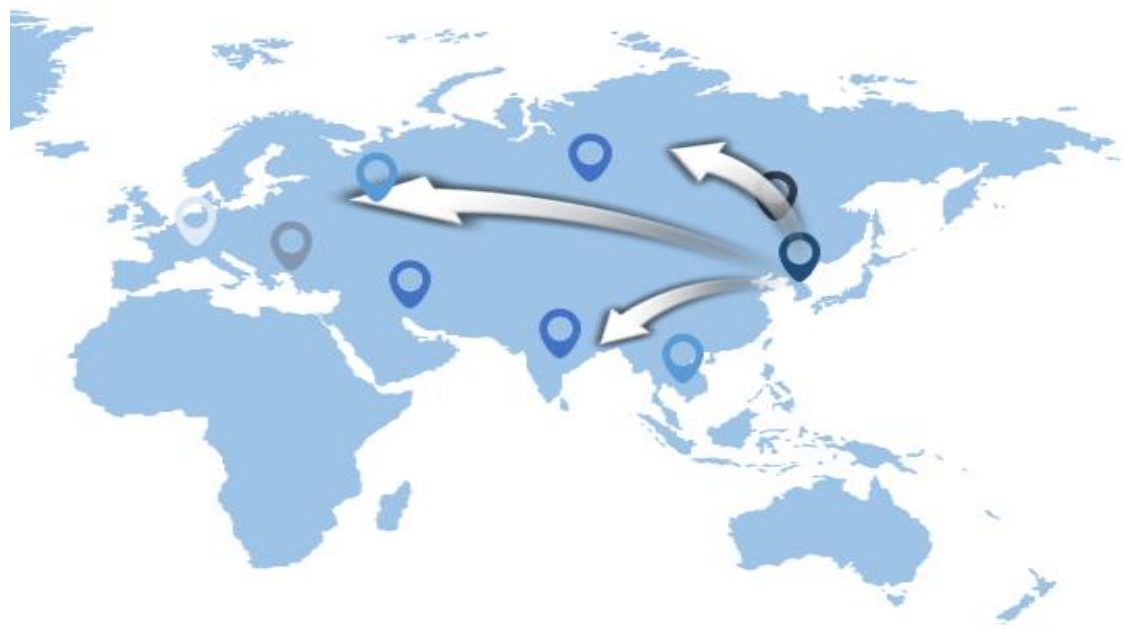
Business Networks


	Genetic Analysis of LSD (Lysosomal Storage Diseases)	
	Validation Study of Reagents	
	ADHD Genetic Study	
	Strategic Alliance in HealthCare Biz	
		
		
		
		

Medical Networks


		
		
		
		
		
		


□ The largest client network with hospitals



 **Europe**
Spain, Italy, Greece,
Turkey

 **Middle East**
UAE, Lebanon, Jordan

 **Asia**
Vietnam, Thailand, China

 **Korea**
All over the country

Accredited Lab



Acquired A grade Accuracy

질병관리본부
질병관리청장

KIGTE 재단 **한국유전자검사평가원**
Korean Institute of Genetic Testing Evaluation

Certified from the Korean Association of Quality Assurance for Clinical Laboratory, Korean Society of Laboratory Medicine and The Korean Society of Pathologists

대한병리학회
The Korean Society of Pathology

대한유전학회
The Korean Society of Human Genetics

대한임상유전학회
The Korean Society of Clinical Human Genetics

The first approval of NGS(Next Generation Sequencing) based solid cancer/ blood cancer/rare disease test in Korea

보건복지부

붙임 승인 세부 폐별명 및 제출 수

요양기관명 (요양기관)	세부 폐별명	승인 횟수
메디노믹스진단센터(서울과학기술대) (41355709)	1) Cancer Predisposition, level I 2) Rare Disease, Retinitis Pigmentosa V2. 3) Rare Disease, Congenital Hearing Loss V2. 4) Rare Disease, Skeletal Dysplasia 5) Rare Disease, Polycystic Kidney Disease V2. 6) SelfTumor, Level I 7) SelfTumor, Level I 8) CancerScan V2. 9) BrainTumor Scan 10) HemoScan	10

Overseas Quality Management Certification

Participate in the quality management program of internationally accredited laboratories

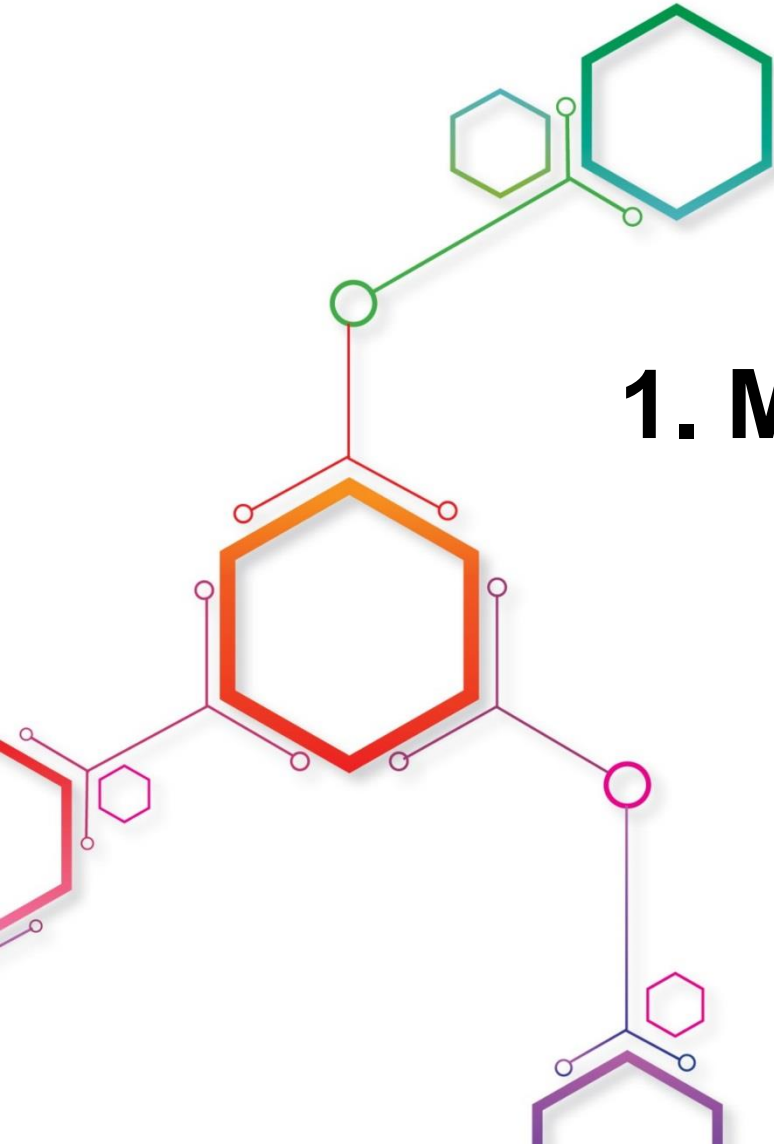
The University of Illinois
The International HLA DNA Exchange of Class I and Class II alleles for Immunology provides quality control reference

CERTIFICATE of PARTICIPATION
Presented to
LabGenomics Corporation, Korea

COLLEGE of AMERICAN PATHOLOGISTS
The College of American Pathologists recognizes
LabGenomics
72160-21-01

As a laboratory demonstrating continuous improvement in quality through participation in CAP's Surveys, EXCEL or similar Assisted Pathology Education Programs.

Carla Cutbert
Carla Cutbert, PhD, FRCMG, FRCM, FRCR
Chief, Newborn Screening and Molecular Diagnostics



1. MDx Solutions, PCR kits

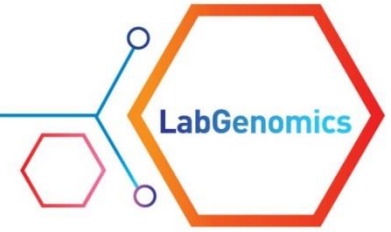


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a. LabGun™ COVID-19 Assay PCR Kit

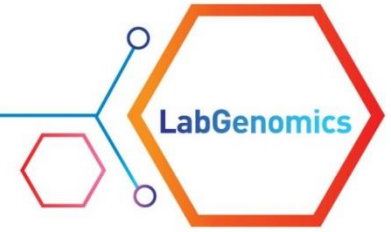
□ Outline



- Purpose of using COVID-19 Assay PCR Kit
- Composition
- Preservation Method
- Process
- Real-Time PCR Machine
- Result Analysis

□ Purpose

LabGun™ COVID-19 Assay PCR Kit



1. Purpose

LabGun™ COVID-19 Assay Kit is designed to qualitatively detect SARS-CoV-2 in sputum, Broncho alveolar lavage fluid, oropharyngeal and nasopharyngeal smears using Real-time reverse-transcription PCR. It is an in-vitro diagnostic medical device.

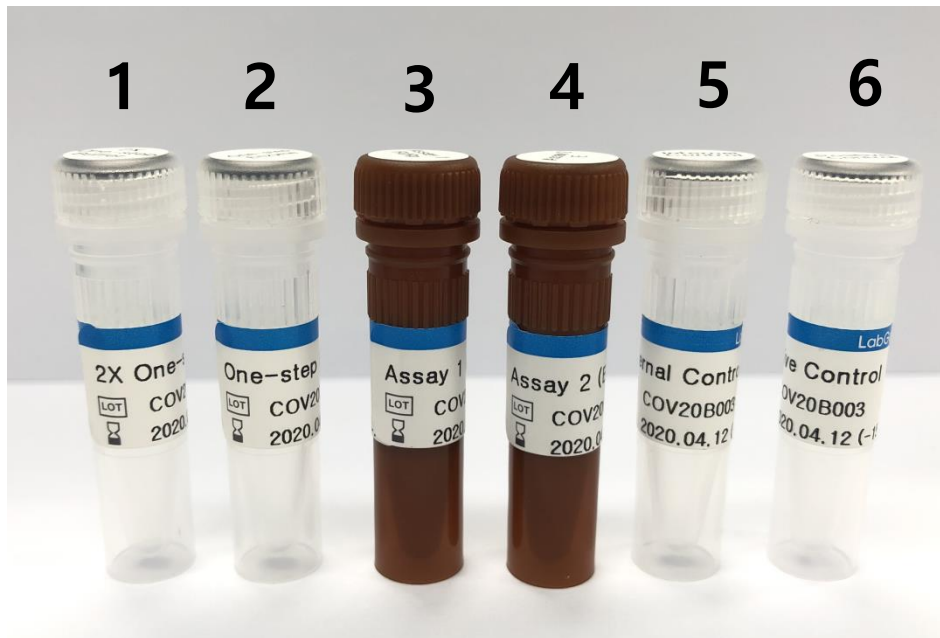
Composition



(Storage at -20°C)

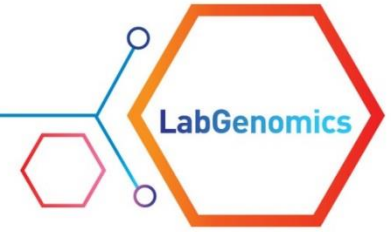
Reagents	Cap	Volume (μℓ)
2 x One-step Buffer	B	1000
One-step Enzyme	E	100
Assay 1 (RdRp gene)*	A1	200
Assay 2 (E gene)*	A2	200
Internal Control	IC	100
Positive Control	PC	100

* Including ROX reference dye



	Composition
1	2x One-step Buffer
2	One-step Enzyme
3	Assay 1 (RdRp gene)
4	Assay 2 (E gene)
5	Internal Control
6	Positive Control

❑ Preservation Method



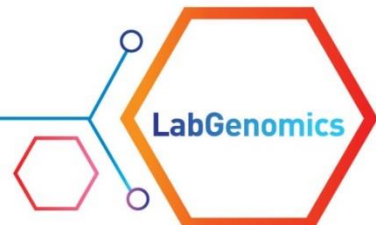
1. Temperature : Less than -20°C

2. Shelf Life : 2 month from Date of Manufacture

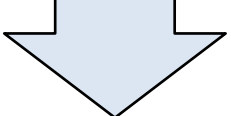
▶ Failure to follow this kit's storage may result in reduced kit performance.

▶ Do not use an expired Kit and not mix with different lots of reagents.

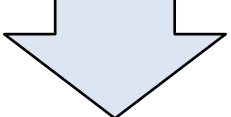
□ Process



Sample Preparation



Real-time RT-PCR



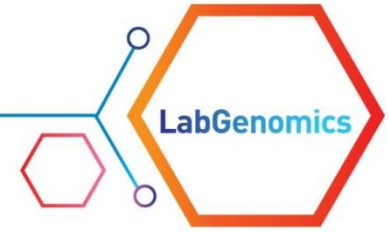
Results

• **Extraction of RNA from clinical samples**

• **Target amplification**
• **Approximately 2.5 hours**

• **Positive or Negative decision**

□ Real-time PCR Machine



Utilization

- Applied Biosystems™ 7500 Real-time PCR Instrument system (Thermo Fisher Scientific)
- Applied Biosystems™ 7500 Fast Real-time PCR Instrument system (Thermo Fisher Scientific)
- CFX96™ Real-time PCR detection system (Bio-Rad)

□ Result of Analysis



- **To confirm the Ct Value for each of target case.**
- Ct ≤ 40, "+", Ct > 40 "-"
- Following the Analysis table

Case	Positive Control	Negative Control	FAM	Cy5	HEX	Interpretation
1	+	-	+	+	+	SARS-CoV-2 Positive
2	+	-	+	+	-	
3	+	-	-	+	+	Sarbecovirus Positive
4	+	-	-	+	-	
5	+	-	-	-	+	Negative
6	+	-	-	-	-	Invalid result / Retest
7	+	-	+	-	+ / -	
8	+	+	+ / -	+ / -	+ / -	
9	-	+	+ / -	+ / -	+ / -	
10	-	-	+ / -	+ / -	+ / -	

Publication News



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Korean firms rush to roll out commercial diagnostic kits for coronavirus

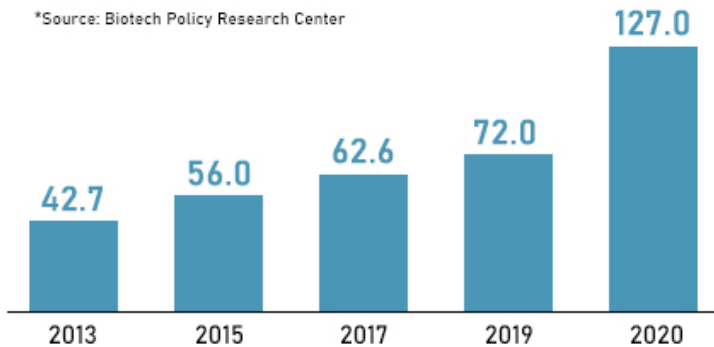
2020.02.03 14:18:23 | 2020.02.03 14:18:59



Development of Diagnostics Kits for 2019–Novel Coronavirus in Korea

Global IVD Market (in billion dollar)

*Source: Biotech Policy Research Center



Graphics by Minu Kim and Song Ji-yoon

Korean diagnostic kit developers are gearing up to fast track the detection of the new deadly coronavirus which is spreading at a breakneck speed in China and around the world, with some expecting to reach the commercial markets within this month.

The EUAL procedure was set up as an extraordinary process to allow the use of in-vitro diagnostic (IVD) products without formal approval during the epidemic. The new reagent was developed according to the detection method guidelines announced by the World Health Organization and KCDC. A company official said demand is rising from Japan and several countries in Europe and Southeast Asia where confirmed cases are reported, and actual orders and commitments are expected to be made after the upcoming Medlab Expo in Dubai this week.

There are no proven preventive or therapeutic products for the 2019–Novel Coronavirus.

LabGenomics are speeding up efforts to develop diagnostic kits for the coronavirus based on their successful launches of similar kits during the outbreak of Middle East respiratory syndrome (MERS) and Zika virus.

Efforts to develop diagnostic technology are also seen in the public sector. On Jan. 30, Center for Convergent Research of Emerging Virus Infection (CEVI) under Korea Research Institute of Chemical Technology signed an agreement with Wells Bio, a subsidiary of Kosdaq-listed Accessbio, for joint development and commercialization of molecular and immunological diagnostics to detect a gene specific to the 2019–Novel Coronavirus and a virus antigen protein. CEVI is a partnership of eight state-funded research centers with an aim to develop technologies to identify, prevent, treat and contain high-risk new and mutated viruses.

By Kim Si-gyun and Minu Kim

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□ Publication News



[코로나19] 국내 바이오기업, 잇따라 진단키트 상용화...수출 문의도 쇄도

국내 바이오 기업들의 신종 코로나바이러스 감염증(코로나/Covid-19) 진단키트 상용화가 줄을 잇고 있다. 또 국내 진단 기술이 전 세계적으로 인정받으면서 글로벌 기업의 수출 문의도 쇄도하고 있다.

25일 바이오업계에 따르면 현재 식품의약품안전처의 긴급 사용 승인을 받은 코로나19 진단키트는 2개다.

긴급사용승인제도는 지난 메르스(MERS-중동호흡기증후군) 유행 이후, 신종 감염병이 유행할 때 원활한 감염병 검사 및 진단을 위해 마련됐다. 국내에서 허가 제품이 없지만 시급히 진단 시역이 필요할 경우 질병관리본부장의 요청에 따라 식약처장이 한시적으로 제조와 판매를 승인하는 제도다.

긴급사용승인 평가 신청 기간은 지난달 28일에서 오는 28일까지다. 이 기간 동안 신청 접수된 제품에 대해 수시로 평가와 심의가 이뤄지는 것.

이에 따라 국내 바이오 기업들이 진단키트 개발을 완료하고 서둘러 긴급사용승인 신청에 나섰다.

현재 랩지노믹스 등이 코로나19 진단키트 개발을 완료하고 현재 긴급사용승인을 한 상태다.

랩지노믹스 관계자도 "진단키트 제품 개발을 완료했으며 지난 19일 긴급사용승인 신청을 한 상태"라고 설명했다.

중국과 미국에서 사용하는 코로나19 진단키트의 결합이 보고되면서 국내 진단키트 기술에 대한 관심이 집중되고 있다. 진단키트 상용화에 성공한 기업들에 수출 문의가 쇄도하고 있다.

국내 바이오기업들은 해외 수출을 염두해 유럽 인증(CE-IVD) 승인을 완료했거나 추진중이다.

한 진단키트 업체 관계자는 "중국, 유럽 등 세계 각국의 기업들이 진단키트 수출 계약을 요청하고 있다"면서 "일단 질병관리본부의 긴급사용승인이 중요한 만큼 승인 이후 본격적인 수출 논의를 할 계획"이라고 밝혔다.

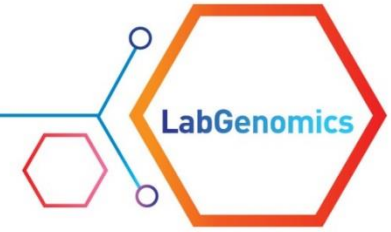
정희영 머니투데이방송 MTN 기자

<저작권자 © "부자되는 좋은습관 대한민국 경제채널 머니투데이방송 MTN">



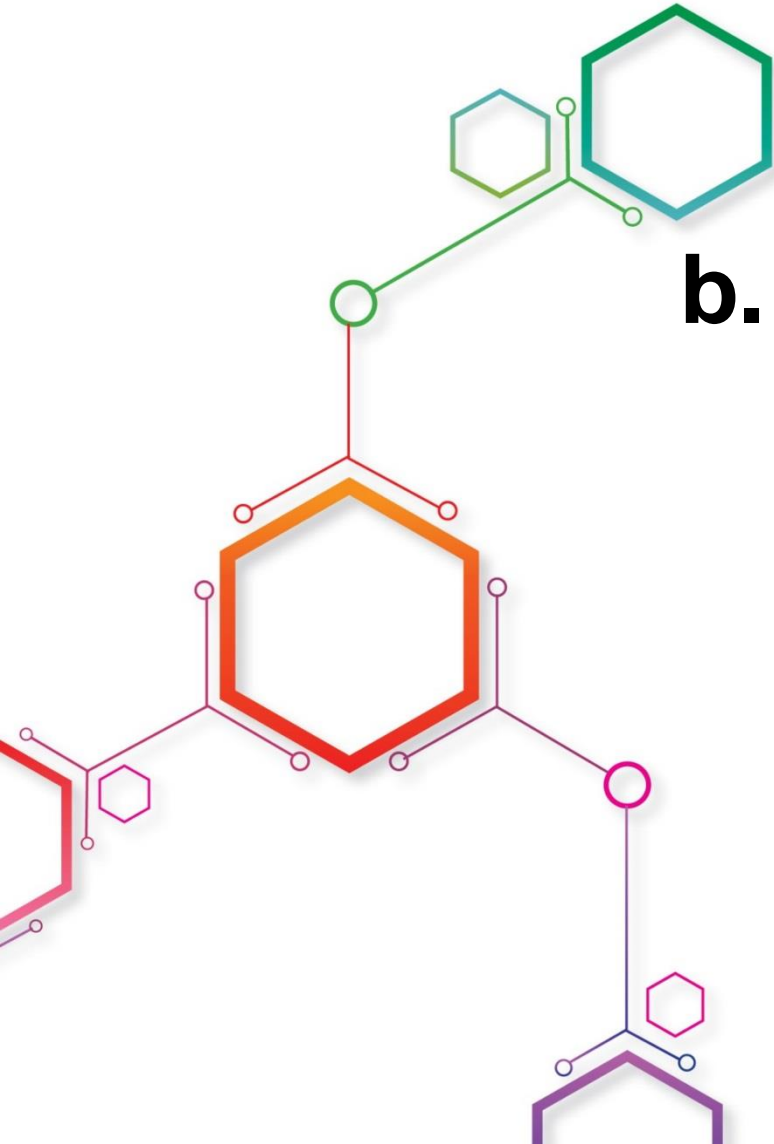
'Export COVID-19 Kit to China, Europe and etc.,'

❑ Usage of LabGenomics COVID-19 kits in Korea



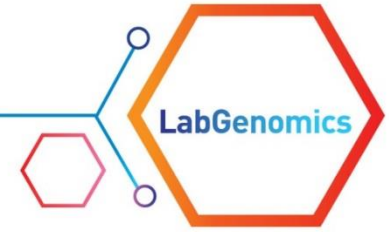
According to government report [last updated, Feb26/2020]

- **Korea has 20,716 of people under inspection(Feb26).**
- **LabGenomics is a diagnostic institution implementing Covid-19 test designated by KOREAN Government.**
- **And, 7,000 tests for COVID-19 has been done at our LabGenomics institution using our LabGenomics COVID-19 kits.**



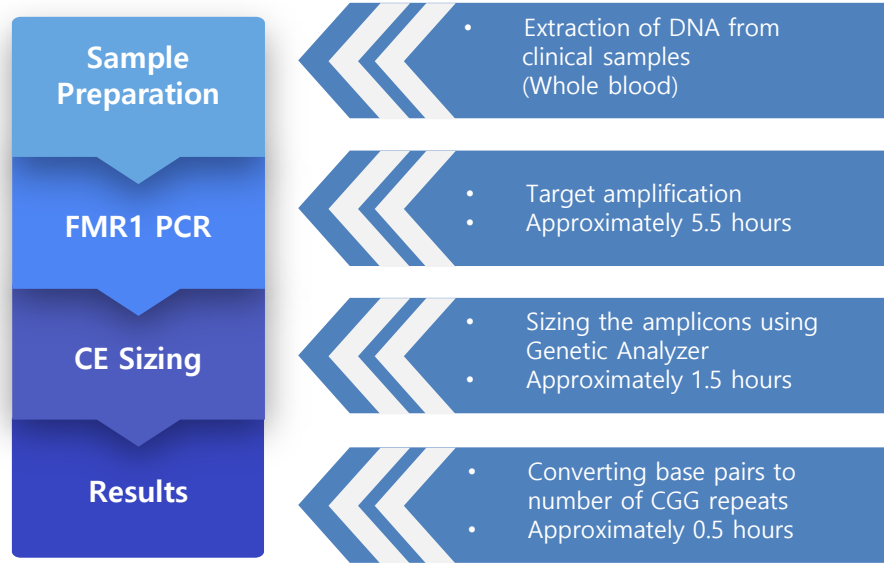
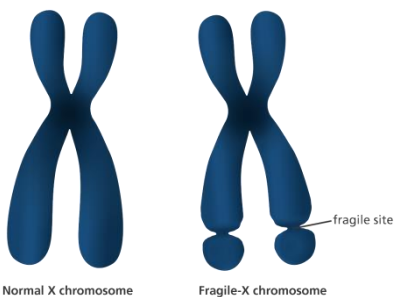
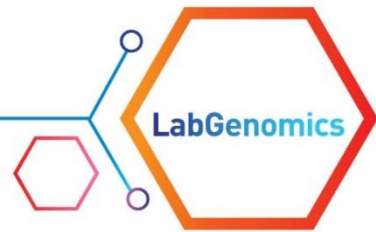
b. LabGscan™ Fragile X Syndrome PCR Kit

□ Intended use



The LabGscan™ FRAXA PCR kit is an in vitro diagnostic test based on PCR technology for the amplification and detection of CGG repeats in the 5'-untranslated region (5'-UTR) of FMR1 (Fragile X mental retardation 1) gene. The kit aids to diagnose 3 genotypes of normal, pre-mutation and full mutation (Table 1), and identify female carriers for fragile X syndrome.

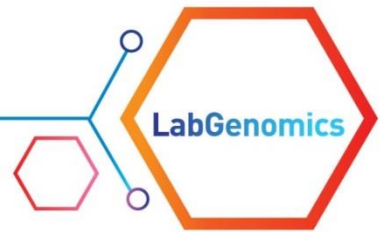
□ Process & reagents



Reagents

Item No	Reagents	Presentation 25 reactions	Presentation 50 reactions	Presentation 100 reactions
1	FMR1 Primer Mix	1 vial, 25 µL	1 vial, 50 µL	1 vial, 100 µL
2	GC-Rich Amp Buffer	1 vial, 300 µL	1 vial, 600 µL	1 vial, 1.2 mL
3	Polymerase Mix	1 vial, 12.5 µL	1 vial, 25 µL	1 vial, 50 µL
4	ROX 1000 Size Ladder	1 vial, 50 µL	1 vial, 100 µL	1 vial, 200 µL

More about



Validity Period

12 months from the date of manufacture (open, unopened)



Storage Temperature

-20±5°C



Applied Sample

Genomic DNA extracted from whole blood (EDTA Whole Blood)



Screening Target and Purpose

Test Screens for possibility of Fragile X Syndrome infant. Fragile X Syndrome is a CGG Trinucleotide repetitive disorder of the FMR1.



Method of analysis

1st to perform prenatal screening test for Fragile X Syndrome since 2002. Developed novel molecular prenatal tests based on cutting-edge molecular biologic technology.



Utilizing test results

Detection through prenatal test is important for Fragile X Syndrome because unaffected mother can give birth to an affected infant, when X chromosome gene sequence are repeated only certain amounts, a state designed as 'carrier'.

PCR
Veriti
(Thermo Fisher Scientific)
C1000 & S1000 (Bio-Rad)

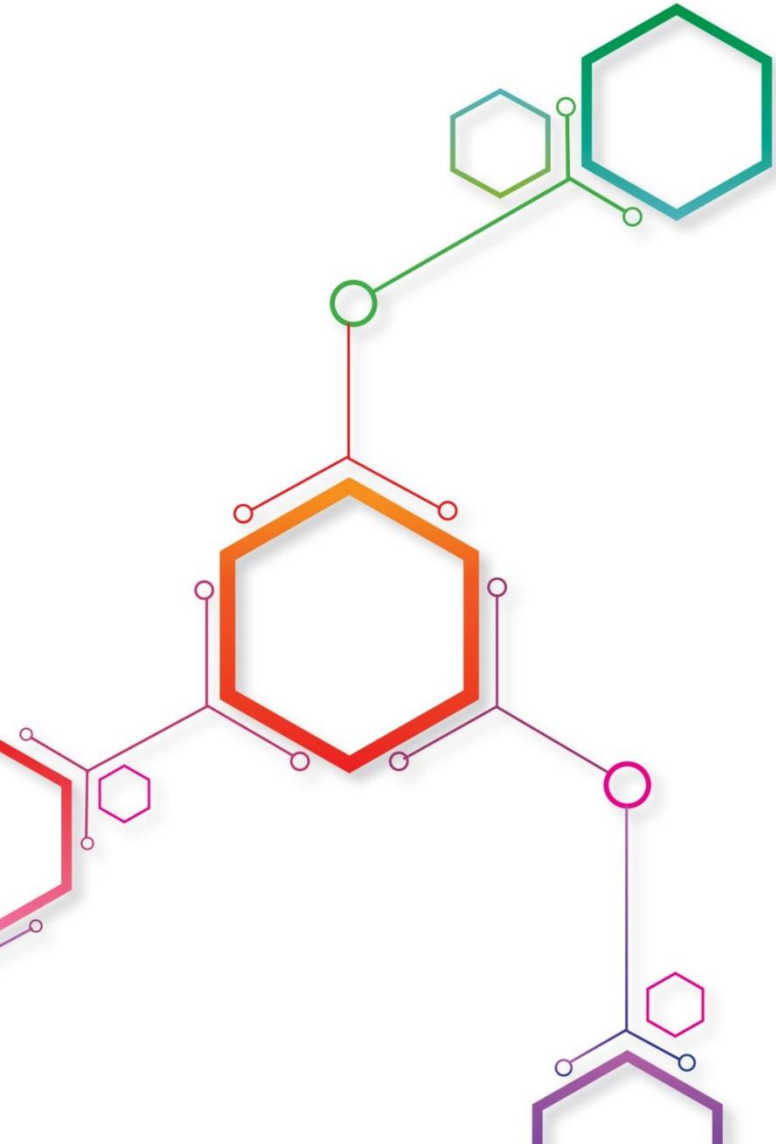
Recommended Instruments



Genetic Analyzer
3730, 3730xl DNA Analyzer (Applied Biosystems)
3130, 3130xl DNA Analyzer (Applied Biosystems)
3500, 3500xL Genetic Analyzer (Applied Biosystems)



A leading bio company in molecular diagnostics



Thank you