

Biotical SARS-CoV-2 Antigen differentiation



All components included: 25 cassette test, 25 STERILE VALIDATED SAWBS, 25 vials, 1 control, 1 buffer, 1 board-grill



Positive control included in the kit, helping to familiarize with the real looking of a positive result and training



The test can be used in combination with a reader without any adaptative piece **Easy configuration** with a card, for a better data management in/out



INFLUENZA A/B-RSV Compatible: Use the same buffer & sample for perform 4 test with the same sample. qPCR compatible: Use the same mix for RNA purification and confirm with Amplion qPCR (procedure validated)



Different colors in test line and control (green-red) for an easy interpretation



Monoclonal antibody in continuous improvement process: We continue working in differentiate our rapid test of the concurrency, through a high investment in R&D



We produce all critical components in house (Spain) having a full control from the process to the supply to our customers

Biotical SARS-CoV-2 Ag test is one of the most accurate, sensitive and specific Antigen rapid test of the market.

A RELIABLE TEST SUPPORTED BY A STRONG VALIDATION AND CERTIFICATION



ISO 13485 CERTIFIED
MEDICAL DEVICE:
QUALITY MANAGEMENT SYSTEM



- Preliminary validation comparing with qPCR: **439 samples** in 3 validation round vs commercial test (Roche) and/vs qpcr, differentiating viral loads.
- Second Validation in compliance with WHO guidelines for Antigen test usability and validation criteria (28th Sept 2020):

262 samples (28 positive confirmed samples and 234 confirmed negative)

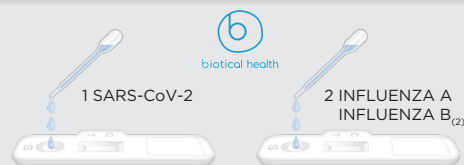
TABLE 08: Ct VALUE VARIATION

	Ct ≤ 25	Ct ≤ 26	Ct ≤ 27	Ct ≤ 28
SENSITIVITY	100,0%	96,3%	92,9%	92,9%
SPECIFICITY	97,9%	99,6%	99,6%	99,6%
ACCURACY	98,1%	99,2%	98,9%	98,9%
PPV	81,5%	96,3%	96,3%	96,3%
NPV	100,0%	99,6%	99,1%	99,1%

Validation performed with different viral load measured with qPCR

BIOTICAL RAPID TEST - 1 sample, 4 diagnostic test

3 possible antigen rapid test with the same sample!⁽¹⁾

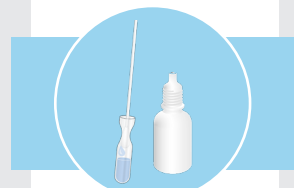


- SARS-CoV-2 Antigen
- INFLUENZA A & INFLUENZA B Ag
- RSVAg

⁽¹⁾ Other configuration options: Gastrointestinal & parasites

⁽²⁾ Biotical Influenza A/B antigen test differentiate both viruses in the same strip

1



Use the same sample for test other respiratory virus

Mix ready for qPCR purification



- Compatible with full line of Amplion qPCR, including SARS-CoV-2 (procedure validated)