

IPFA/PEI 28th International Workshop on Surveillance and Screening of Blood-borne Pathogens

21 & 22 September 2022 | Porto, Portugal



September 22nd 9-11am Session 5. manufacturer's session

Efficient Multiplex TTID Management in the Era of Pandemics

Soyoun Kim, Ph.D

CEO/Founder, PCL Inc.

**Professor, Convergence Research Institute,
Korea University, Korea**

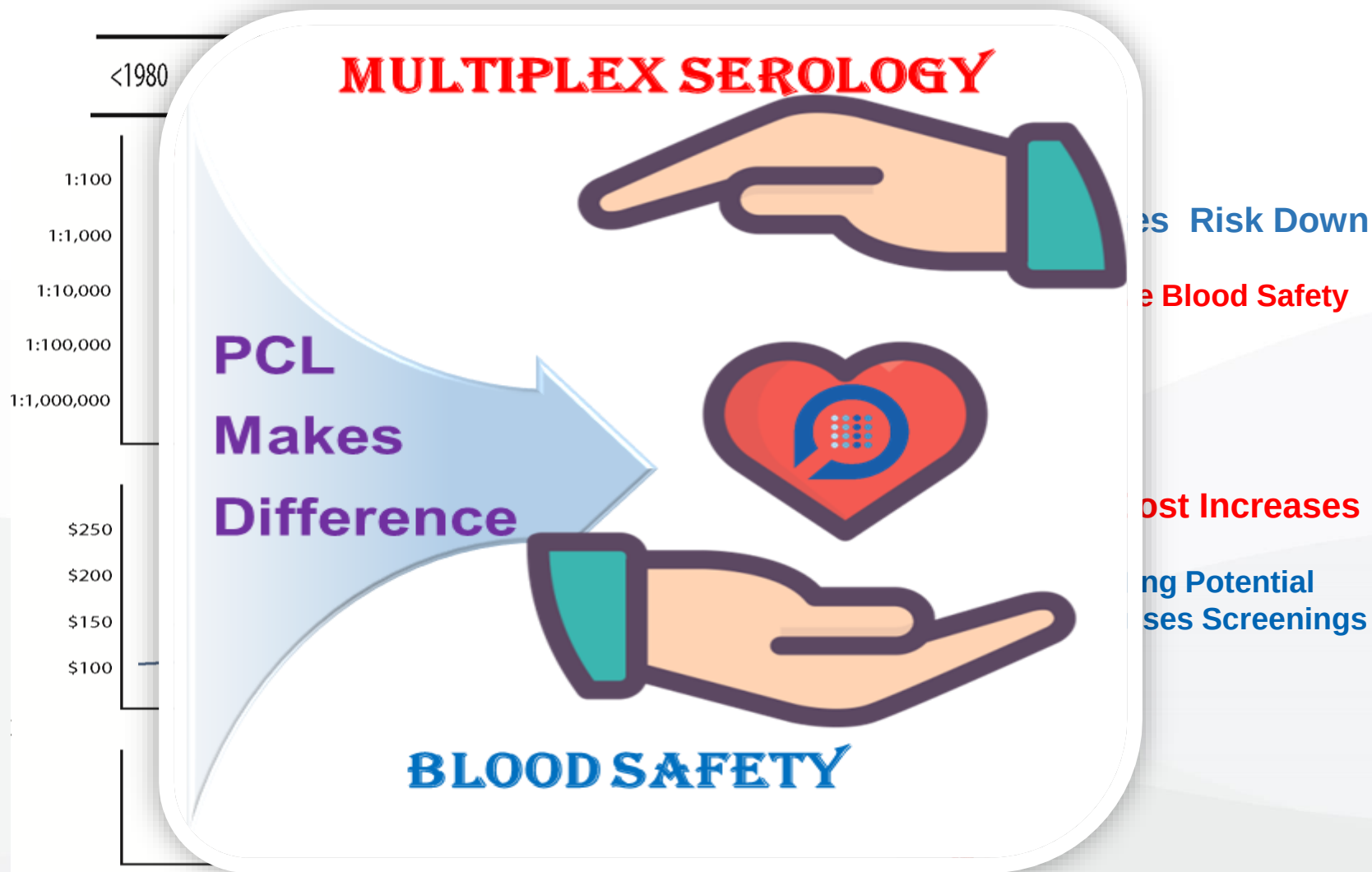


52 WEEK RANGE

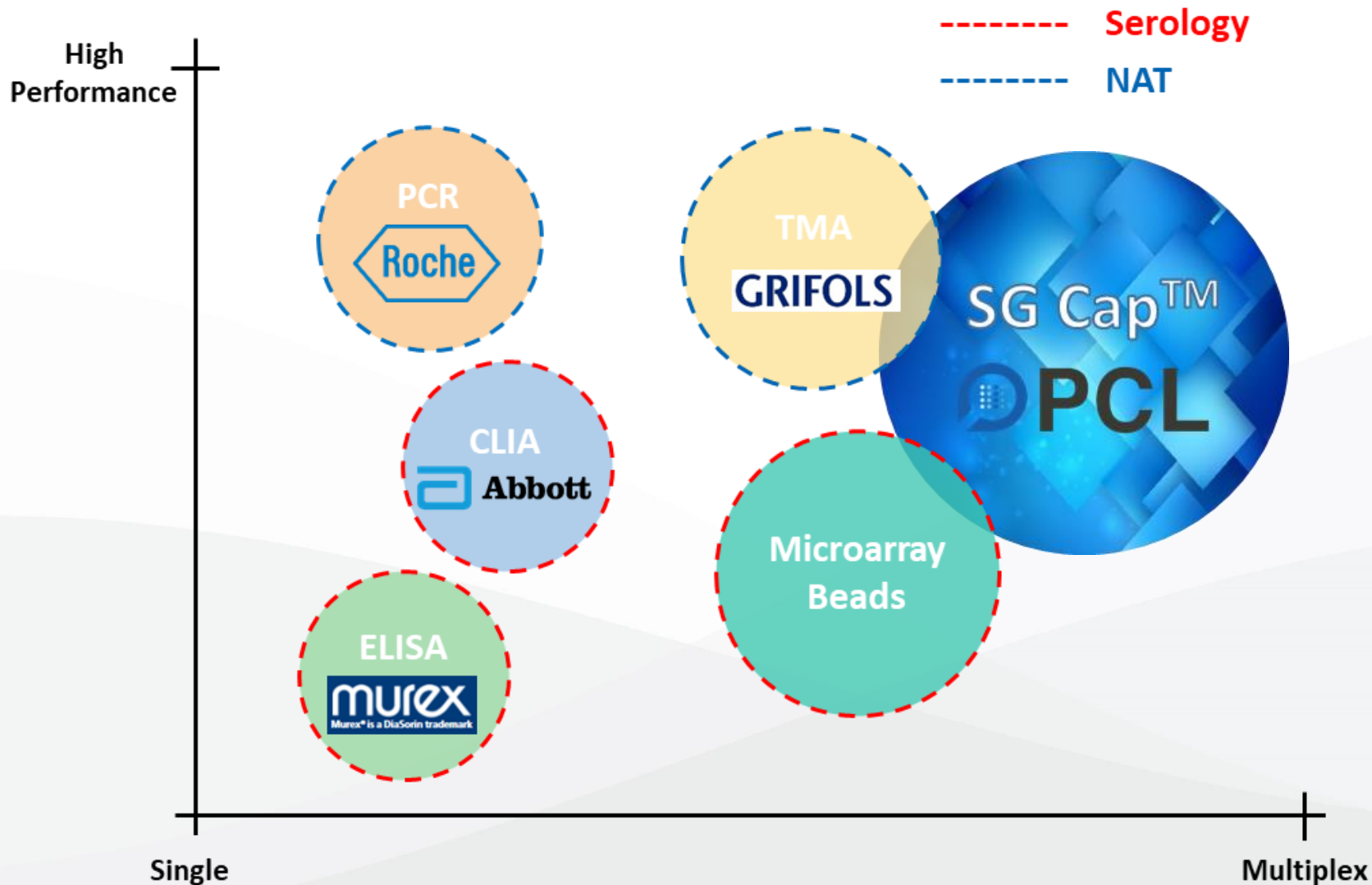
12,900.00 - 51,000.00



PCL is the Multiplex Blood Safety Solution Provider

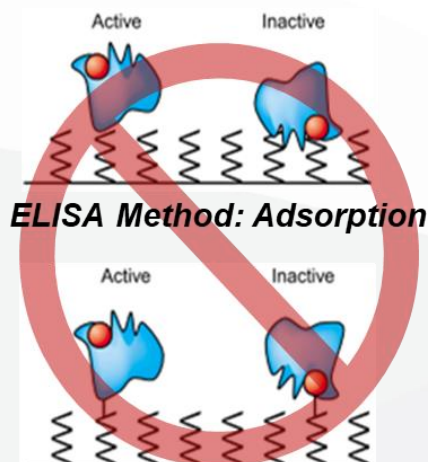
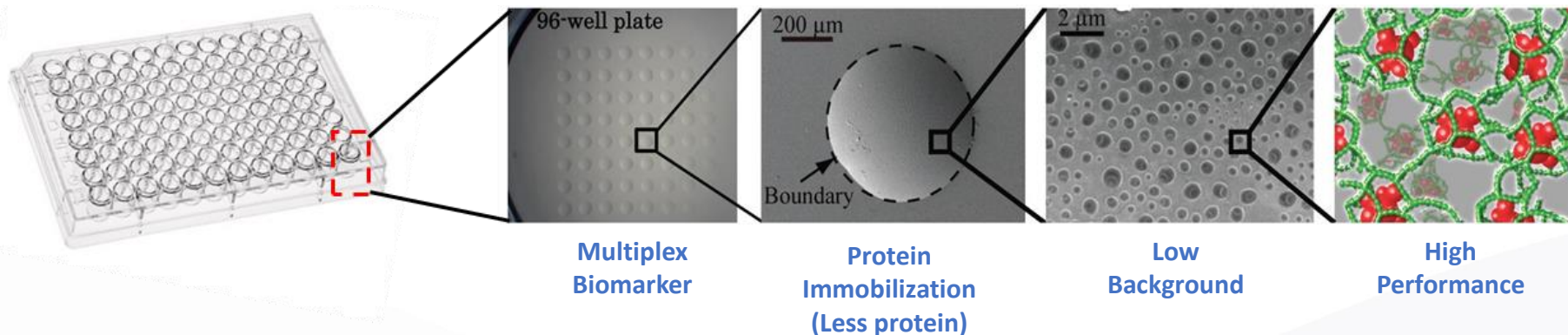


SG-Cap technology has competitive advantages over other serology technology

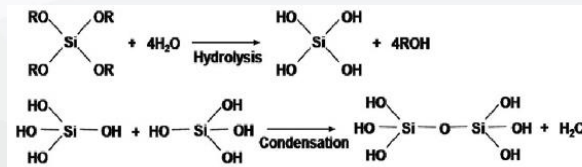
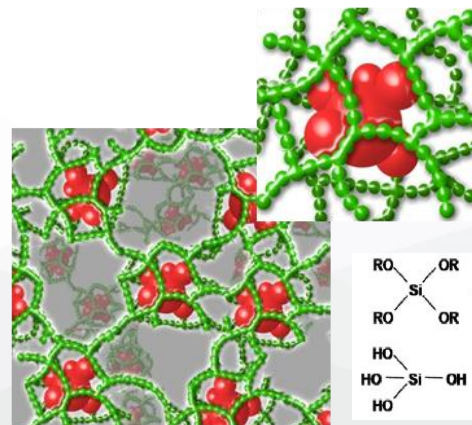


SG-Cap technology makes difference

3-D Sol-gel capturing system Immobilizes various disease markers.



CLIA Method covalent cross linking
Less Protein Activity



Modified from Keynote address from Mayo Clinic, Microarrays for Diagnostics, March 2002

High Protein Activity



High Throughput Screening

- Suitable for blood banks/hospitals
- High-risk virus detection
- Compatible with an open platform
- 167T / hr

- Hi01 - HIV + HCV Ab
- Hi02 - HBsAg Ag
- Hi04 - HIV + HCV + Syphilis Ab
- Hi05 - HIV p24 + HBsAg Ag
- Hi08 - Syphilis + Malaria Ab
- Hi09 - Malaria(*P.vivax*) Ag
- Hi12' - HTLV I/II + Chagas Ab

Pandemic solution

- Quick and accurate
- Self-test kit within 10 mins
- Naso/oropharyngeal Saliva, serum plasma specimens

- COV01 - COVID-19 Total Ab EIA
- COV03 - COVID-19 IgG/M Rapid gold
- COV04S - COVID-19 Ag gold
- COV05 - COVID-19 Ag Rapid FIA
- COV011 - COVID-19(S1) IgG EIA
- Ri02 - FluA/B+COVID-19 Ag
- Ri03 - S1/NP COVID-19 IgG

Point of care testing

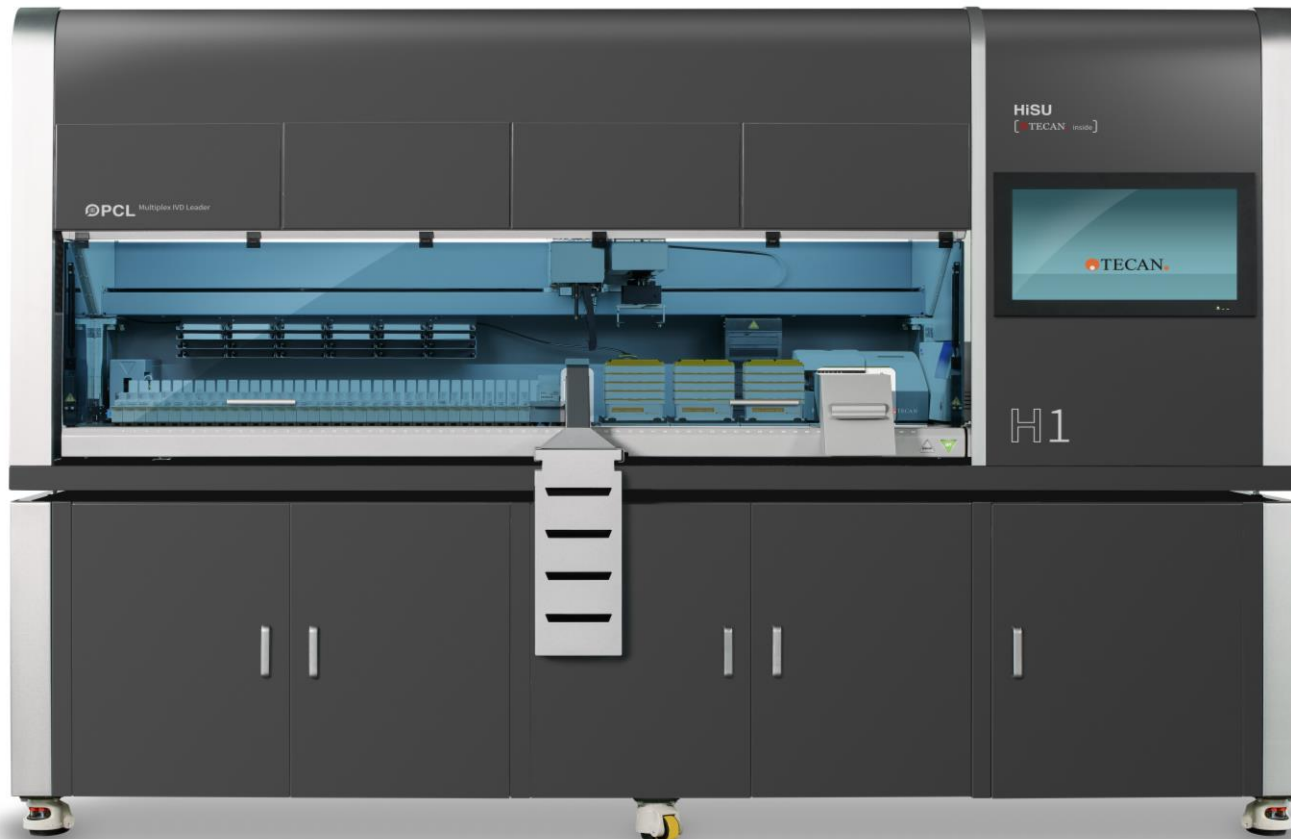
- Suitable for Small, Medium sized hospital animal hospital and Health center
- Portable immunoassay system
- 12T / 30min

- Hi06 - HIV+HCV+Syphilis Ab
- Hi07 - HBsAg+HIV p24 Ag
- Hi10 - Toxoplasmosis+Rubella+CMV+HSV IgG Ab
- Hi11 - Toxoplasmosis+Rubella+CMV+HSV IgM Ab
- Ci02 - CA19-9+AFP+CEA+PSA Ag
- Ci03 - CA19-9+AFP+CEA+CA125
- Ci04 - AFP+PIVKA II
- Ci05 - CA125+HE4
- Vi01 - CDV+CPV+CAV-2+CCV
- Vi02 - FCF+FPV+FVR+FIP+ChI

**PCL
Platform**

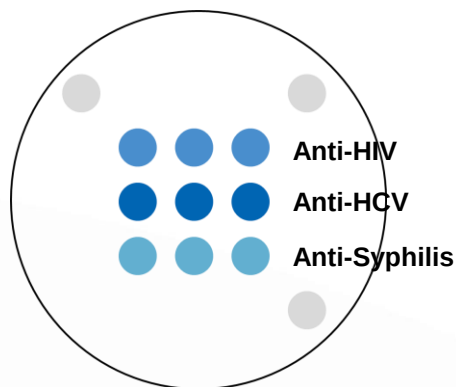
HiSU Platform Series

- Fully automated multiplex immunoassay analyzer
- Designed for high-volume blood screening system
- Increases throughput by running multiplex blood screening assays



I Blood bank screening

HIV, HCV and Syphilis (Hi04)

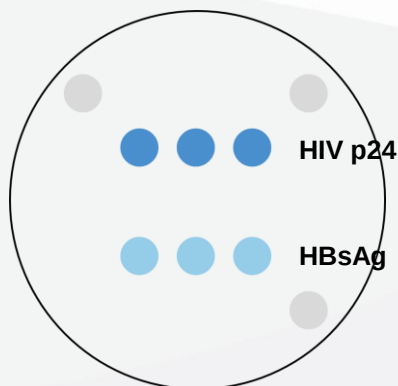


Purpose

- Multiplex diagnostic kit that qualitatively detects **IgG antibodies** for HIV, HCV and **Syphilis** in human serum and plasma.
- Automated Fluorescence immunoassay to provide test results with **AI, deep learning image analysis**.

Clinical performance	anti-HIV1/2	Anti-HCV	Anti-syphilis
Sensitivity	100% (500/500)	100% (400/400)	100% (100/100)
Specificity	99.94% (5003/5006)	99.90% (5001/5006)	99.76% (4994/5006)

HIV p24 and HBsAg (Hi05)



Purpose

- Multiplex diagnostic kit that qualitatively detects **antigens** for HIV and HBsAg in human serum and plasma.
- Automated Fluorescence immunoassay to provide test results with **AI, deep learning image analysis**.

Clinical performance	HIV p24	HBsAg
Sensitivity	100% (400/400)	100% (400/400)
Specificity	99.88% (5000/5006)	99.94% (5003/5006)

Hi04 Panel test result

HIV Panel	Abbott anti-HIV1/2		Hi04	
	S/Co	Result	S/Co	Result
PRB914-01	8.4	POS	9.2	POS
PRB914-02	7.8	POS	11.5	POS
PRB914-03	8.0	POS	12.1	POS
PRB914-04	12.8	POS	25.3	POS
PRB914-05	11.4	POS	24.5	POS

HCV Panel	Abbott HCV		Hi04	
	S/Co	Result	S/Co	Result
PRB921-01	0.2	NEG	0.2	NEG
PRB921-03	1.4	POS	22.2	POS
PRB921-04	2.0	POS	26.2	POS
PRB921-05	3.1	POS	21.6	POS
PRB921-06	3.3	POS	22.4	POS
PRB921-07	3.8	POS	27.8	POS
PRB921-08	4.0	POS	19.5	POS
PRB921-09	5.0	POS	29.8	POS
PRB921-10	5.7	POS	27.1	POS
PRB921-11	7.2	POS	25.8	POS

Syphilis Panel	Abbott anti-syphilis		Hi04	
	S/Co	Result	S/Co	Result
0615-0071 01	0.0	NEG	0.2	NEG
0615-0071 02	0.0	NEG	0.1	NEG
0615-0071 03	0.0	NEG	0.3	NEG
0615-0071 04	0.0	NEG	0.2	NEG
0615-0071 05	0.0	NEG	0.2	NEG
0615-0071 06	5.0	POS	2.3	POS
0615-0071 07	9.1	POS	5.7	POS
0615-0071 08	14.1	POS	15.9	POS
0615-0071 09	27.4	POS	13.5	POS

Hi05 Limit of detection test result

HBsAg LoD test result

HBsAg IU/ml	Signal	S/Co	Result
2	25.71	19.78	POS
1	15.35	11.81	POS
0.5	7.54	5.8	POS
0.13	1.87	1.44	POS
0.065	0.98	0.75	NEG

* Result of 12/226 WHO standard

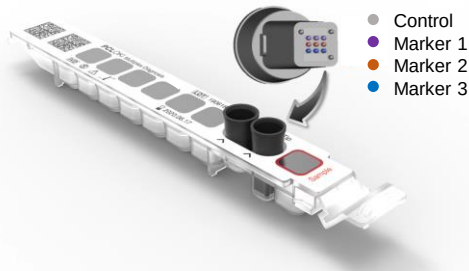
HIV p24 LoD test result

HIV p24 IU/ml	Signal	S/Co	Result
10	17.56	8.78	POS
5	9.12	4.56	POS
2.5	4.35	2.18	POS
2	3.55	1.78	POS
1	1.65	0.83	NEG

* Result of 90/636 WHO standard

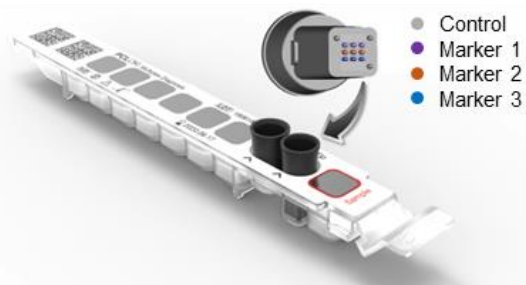
I PCLOCK II Platform Series

- Convenient and powerful immunoassay analyzer (FIA)
- POCT analyzer. Its portable feature and accurate test result will improve the quality of the patient management.
- Quantitative/ Qualitative test available.

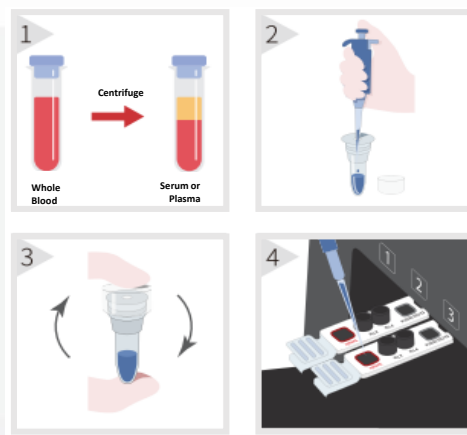




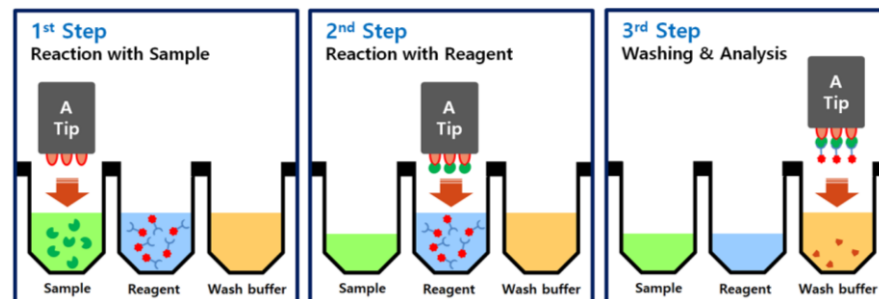
PCLOCK II How to use?



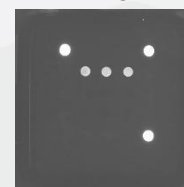
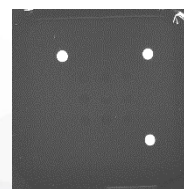
Portable All-in-One Cartridge
On Site Multiplex Test



PCLOCK II How it works?



Using Deep learning, AI
Image analyzer



Test Result

No.	Patient ID	HIV 1/2	HCV	Syphilis
1	221878	NEG -	NEG -	NEG -
2	234841	POS 2.42	NEG -	NEG -
3	220712	NEG -	POS 5.67	NEG -
4	231215	NEG -	NEG -	POS 17.7
5	357821	NEG -	POS 34.2	NEG -
6	143879	NEG -	POS 11.2	NEG -

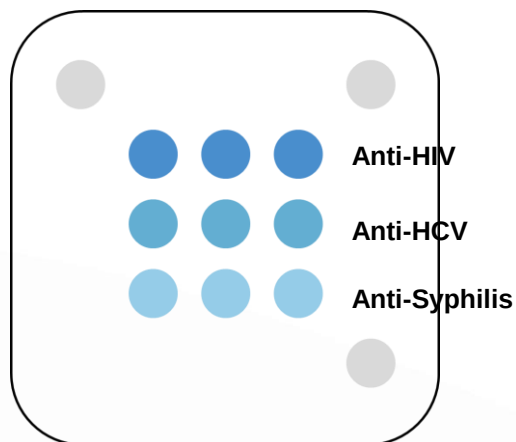


I PCLOCK II How to use?



Blood bank screening

HIV, HCV and Syphilis (Hi06)

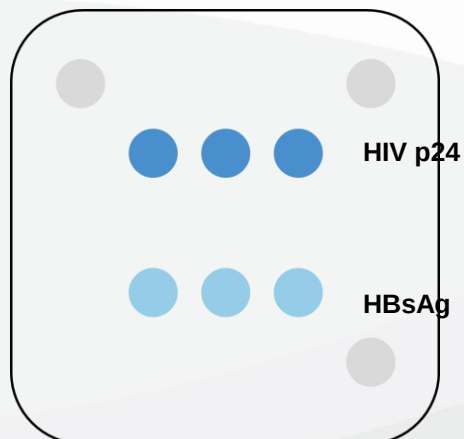


Purpose

- Multiplex diagnostic kit that qualitatively detects **IgG antibodies** for HIV, HCV, and **Syphilis** in human serum and plasma.
- Automated Fluorescence immunoassay to provide test results

Clinical performance	anti-HIV1/2	Anti-HCV	Anti-syphilis
Sensitivity	100% (500/500)	100% (400/400)	99.00% (99/100)
Specificity	99.62% (4987/5006)	99.95% (5003/5006)	99.33% (5005/5006)

HIV p24 and HBsAg (Hi07)



Purpose

- Multiplex diagnostic kit that qualitatively detects **antigens** for HBsAg and HIV p24 in human serum and plasma.
- Automated Fluorescence immunoassay to provide test results

Clinical performance	HBsAg	HIV p24
Sensitivity	100% (400/400)	100% (400/400)
Specificity	99.92% (5002/5006)	99.90% (5001/5006)

Hi06 Panel test result

HIV Panel	Abbott anti-HIV1/2		Hi06	
	S/Co	Result	S/Co	Result
PRB914-01	8.4	POS	11.2	POS
PRB914-02	7.8	POS	14.7	POS
PRB914-03	8.0	POS	18.3	POS
PRB914-04	12.8	POS	31.6	POS
PRB914-05	11.4	POS	35.3	POS
HCV Panel	Abbott HCV		Hi06	
	S/Co	Result	S/Co	Result
PRB921-01	0.2	NEG	0.0	NEG
PRB921-03	1.4	POS	24.0	POS
PRB921-04	2.0	POS	28.8	POS
PRB921-05	3.1	POS	29.6	POS
PRB921-06	3.3	POS	27.6	POS
PRB921-07	3.8	POS	38.6	POS
PRB921-08	4.0	POS	25.9	POS
PRB921-09	5.0	POS	35.5	POS
PRB921-10	5.7	POS	33.2	POS
PRB921-11	7.2	POS	39.9	POS
Syphilis Panel	Abbott anti-syphilis		Hi06	
	S/Co	Result	S/Co	Result
0615-0071 01	0.0	NEG	0.4	NEG
0615-0071 02	0.0	NEG	0.4	NEG
0615-0071 03	0.0	NEG	0.4	NEG
0615-0071 04	0.0	NEG	0.4	NEG
0615-0071 05	0.0	NEG	0.0	NEG
0615-0071 06	5.0	POS	3.9	POS
0615-0071 07	9.1	POS	9.2	POS
0615-0071 08	14.1	POS	16.6	POS
0615-0071 09	27.4	POS	15.6	POS

Hi07 Limit of detection test result

HBsAg LoD test result

HBsAg IU/ml	Signal	S/Co	Result
2	7.26	31.29	POS
1	3.55	12.76	POS
0.5	2.13	5.67	POS
0.13	1.42	2.11	POS
0.065	1.24	1.22	POS

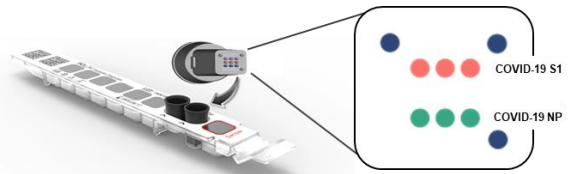
* Result of 12/226 WHO standard

HIV p24 LoD test result

HIV p24 IU/ml	Signal	S/Co	Result
10	9.4	41.8	POS
5	4.6	17.8	POS
2.5	2.5	7.5	POS
1.25	1.2	1.1	POS
1	0.9	0.0	NEG

* Result of 90/636 WHO standard

Pandemic Solution

Platform	Product Line	Product	Image
Pandemic Solution	Antigen Test Kit	COV04S (PCL COVID19 Ag Gold)	 COV04S COV05
		Ri02 (PCLOK II Influenza A/B, Covid-19)	
		COV05 (PCL COVID19 Ag Rapid FIA)	
	Antibody Test Kit	Ri03 (PCLOK II Anti-SARS-CoV-2 Dual IgG)	 PCLOK II ABC COV03 COV011
		COV03 (PCL COVID19 IgG/IgM Rapid Gold)	
		COV01 (PCL COVID19 Total Ab EIA)	
		COV011 (PCL SARS-CoV-2 IgG EIA)	
			 PCLOK II Anti-SARS-CoV-2 Dual IgG

PCL COVID19 Ag Gold (Saliva)



Purpose

- In vitro diagnostic medical device for qualitative detection of SARS-CoV-2 antigen in human saliva specimen

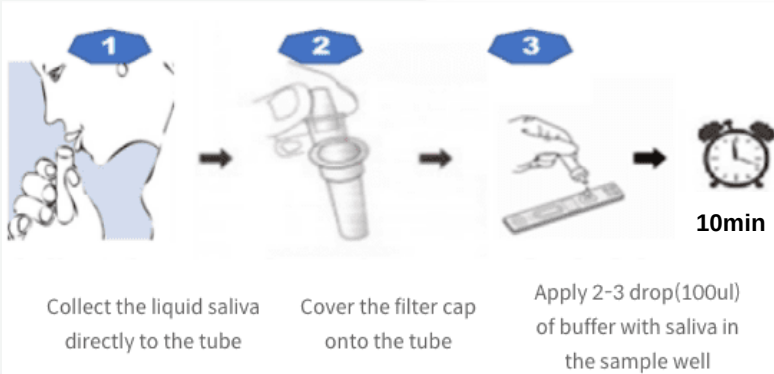
Performance Summary

- Clinical sensitivity: 94.29% (33/35)
- Clinical specificity: 99.99% (70/70)
- First approval for saliva use by the Ministry of Food and Drug Safety, CE certification in Europe, permission to use in Canada
- Clinical trials for adolescents under the age of 18 (44 infants, 53 adolescents)
- Ease of use in children and adolescents, accurate measurement of omicrons and other mutations

Certification

- CE Certificate
- FSC from Korea FDA
- Austria(Self Test)
- Bosnia Hercegovina
- El Salvador
- Germany_[BfArM]
- Guatemala

How to use



I PCL COVID19 Ag Gold (Saliva) Clinical performance summary

Clinical performance results

- Sensitivity : 91.76% (95% CI: 83.77% - 96.92%)
- Specificity : 99.54% (95% CI: 97.48% - 99.99%)
- PPV : 98.7% (95% CI: 93.60% - 99.90%)
- NPV : 96.9% (95% CI: 95.10% - 97.30%)

Distribution of people participating in clinical trials

Age group	Number of persons (%)
0 - 9	44 (14.0%)
10 - 18	53 (16.9%)
19 - 29	29 (9.2%)
30 - 39	41 (13.1%)
40 - 49	89 (28.3%)
50 - 59	26 (8.3%)
60 - 69	20 (6.4%)
70 - 79	2 (0.6%)
80 - 89	7 (2.2%)
90 - 99	3 (1.0%)
Total	314

Clinical sensitivity based on 5 days of symptom onset

Onset of symptoms	Result	Sensitivity
0~4 day	37/39	94.9% (95% CI: 83.1% - 98.6%)
5~10 day	14/15	93.3% (95% CI: 70.2% - 99.8%)

Clinical sensitivity based on Ct values

Ct value	Result	Sensitivity
Ct ≤ 20	48/48	100% (95% CI: 92.60% - 100%)
20 < Ct ≤ 30	24/25	96% (95% CI: 79.65% - 99.9%)
Ct>30	6/12	50% (95% CI: 21.09% - 78.91%)

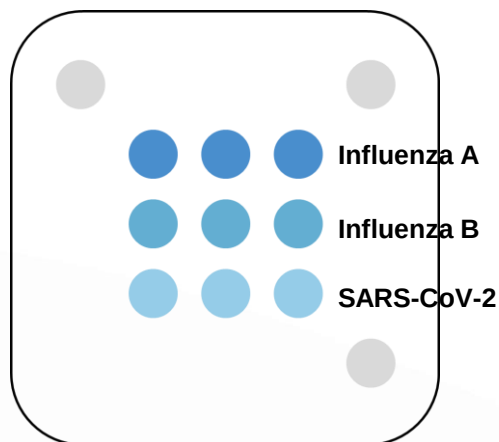
Sensitivity based on limit of detection

Ct value	Result	Sensitivity
Ct ≤ 27.48	72/72	100.0% (95% CI: 94.9% - 100.0%)
Ct>27.48	6/13	46.2% (95% CI: 23.2% - 70.9%)



I PCLOK II Solution for Pandemic

ABC (Ri02)



Purpose

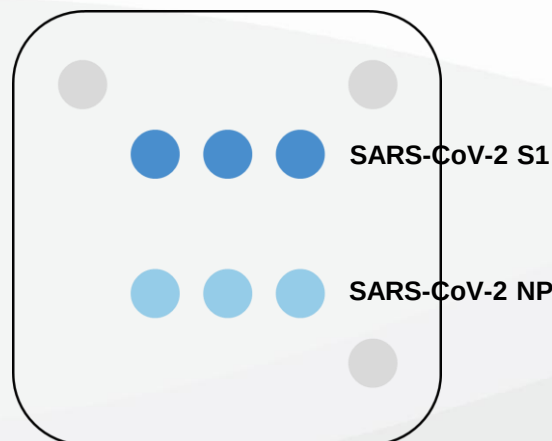
- Multiplex diagnostic kit that qualitatively detects antigens for Influenza A, B, and COVID-19 using human nasopharyngeal samples.
- Automated Fluorescence immunoassay to provide test results

Clinical performance	Influenza A	Influenza B	COVID-19
Sensitivity	90.14% (128/142)	88.97% (129/145)	91.43% (128/140)
Specificity	100.0% (149/149)	99.33% (148/149)	99.33% (148/149)

Collection Point	Positive	Negative	Sensitivity
Before 7 days	111	1	99.11% (95%CI:95.13%-99.98%)
After 7 days	17	11	60.71% (95%CI:40.58%-78.50%)

*Elapsed days from the onset of symptoms to collection of samples

SARS-CoV-2 Dual IgG (Ri03)

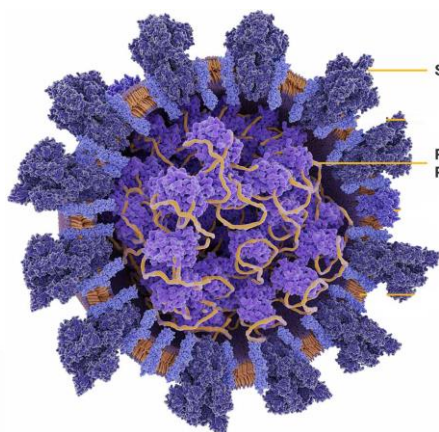


Purpose

- Multiplex diagnostic kit that qualitatively detects IgG antibodies for SARS-CoV-2 Spike proteins(S1) and Nucleocapsid protein (NP) in human serum and plasma.
- Automated Fluorescence immunoassay to provide test results

Clinical performance				
Specificity			99.3%(149/150)	
Days post symptom onset	N	NEG	POS	Positive Agreement to RT-PCR (%)
0-7	24	14	10	41.7%
8-14	28	3	25	89.3%
15-21	25	1	24	96.0%
≥ 22	73	0	73	100.0%
Total Sensitivity	150	18	132	88.0%

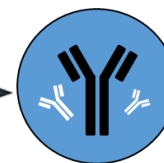
PCLOK II Anti-SARS-CoV-2 Dual IgG



Spike Glycoprotein (S)

RNA and Nucleocapsid
Protein (N)

PERSON
VACCINATED

AFTER 2nd
VACCINATION


S Antibody


PERSON
INFECTED

1 - 3 WEEKS

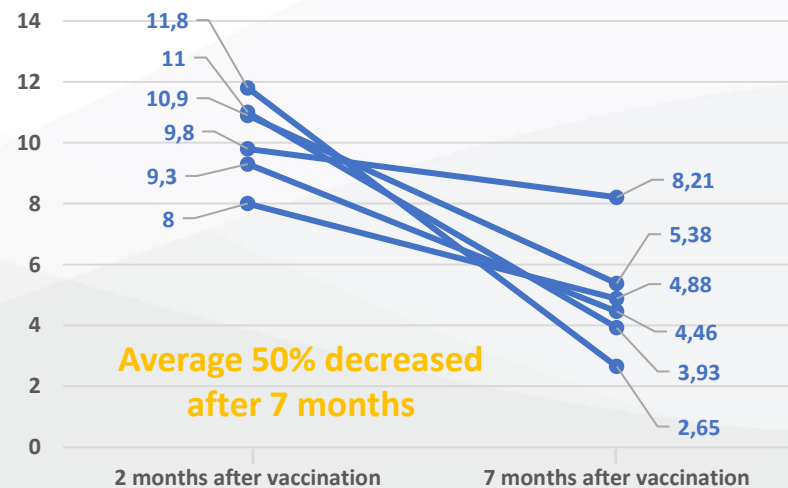


N Antibody

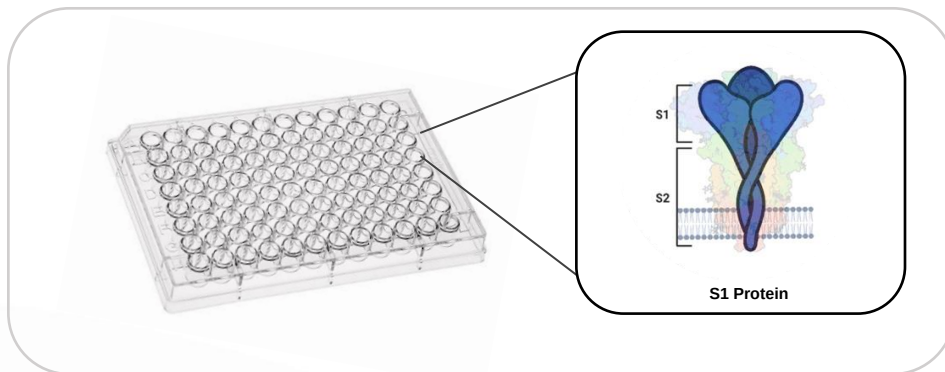
After SARS-CoV-2 infection (n=7) N Antibody



After COVID-19 vaccination (n=6) S Antibody



HiSU COVID-19 S1 Protein (COV011)



Purpose

- ELISA kit that qualitatively detects IgG antibodies for SARS-CoV-2 Spike S1 in human serum and plasma.
- Automated Fluorescence immunoassay to provide test results.

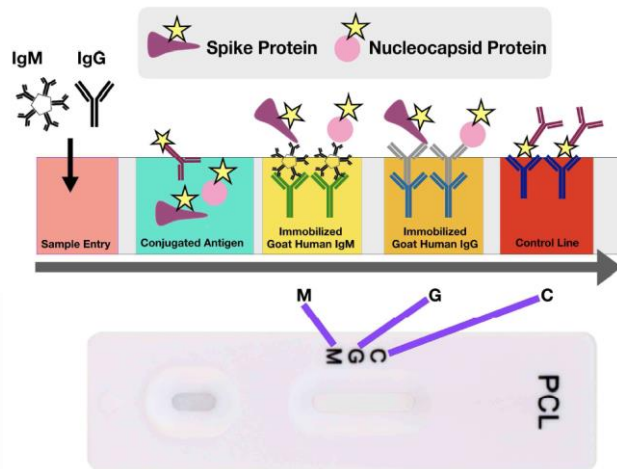
Performance Summary

Clinical performance	COVID-19 S1 Protein
Sensitivity	84.67% (127/150)
Specificity	97.33% (146/150)

Panel test result

COVID-19 Panel	Expected Result	S/Co	COV011 Result
20/B770-01	POS	2.37	POS
20/B770-02	POS	3.40	POS
20/B770-03	POS	13.94	POS
20/B770-04	POS	14.00	POS
20/B770-05	POS	13.92	POS
20/B770-06	POS	7.96	POS
20/B770-07	POS	9.71	POS
20/B770-08	POS	13.98	POS
20/B770-09	POS	13.98	POS
20/B770-10	POS	13.98	POS
20/B770-11	POS	6.76	POS
20/B770-12	POS	7.73	POS
20/B770-13	POS	8.90	POS
20/B770-14	POS	8.41	POS
20/B770-15	POS	10.43	POS
20/B770-16	POS	7.27	POS
20/B770-17	POS	10.87	POS
20/B770-18	POS	13.97	POS
20/B770-19	POS	10.93	POS
20/B770-20	POS	13.34	POS
20/B770-21	POS	12.12	POS
20/B770-22	POS	13.08	POS
20/B770-23	POS	11.29	POS
20/B770-24	NEG	0.08	NEG
20/B770-25	NEG	0.10	NEG
20/B770-26	NEG	0.10	NEG
20/B770-27	NEG	0.09	NEG
20/B770-28	NEG	0.07	NEG
20/B770-29	NEG	0.10	NEG
20/B770-30	NEG	0.14	NEG
20/B770-31	NEG	0.14	NEG
20/B770-32	NEG	0.15	NEG
20/B770-33	NEG	0.11	NEG
20/B770-34	NEG	0.09	NEG
20/B770-35	NEG	0.09	NEG
20/B770-36	NEG	0.08	NEG
20/B770-37	NEG	0.06	NEG

COV03 Antibody POCT Rapid



Purpose

- Antibody diagnostic kit detecting **IgG** and **IgM** antibodies for **COVID-19** diagnosis in human hand-end blood.

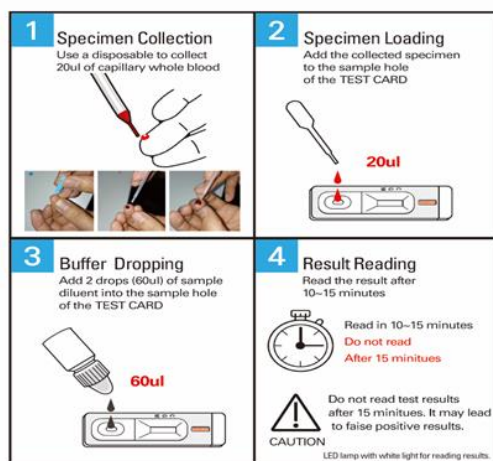
Performance Summary

- IgG: Limits of detection - 1:20000
- IgM : Limits of detection - 1:10000
- Clinical sensitivity: 91.06%** (112/123)
- Clinical specificity: 99.37%** (1104/1111)

Certification

- CE Certificate
- Australia TGA
- Russia Federation
- India / Greece
- Bolivia
- FSC from Korea FDA
- FIND Listed
- UNGM Supplier

How to use



I Most Recommended COVID-19 Antibody Kit from a South Korean Company

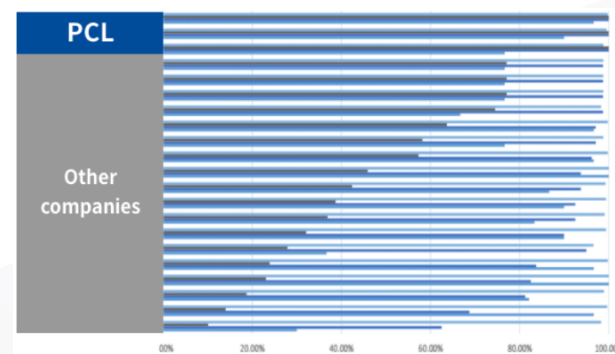
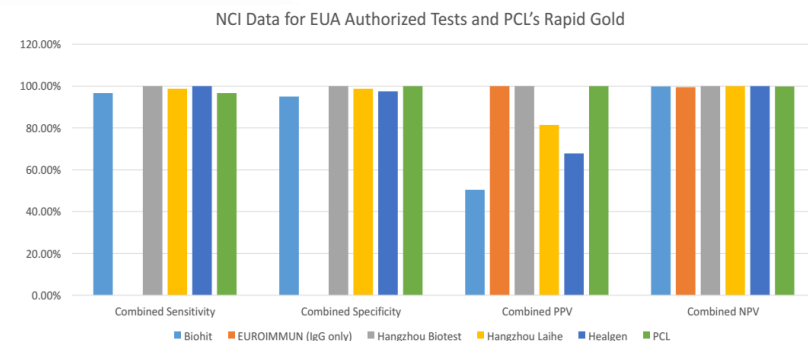
Recommended products by Korean doctors to WHO

PCL Rapid Antibody Diagnostic Kit shows equivalent or better performance to products of other companies that have received Emergency Use Authorization (EUA) in the evaluation of the US FDA.

The world's best performing diagnostic kit (provided by Seoul C University Hospital)

It was mentioned that the sensitivity of the PCL antibody diagnostic kit was 92.9% and the specificity was 96.2%.

*Performance paper of immunodiagnostic kit for rapid detection of IgM and IgG in 2019 coronavirus disease published by users of top university hospitals



Comparison with products from other companies that have received EUA

As a result of the US FDA evaluation, PCL rapid diagnostic kits all proved excellent performance in sensitivity, specificity, PPV, NPV, and etc (refer to the yellow-green bar shown in the graph above).

Comparison with products of other companies that have applied for EUA

As a result of the US FDA evaluation, PCL rapid diagnostic kits demonstrated excellent performance in sensitivity, specificity, PPV, and NPV (refer to the graph above).

Outstanding Performance Study by the German Red Cross 'GFE Blut'

DRK-Blutspendedienst
Baden-Württemberg | Hessen
gemeinnützige GmbH



Comparison of three SARS Antigen Rapid Assays



Prof. Dr. M. Schmidt
Prof. Dr. E. Seifried

- Roche SD BIOSENSOR SARS-CoV-2 Rapid Antigen Test
- Abbott Panbio™ COVID-19 Ag Rapid Test Device
- PCL COVID19 Ag Gold
- Dilution series of SARS Standard; quantitated with GFE SARS-CoV-2 PCR Kit, PCR Threshold Cycle (Ct) Ct 18 - Ct 22
- Triplicate determination of each dilution level in each Rapid Assay

Summary

- Analytical Sensitivity of PCL COVID Assay superior to Roche & Abbott
- Diagnostic Sensitivity comparable in 200 samples from routine
- Amount of positive tested samples correlates with incidence
- Rapid assays are very suitable in environments with symptomatic individuals

Diagnostic Specificity, swab samples

- 200 samples each tested negative in GFE SARS-CoV-2 PCR were tested in the rapid assays

	POS	NEG
Roche rapid assay	3	197
Abbott rapid assay	1	199
PCL rapid assay	0	200 ★

Dilution level no.	Ct value	Roche	Abbott	PCL
Level 4	18	3/3	3/3	3/3
Level 5	19	3/3	3/3	3/3
Level 6	20	3/3	3/3	3/3
Level 7	21	3/3	3/3	3/3
Level 8	22	0/3	0/3	3/3 ★

10 fold



| PCL in world-wide

- Da Asti il test salivare che sostituirà i tamponi per il Covid (2021.06.16) Germany Stern
- Da Asti il test salivare che sostituirà i tamponi per il Covid. (2021.05.26) Italia LASTAMPA
- Corona Mitsuke Taro Installed inspection kit vending machines at Nagoya Osu store and Aeon Town Chikusa store! (2021.05.26) Japan News
- Video-Anleitung zum Spucktest -PCL COVID19 Rapid Antigen Test Kit.(2021.04.18) Burgenland homepage
- PCL COVID19 Ag Gold: Burgenland beendet Lockdown am Montag (2021.04.14) Burgenland homepage
- Aumenta procura de testes de antigénio de PCL saliva COVID-19 (2021.04.05) TV europa
- PCL COVID19 Ag Gold: Land will über Ostern gesamte Bevölkerung testen. (2021.03.30) Burgenland homepage
- Health Canada Authorizes Datametrex to Sell PCL COVID19 Rapid Antigen Test Kit. (2021.03.26) Stockhouse
- Datametrex Secures Authorization by Health Canada for PCL COVID19 Rapid Antigen Test Kit(2021.03.23) Finance yahoo
- BITZ: PCL Tests künftig auch ohne Voranmeldung.(2021.03.23) Burgenland homepage
- PCL Antigen Covid-Spucktest von Kärnter Unternehmen mit höchster Wirkung.(2021.02.12) Open PR
- PCL COVID19 Ag Gold: Dostupni brzi covid-19 testovi na pljuvačku u apotekama –Zaštitite sebe i ostale(2021.01.29) Vijesti



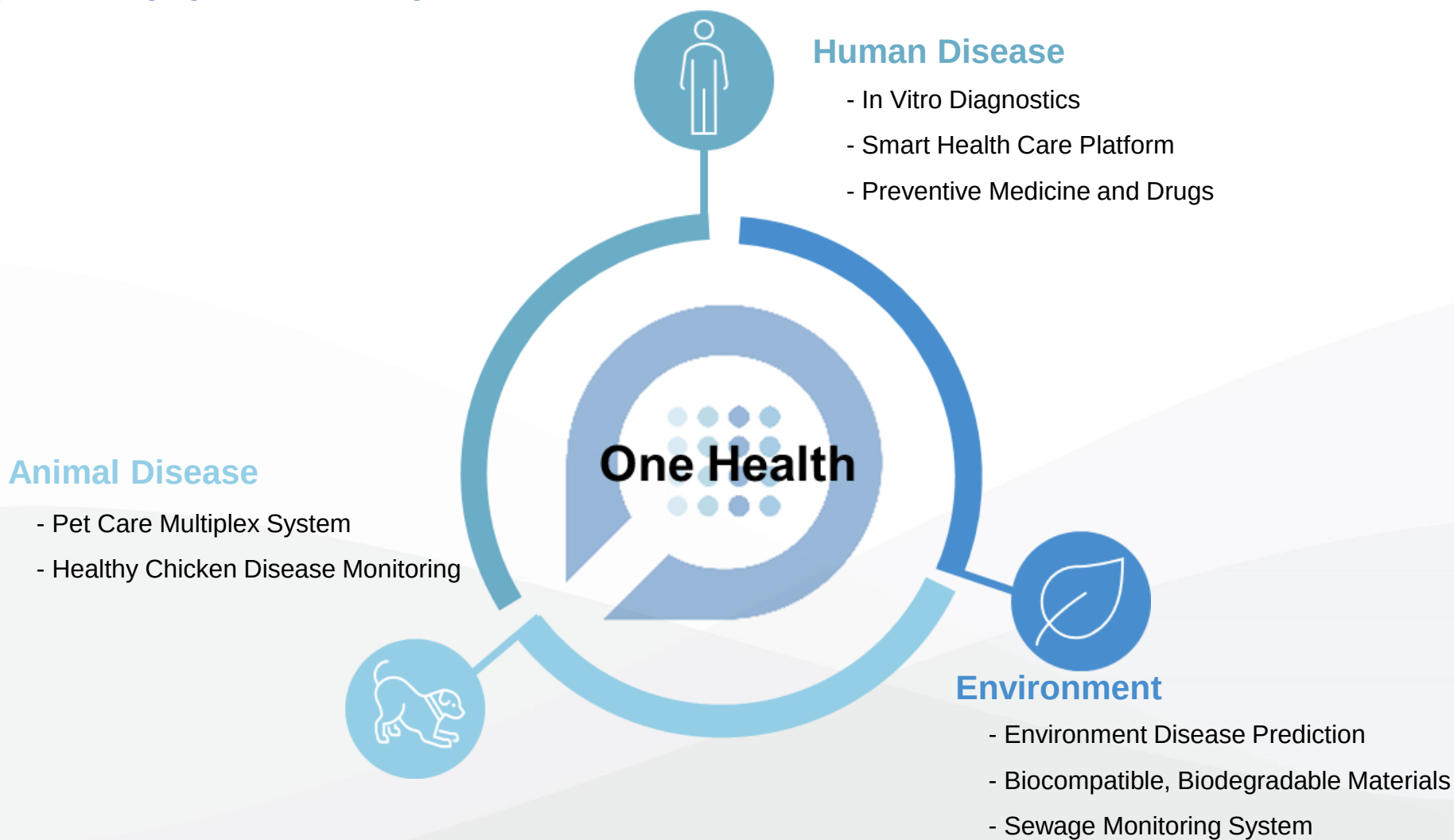
| PCL in world-wide

Exporting to more than 77 countries





I PCL “is” ONE HEALTH COMPANY





Multiplex IVD Leader

Total Supplier of Multiplex In Vitro Diagnostics
with State-of-the art SG Cap™ Technology



17F, SKV1GL METROCITY B ,128, Beobwon-ro, Songpa-gu, Seoul, Republic of Korea

Tel : +82-2-2144-3901/ Fax : +82-0504-415-2348/ E-mail : pclchip@pclchip.com / www.pclchip.co.kr