

JICA COVID-19 Webinar Series #5  
– Sharing of Japanese Experiences –

***FUJIFILM COVID-19 Ag Test***  
***~Patented Silver Amplification Technology~***

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# FUJIFILM Healthcare Business

## Healthcare

Digital X-ray



Medical IT system



Mammography



Endoscopes



Ultrasound



**In Vitro  
Diagnostics  
(IVD)**

## IVD

Dry  
Chemistry



Clinical  
Chemistry



Infectious



Immunoassay



Cancer  
biomarkers



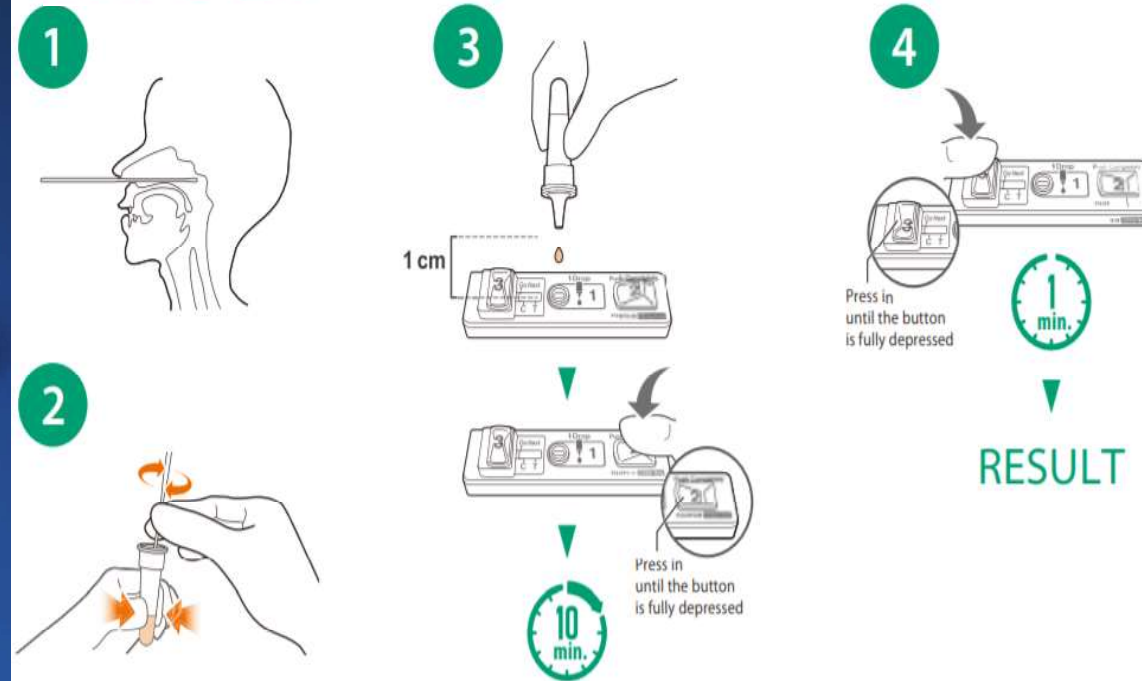
# High Performance Covid-19 Antigen Test

**NEVER  
STOP**

EMPOWERING THE DIGITAL  
EXPERIENCE



## How to use



**[Easy] No Reader Needed**  
**[Rapid] Result in 10-13 minutes**  
**[Sample] Nasopharyngeal**  
**[High Performance] FUJIFILM**  
**Proprietary Silver Amplification**  
**Technology for Increased Accuracy**

## Regulatory Status

Done

Done

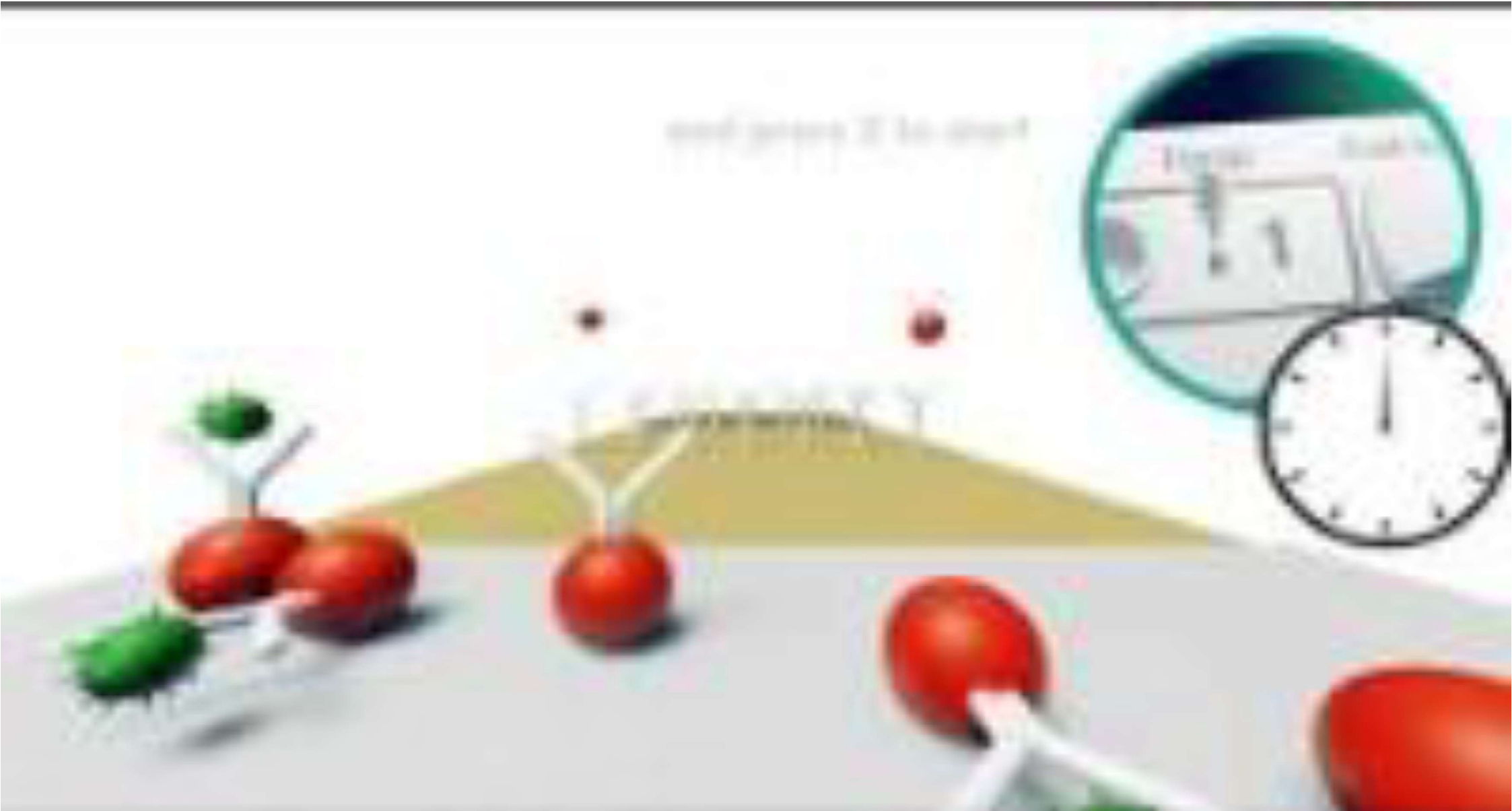
**Pmda**  
**JAPAN**

**CE**  
**IVD**

# Product Introduction Video

<https://www.youtube.com/watch?v=9zKvmnplYvs>

FUJIFILM Ag Test - Rapid Antigen Test for COVID-19 | Fujifilm





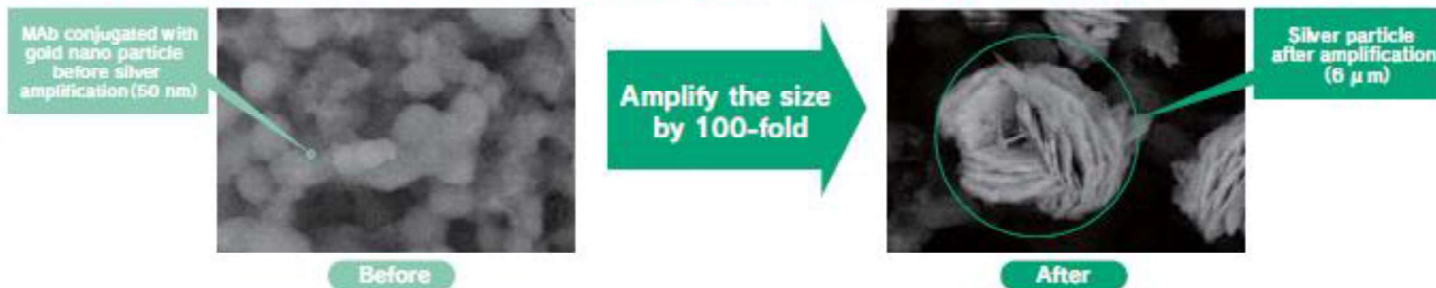
# FUJIFILM Unique Silver Amplification Technology

## New technology with high sensitivity to detect viruses

Highly sensitive immunochromatographic detection using silver amplification

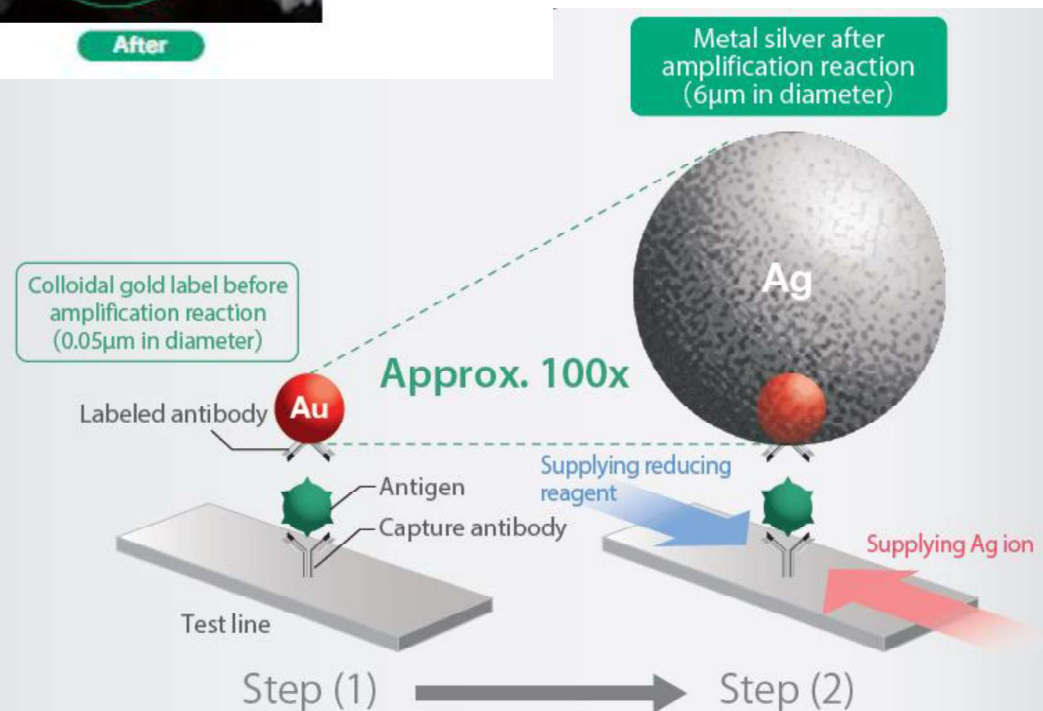
### Features

The immunochromatographic assay was designed based on silver halide photography technology to amplify the size of colloidal gold particles approximately 100-fold.



## High sensitivity detection technology

The immunochromatographic assay was designed based on silver halide photography to amplify the size of gold colloidal particles approximately a 100-fold, leading to the improvement of detection sensitivity. This offers a greater ability to detect even in small amounts of antigen.



# Clinical Evaluation in Yokohama City University in Japan

\*Paper Preprint  
online



**① Positive Percent Agreement (PPA=Sensitivity) is 82.2%.  
No.1 Performance among compared JP/US/EU brands.**

**② Negative Percent Agreement (NPA=Specificity) is 100%.  
Same performance as others.**

FUJIFILM (Japan)		RT-PCR		
		Positive	Negative	Total
YCU-FF	Positive	37	0	37
	Negative	8	63	71
	Total	45	63	108

PPA= 82.2%  
NPA= 100.0%

		RT-PCR		
		Positive	Negative	Total
Abbott	Positive	29	0	29
	Negative	16	45	61
	Total	45	45	90

PPA= 64.4%  
NPA= 100.0%

		RT-PCR		
		Positive	Negative	Total
Roche	Positive	35	0	35
	Negative	10	45	55
	Total	45	45	90

PPA= 77.8%  
NPA= 100.0%

		RT-PCR		
		Positive	Negative	Total
Fujirebio	Positive	33	0	33
	Negative	12	45	57
	Total	45	45	90

PPA= 73.3%  
NPA= 100.0%

# Sensitivity Comparison by PCR CT value

\*Paper Preprint  
online

**FUJIFILM sensitivity is over 70% even in CT value 27-31.**

**\*CT value 27-31  $\Rightarrow$  low virus but still infectious)**



**C**

<b>FUJIFILM</b>	YCU-FF Positive	YCU-FF Negative	Sensitivity/ Specificity
PCR-Positive			
Ct <23	11	0	100.0%
Ct 23-27	18	1	94.7%
Ct 27-31	8	3	72.7%
Ct >31	0	4	0.0%
PCR-Negative	0	45	100.0%

	Roche Positive	Roche Negative	Sensitivity/ Specificity
PCR-Positive			
Ct <23	11	0	100.0%
Ct 23-27	18	1	94.7%
Ct 27-31	6	5	54.5%
Ct >31	0	4	0.0%
PCR-Negative	0	45	100.0%

	Fujirebio Positive	Fujirebio Negative	Sensitivity/ Specificity
PCR-Positive			
Ct <23	11	0	100.0%
Ct 23-27	18	1	94.7%
Ct 27-31	4	7	36.4%
Ct >31	0	4	0.0%
PCR-Negative	0	45	100.0%

	Abbott Positive	Abbott Negative	Sensitivity/ Specificity
PCR-Positive			
Ct <23	11	0	100.0%
Ct 23-27	14	5	73.7%
Ct 27-31	4	7	36.4%
Ct >31	0	4	0.0%
PCR-Negative	0	45	100.0%

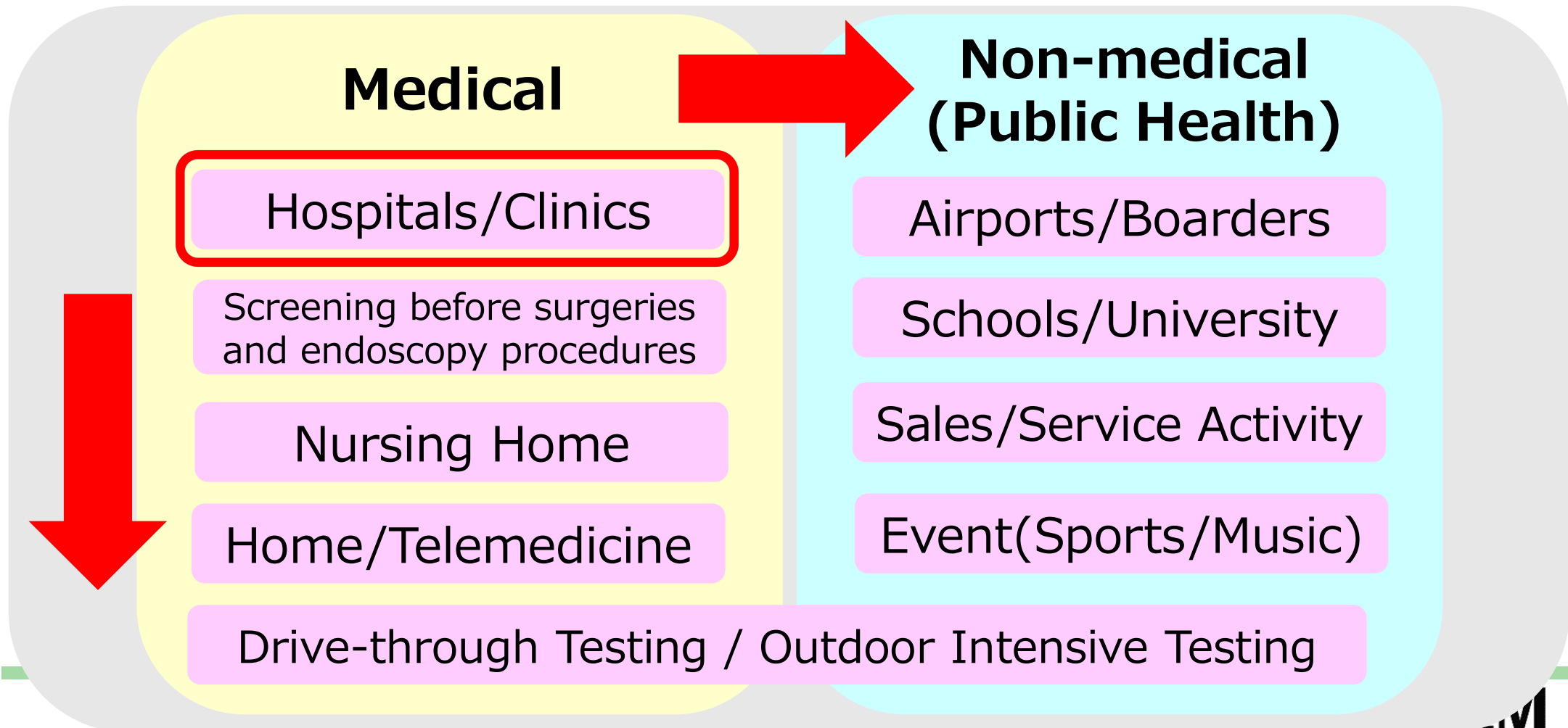
	SD Bio. Positive	SD Bio. Negative	Sensitivity/ Specificity
PCR-Positive			
Ct <23	11	0	100.0%
Ct 23-27	18	1	94.7%
Ct 27-31	6	5	54.5%
Ct >31	0	4	0.0%
PCR-Negative	0	45	100.0%

**(C)** Sensitivity and specificity of indicated SARS-CoV-2 Ag-RDTs in PCR-positive (n=45) and -negative (n=45) specimens in nasopharyngeal swabs.

medRxiv / SARS-CoV-2 antigen rapid diagnostic test enhanced with silver amplification technology

# Various Use Cases

- Broader testing needs outside of hospitals and clinics where normally testing is done. EX, Influenza.
- To meet this demand, Cheap, Fast and Simple Antigen RDT would be better fit over PCR especially for screening purposes.





# Various Use Cases

## Airport/Border Control



## Scale up testing – POCT@Clinic/GP



## School/University



## Scale up testing – Mass Testing



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# Thank you for your attention



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