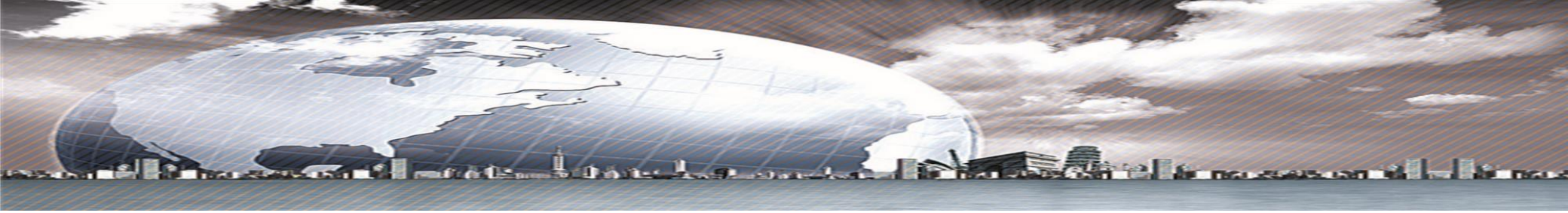


Introduction of Company

COVID-19 RDTs

RapiGEN Inc.

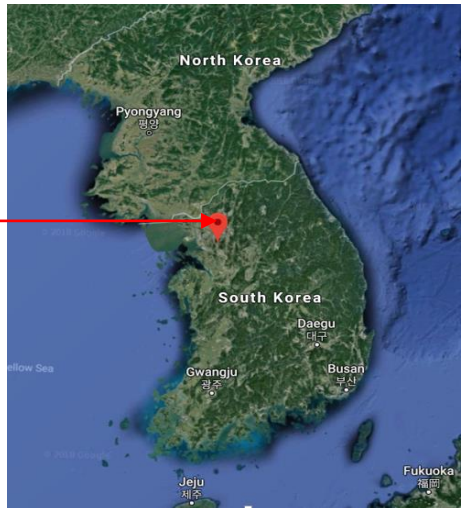
“No Compromise on Quality”

CONTENTS

1. Overview of RapiGEN

Company Overview

Company Name	RapiGEN INC.
CEO	Dr. Jae-Ku Park
Establishment	18th of June, 2002
Industry	Medical Supplies, Medical Equipment
Quality Management System	ISO 13485:2016 (14 June 2020 ~ 13 June 2023)
Main Product	Rapid Diagnosis Kit using Gold Particle Technology
Head office Address	3-4F 16, 91beon-gil Dongan-gu, Anyang-si, Gyeonggi-do 14119 Republic of Korea
Factory Address	3-4F 16, 91beon-gil Dongan-gu, Anyang-si, Gyeonggi-do 14119 Republic of Korea



Certificates

2. History of RapiGEN

2002
Establishment of RapiGEN Inc.

2003 2004
Establishment of RapiGEN R&D Center and recognized by Korea Industry and Technology Promotion Association

Certified for ISO 13485:2003

Certified for NET Mark (KT Mark)

2007
Certified for ISO 9001

Approval of AIV H5 Ag test, AIV/NDV Ag Combo kit by National Veterinary Research Qurantine Service

2008 2009
Approval of NDV Ag kit by National Veterinary Research Qurantine Service

Approval of CCV Ag, CCPV Ag Combo, FPV Ag Test kit by National Veterinary Research Qurantine Service

2010
Approval of BIOCREDIT Influenza A&B Ag kit by KFDA

Approval of BIOCREDIT HAV IgG kit by KFDA

Auto-production
HAV IgG CE certified

Certified for 9 types product by CE mark

Passed Malaria Ag Pf/Pam WHO round 6 RDT test

20 types of IVD product launch

2015
Approval of BIOCREDIT Ebola Ag kit by KFDA

GMP certified by KFDA

Approval of BIOCREDIT Zika NS1 Ag and Zika IgG/IgM kit by KFDA

Approval of BIOCREDIT MERS-CoV Ag kit by KFDA

Launca of Influenza A&B Ag Card 3 min kit

2020
Winner of a Slovakian public tender of 1M Ag test

Winner of an Italian public tender of 13M Ag test

Winner of an Austrian public tender of 1.3M Ag test

Winner of a Hungarian public tender of 3M Ag test

Winner of a Romanian public tender of 2.7M Ag test

Approval of BIOCREDIT COVID-19 Ag kit by KFDA (CE certified)

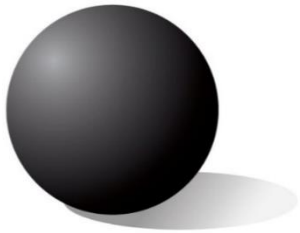
Approval of BIOCREDIT COVID-19 IgG/IgM kit by KFDA (CE certified)

Approval of BIOCREDIT CoviFlu Ag Duo kit by KFDA (CE certified)

3. Core Technique – Black Gold Particle

- The first commercial technique in the world.
- Upgrade of origin Red Gold method
- Accumulation of technique for 10 years

Black Gold Particle



Black Gold Particle

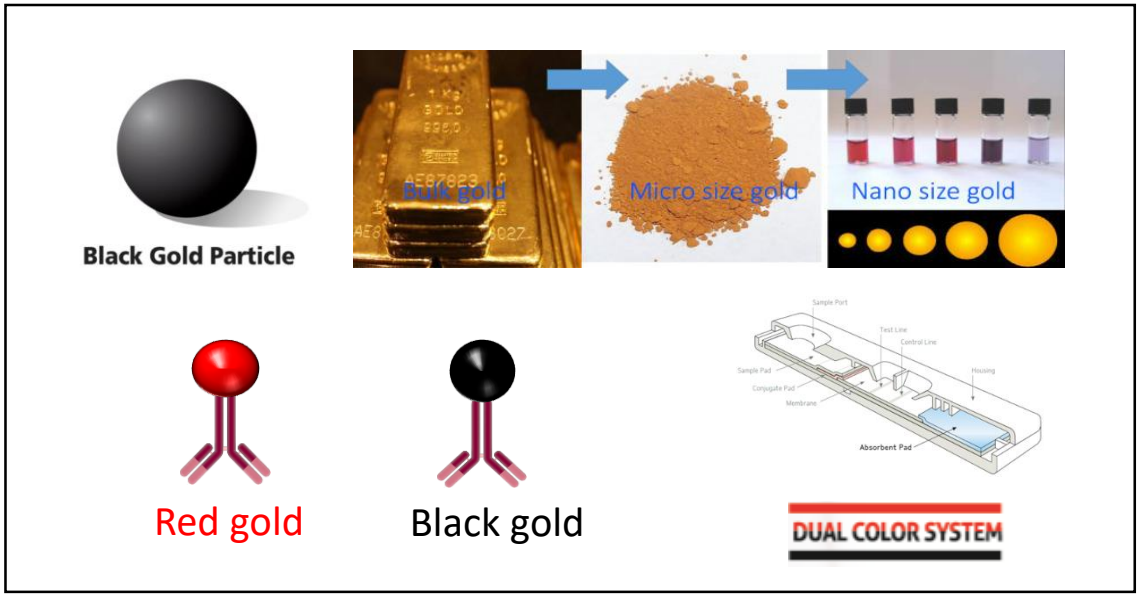
Strong Point

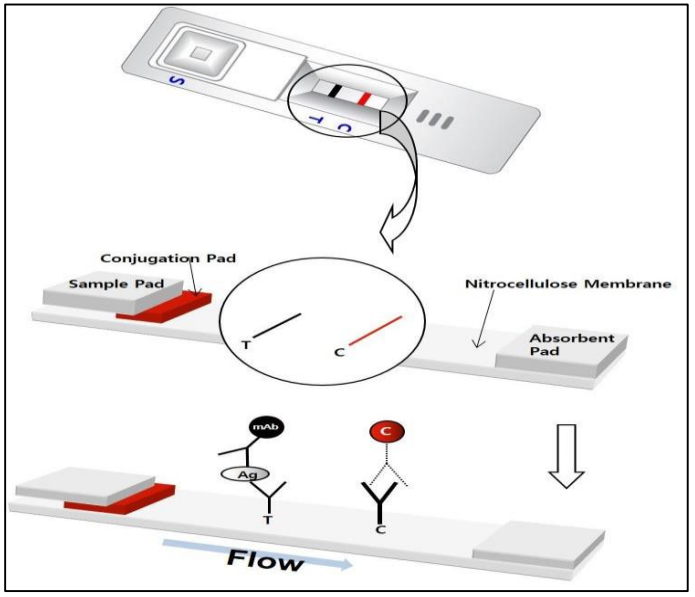
1. High Sensitivity (More than 4-32times – Best Quality in the world)
2. Easy to inspect using dual color lines (Control : Red, Test : Black)
3. High repeatability and stability using gold conjugation
4. High concentration manufacture system

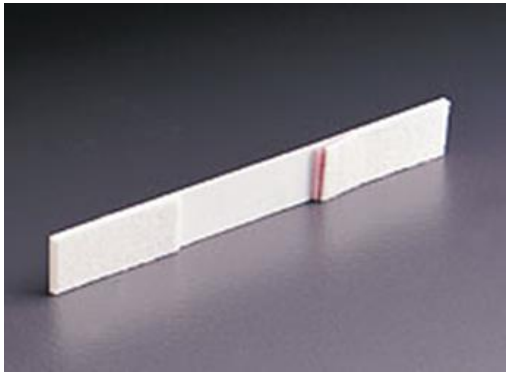
(High manufacture effectiveness : 900,000 gold/Per day & person

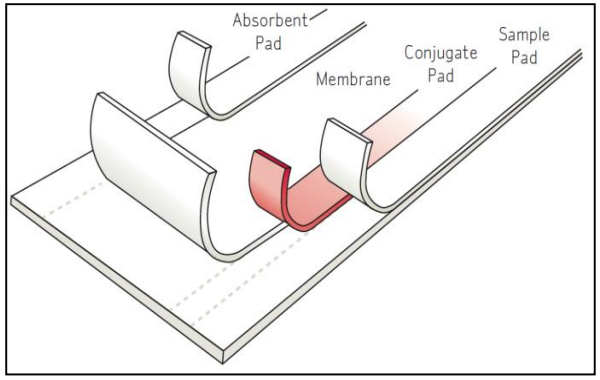
- Available to manufacture annually 230Million gold conjugation

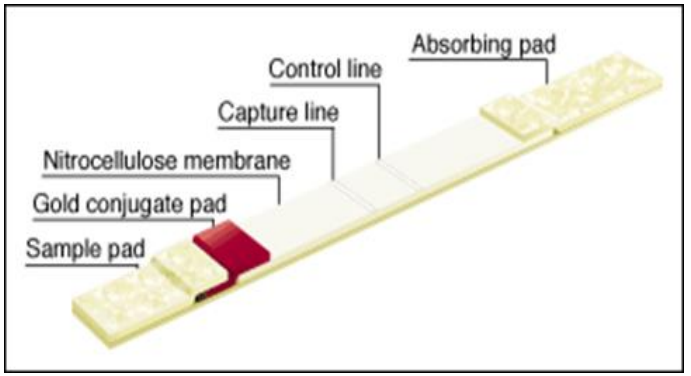
3. Core Technique – Black Gold Particle





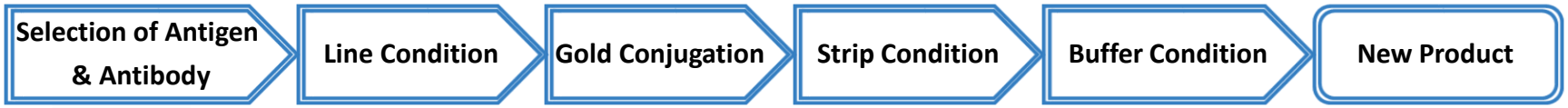






3. Core Technique – Platform

Platform of Product Development



Compact Platform Technology for various variables

Technology Competitiveness

- Possible to develop new product within 1~4 weeks
- Screening technology for the best antibody pair (High Sensitivity)
- High sensitivity using small raw materials (High Quality and cost competitiveness)
- Buffer technology applied to various specimen

Market Competitiveness

- Available Quick Response to outbreaks or customers' requests
- Optimized platform for small quantity batch production

4. COVID-19 Product Lines

Rapid Test

5-8

Minutes

5-1. Kit Components of BIOCREDIT COVID-19 Ag

BIOCREDIT COVID-19 Ag
rapid test kit

Intended Use	Detection of SARS-CoV2 antigen
Package	20 Tests / kit
Storage	2~30℃
Specimen Type	Nasopharynx / Nasopharyngeal
Shelf life	24 months from manufacture date
Time to result	5~8 minute

Test Device (COVID-19 Ag)

Sterilized swab for nasopharyngeal specimen collection

Assay Diluent tubes & filter cap

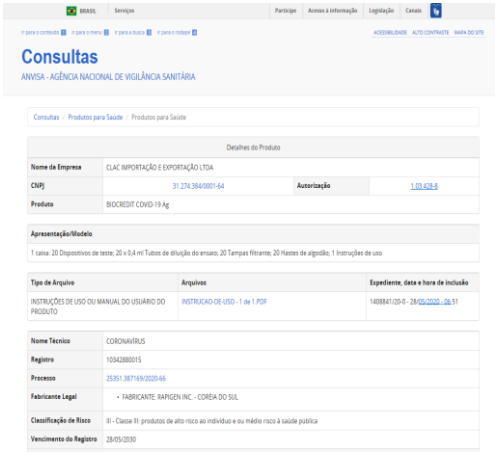
6-1. Regulatory Approval Status of COVID-19 Ag

Regulatory approvals

No	Name of the country	Approved indication	Date of approval
1	S. Korea	Qualitative detection of SARS-CoV-2 antigen in human nasopharynx	21 Apr., 2020
2	CE mark		02 Apr., 2020
3	Brazil		27 May, 2020
4	Russia		02 July, 2020
5	USA		On-going
6	Other countries (Chile, Guatemala, Portugal, Turkey, Bosnia and Herzegoviba, Bolivia, Honduras, Colombia, Indonesia, Panama, Serbia, Hungary, Dominican Republic)		


Certificate of Free Sales


Certificate
of EU product notification


Consultas
ANVISA - AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA


РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

7-1. Clinical Performance of COVID-19 Ag

Russia		PCR (after symptoms occur)		Sensitivity	Specificity
		Pos.	Neg.		
BIOCREDIT COVID-19 Ag	Pos.	24	0	96.0 %	100.0 %
	Neg.	1	25		
Total		25	25		

Brazil		PCR (after symptoms occur)		Sensitivity	Specificity
		Pos.	Neg.		
BIOCREDIT COVID-19 Ag	Pos.	10	0	90.9 %	100 %
	Neg.	1	109		
Total		11	109		

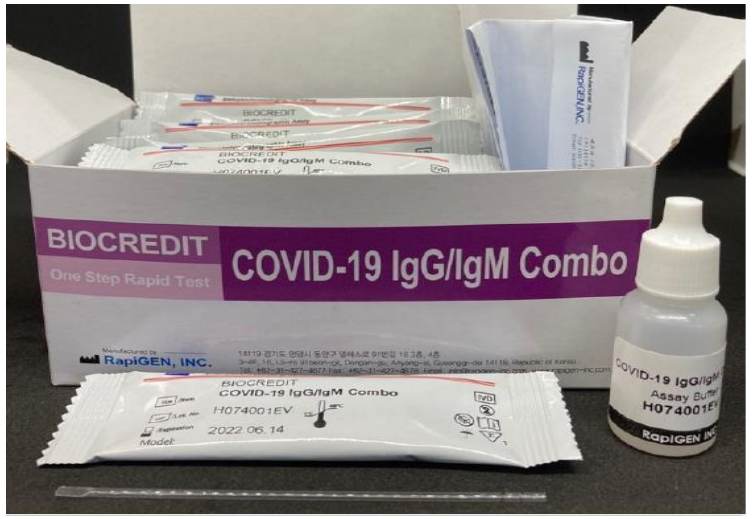
KOREA		PCR (after symptoms occur)		Sensitivity	Specificity
		Pos.	Neg.		
BIOCREDIT COVID-19 Ag	Pos.	12	0	80.0 %	100.0 %
	Neg.	3	2		
Total		15	2		

Product performance

BIOCREDIT COVID-19 Ag		PCR (after symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
Ag	Positive	46	0	90.2 % (46/51)	100 % (136/136)
	Negative	5	136		
Total		51	136		

Clinical trial centers: 3 different studies that have been conducted in Brazil, Russia and Korea.

5-2. Kit Components of BIOCREDIT COVID-19 IgG/IgM Combo



BIOCREDIT
COVID-19 IgG/IgM Combo
rapid test kit

Intended Use	For the qualitative detection of IgG and IgM antibody specific to SARS-CoV-2
Package	25 Tests / kit
Storage	1~40℃ (33.8~ 104°F)
Specimen Type	Serum, Plasma or Whole blood
Shelf life	24 months from manufacture date
Time to result	10~ 15 minutes

Test Device
(COVID-19 IgG/IgM Combo)

Capillary pipette (10~ 20 ㎕)

Assay Buffer Bottle

6-2. Regulatory Approval Status of COVID-19 IgG/IgM Combo

Regulatory approvals

No	Name of the country	Approved indication	Date of approval
1	S. Korea	Qualitative detection of SARS-CoV-2 antigen in human nasopharynx	10 Aug., 2020
2	CE mark		27 July., 2020

Document Number : QX39-S5XI-W4ND-BT5E

Ministry of Food and Drug Safety

Osong Health Technology Administration Complex, 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea, 28159 Tel: +82-43-719-5356 , Fax: +82-43-719-5350

Certificate of Free Sales

No. of Certificate : 20200106830
Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following product(s) is(are) permitted to be freely sold in overseas market only.

○ Applicant (=Product-license holder)
(This certificate shall not be issued to others than the product-license holder)

- Name : RapiGEN INC.
- Address : 3-4F, 16, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
- Registered No. : Manufacturer IVD-3897

No. and date of product-license, comments	Classification
IVD-20-629 / AUG. 10. 2020.	Name of Product : BIOCREDIT COVID-19 IgG/IgM Combo

※ Attached, if necessary (approved product information)
■ Model(Export Name) ☐ Medical Device Accessaries ☐ Manufacturer/Legal manufacturer
☐ Combined/Composite medical device

Issued date : AUG. 27. 2020 (Certificate No.20200106830)

Certified by

www.mt-procons.com

promedt CONSULTING

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

RapiGen Inc.
2F, 25 Heungan-daero,
Gunpo-si, Gyeonggi-do 15809
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).
The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

2 April 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

7-2. Clinical Performance of COVID-19 IgG/IgM Combo

BIOCREDIT COVID-19 IgG/IgM Combo		PCR (after symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
IgM	Positive	52	2	100% (52/52)	98.7% (148/150)
	Negative	0	148		
Total		52	150		
IgG	Positive	49	2	94.2% (49/52)	98.7% (148/150)
	Negative	3	148		
Total		52	150		

Product performance

BIOCREDIT COVID-19 IgG/IgM Combo	PCR (after symptoms occur)		Sensitivity	Specificity
	Positive	Negative		
Positive	52	4	100 % (CI, 95%: 91.43 – 100.00)	97.3 % (CI, 95%: 92.89 – 99.14)
Negative	0	146		
Total	52	150		
Positive predictive value (PPV)			92.9% (CI, 95%: 81.87 – 97.69)	
Negative predictive value (NPV)			100% (CI, 95%: 96.80 – 100.00)	

5-3. Kit Components of BIOCREDIT COVI-FLU

BIOCREDIT CoviFlu Ag Duo
rapid test kit

Intended Use	For the qualitative detection of SARS-CoV-2 and Influenza virus (type A and type B) antigen
Package	20 Tests / kit
Storage	2~ 30℃
Specimen Type	Nasopharyngeal swab
Shelf life	24 months from the date of manufacture
Time to result	5~ 8 minutes

Test Device (COVID-19 COVI-FLU)

Sterilized swab for nasopharyngeal specimen collection

Assay Diluent tubes & filter cap

6-3. Regulatory Approval Status of BIOCREDIT COVI-FLU

Regulatory approvals

No	Name of the country	Approved indication	Date of approval
1	S. Korea	Qualitative detection of SARS-CoV-2 antigen in human nasopharynx	05 Sep., 2020
2	CE mark		21 Aug., 2020

Document Number : QX39-S5XI-W4ND-BT5E

Ministry of Food and Drug Safety

Osong Health Technology Administration Complex, 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea, 28159 Tel: +82-43-719-5356 , Fax: +82-43-719-5350

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- Registered No. : Manufacturer IVD-3897

No. and date of product-license, comments	Classification
IVD-20-629 / AUG. 10. 2020.	Name of Product : BIOCREDIT COVID-19 IgG/IgM Combo

※ Attached, if necessary (approved product information)
■ Model(Export Name) ☐ Medical Device Accessories ☐ Manufacturer/Legal manufacturer
☐ Combined/Composite medical device

Issued date : AUG. 27. 2020 (Certificate No.20200106830)

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2 April 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

7-3. Clinical Performance of CoviFlu Ag Duo

Product performance

BIOCREDIT COVID-19 Ag		PCR (after symptoms occur)		Sensitivity	Specificity
		Positive	Negative		
Ag	Positive	46	0	90.2 % (46/51)	100 % (136/136)
	Negative	5	136		
Total		51	136		

Product performance

BIOCREDIT Influenza A&B Ag	PCR (after symptoms occur)			Total	Sensitivity	Specificity
	A	B	Negative			
A Positive	52	0	0	52	94.5%	
B Positive	0	27	0	27	90.0%	
Negative	3	3	80	86		100.0%
Total	55	30	80	165		

8. List of Export Countries


1. Bulgaria


2. Germany


3. Greece


4. Hungary


5. Italy


6. Poland


7. Romania


8. Russia


9. Egypt

10. Indonesia


11. Malaysia


12. Bolivia


13. Brazil


14. Honduras


15. Panama


16. Uzbekistan


17. Thailand


18. UK


19. Slovenia


20. Netherland


21. Slovakia


22. Bosnia


23. Czech Republic


24. North Macedonia


25. Serbia


26. Austria


27. Turkey


28. Philippines


29. Pakistan


30. Colombia


31. Chile


32. Ecuador


33. Guatemala


34. Mexico


35. Japan

36. Ivory Coast


37. Myanmar


38. Portugal


39. Spain


40. Jordan


41. Oman

9. Production Capacity

Month-Year	TOTAL CAPACITY (number of COVID-19 rapid diagnostic tests per month)
Jul-20	8,400,000
Aug-20	8,400,000
Sep-20	8,400,000
Oct-20	10,000,000
Nov-20	16,800,000
Dec-20	20,000,000
Jan-21	24,000,000
Feb-21	24,000,000
Mar-21	24,000,000
Apr-21	24,000,000
May-21	24,000,000


Thank You
Simple, Accurate and Convenient!!
RapiGEN Inc.