SARS-CoV-2 antigen detection assays

FIND initiative

SUGGESTED USES FOR Ag- AND Ab-DETECTION RDTs GIVEN OUR CURRENT UNDERSTANDING

- **Ag RDTs** should be prioritized for **case management** to enable decentralized testing, especially when access to PCR testing is limited.

- **Ab RDTs** should be prioritized for **seroprevalence surveys** to inform public health measures and testing of contacts to establish previous spread of the virus.

Suggested use		Ag	Ab
Case management in high prevalence/ active outbreak settings	Triage suspect cases **Positive:** no confirmatory testing required **Negative:** confirmatory testing with PCR recommended, if available	✓	
	Aid diagnosis in symptomatic cases presenting late (≥10 days post-symptom onset) In addition to PCR/Ag, not a replacement		✓
	Monitor active infection	✓	
Public health measures	Screen contacts for infection	✓	
	Screen contacts for previous exposure (≥10 days post exposure)		✓
	Seroprevalence surveys to define levels of population exposure,* including vaccine trial support		✓

* Insufficient data supporting effectiveness of protection or duration of immunity.

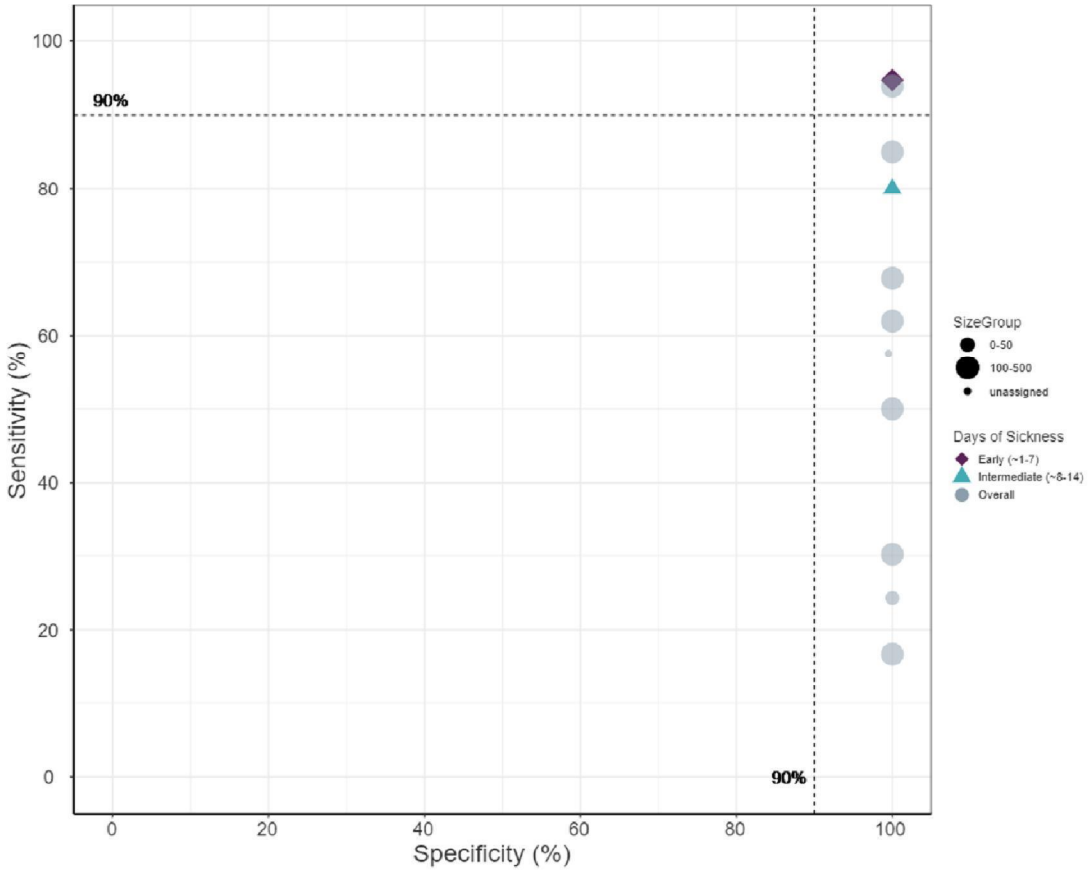
Table 1. Antigen(Ag)-based RDTs undergoing evaluation

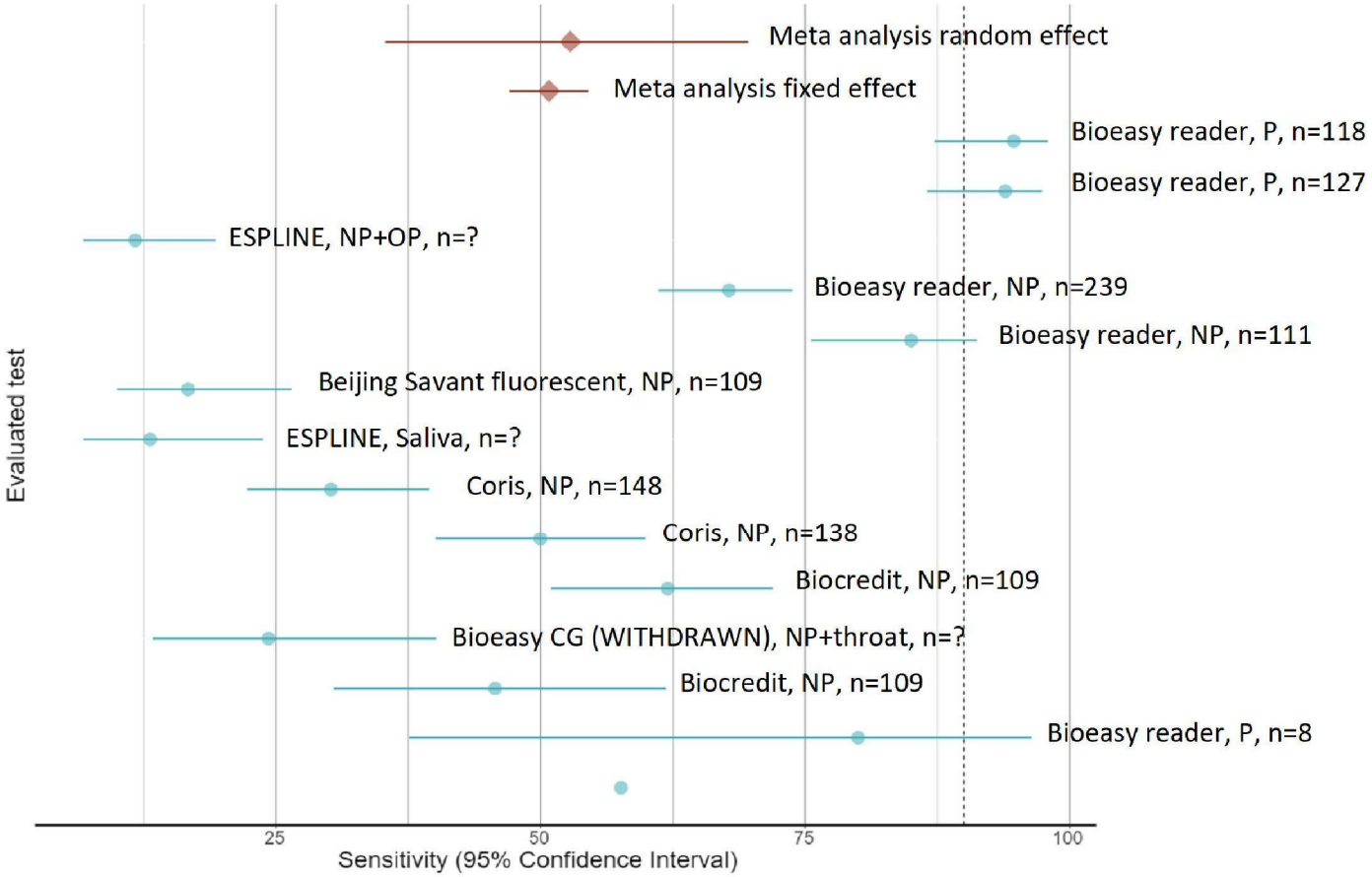
Company	Assay	Country of manufacturer	Interpretation	Regulatory status
Coris BioConcept	COVID-19 Ag Respi-Strip	Belgium	Visual	CE-IVD
RapiGEN, Inc.	BIOCREDIT COVID-19 Ag	Rep. of Korea	Visual	CE-IVD
SD BIOSENSOR, INC.	STANDARD F COVID-19 Ag FIA	Rep. of Korea	Reader	CE-IVD; Brazil
SD BIOSENSOR, INC.	STANDARD Q COVID-19 Ag Test	Rep. of Korea	Visual	CE-IVD; Brazil
Shenzhen Bioeasy Biotechnology Co., Ltd	Bioeasy 2019-nCoV Ag Fluorescence Rapid Test Kit (Time-Resolved Fluorescence) [1]	China	Reader	CE-IVD

[1] This fluorescence-based test is different from the colloidal gold Ag test that was withdrawn by the company.

https://www.finddx.org/wp-content/uploads/2020/04/20200421-COVID-Ag-RDT-Evaluation-Synopsis.pdf

Primary objective(s)	1.1 [Lab Evaluation]To determine the relative analytical sensitivity of COVID-19 antigen RDTs (index test) using contrived specimens: respiratory swab samples spiked with known quantities of cultured viral isolate. 1.2 [Clinical Evaluation] To determine the diagnostic accuracy of COVID-19 antigen RDTs in patients presenting with influenza-like illness using upper respiratory tract specimens compared to gold-standard RT-PCR.
Secondary objective(s)	2.1 [Clinical Evaluation] To determine the association of positive index test results with disease stage (days since symptom onset, e.g. acute, early, late) and symptom severity
Exploratory objective(s)	3.1 [Lab Evaluation] To compare the relative analytical sensitivity of COVID-19 antigen RDTs (index test) using different swab preparation methods of contrived specimens (e.g. fresh swab in proprietary buffer, in UTM and in UTM that is frozen and thawed) 3.2 To assess the feasibility, ease of use of the index test (NP swabs and processing with RDT)

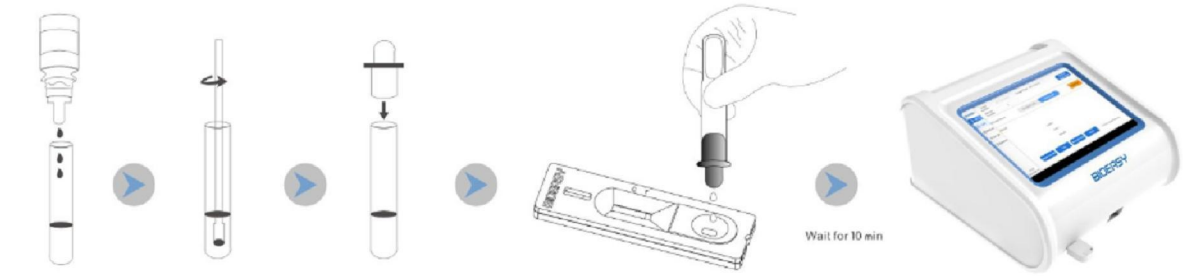

100
80
60
40
20
0
Sensitivity (%)
90%
90%
0
20
40
60
80
100
Specificity (%)
SizeGroup
0-50
100-500
unassigned
Days of Sickness
Early (~1-7)
Intermediate (~8-14)
Overall


Meta analysis random effect
Meta analysis fixed effect
Bioeasy reader, P, n=118
Bioeasy reader, P, n=127
ESPLINE, NP+OP, n=?
Bioeasy reader, NP, n=239
Bioeasy reader, NP, n=111
Beijing Savant fluorescent, NP, n=109
ESPLINE, Saliva, n=?
Coris, NP, n=148
Coris, NP, n=138
Biocredit, NP, n=109
Bioeasy CG (WITHDRAWN), NP+throat, n=?
Biocredit, NP, n=109
Bioeasy reader, P, n=8
Evaluated test
25
50
75
100
Sensitivity (95% Confidence Interval)

BIOEASY

Application: People with close contact of infected patients and people under quarantine control.

Test Procedure



Add 500μL(10 drops) of sample extraction buffer to the tube

Immerse the sample swab into the buffer and fully elute the the sample

Cover with the dripper

Add 100μL (2 drops) of the processed sample into the well

Read the result with Fluorescence Immunoassay Analyzer

Specification

Cat. No.	Product	Format	Specimen	Pack	Qualification
YRLF04401025	Diagnostic Kit for 2019-Novel Coronavirus (2019-nCoV) Ag Test (Fluorescence Immunochromatographic Assay)	Cassette	Nasal swab/Deep sputum	25T	CE