
BOSON
BIOTECH
IVD
Rapid 2019-nCoV IgG/IgM Combo
Catalog Number REF 1N38C2
An immunochromatographic assay for the rapid visual detection of IgG and IgM antibodies to 2019 novel coronavirus (2019-nCoV) in human serum,plasma or whole blood
Contents Of Kit:
2019-nCoV IgG/IgM Combo Test Card 25ea
Sample Buffer 1ea
Capillary Pipet 26ea
Instructions For Use 1ea
4 - 30°C
LOT H20031301
2022-03
Σ 25
EC REP
Lotus NL B.V.
Koningin Julianaplein 10,
1e Verd, 2595AA, The Hague, Netherlands.

4. Handle all specimens as potentially infectious.
5. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material. When the assay procedure is completed, dispose specimens after autoclaving at 121° C for at least 20 min or treating with 0.5% Sodium Hypochlorite for 1-2 hours.

SPECIMEN COLLECTION AND PREPARATION

1. The serum or plasma specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. Patient samples have the best performance when tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the assay is not performed immediately, serum or plasma specimens may be refrigerated at 2-8°C up to 3 days. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods. Allow sample to reach room temperature before proceeding.
4. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

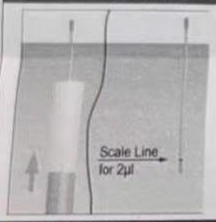
QUALITY CONTROL

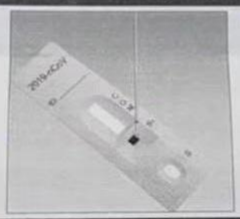
1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

PROCEDURE

1	Bring the kit components to room temperature before testing.
2	Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3	Label the test card with patient identity.

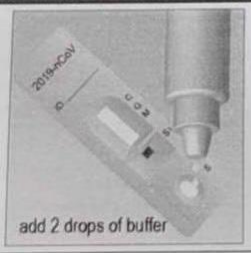
4





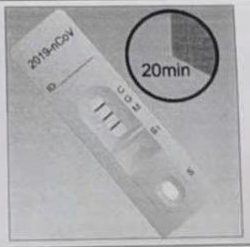
Withdraw the blood specimen with the capillary pipet provided, gently squeeze out the extra specimen to leave 2µL in the pipet as marked with the scale line. Apply 2µL of blood specimen to the "S1" area as marked.

5



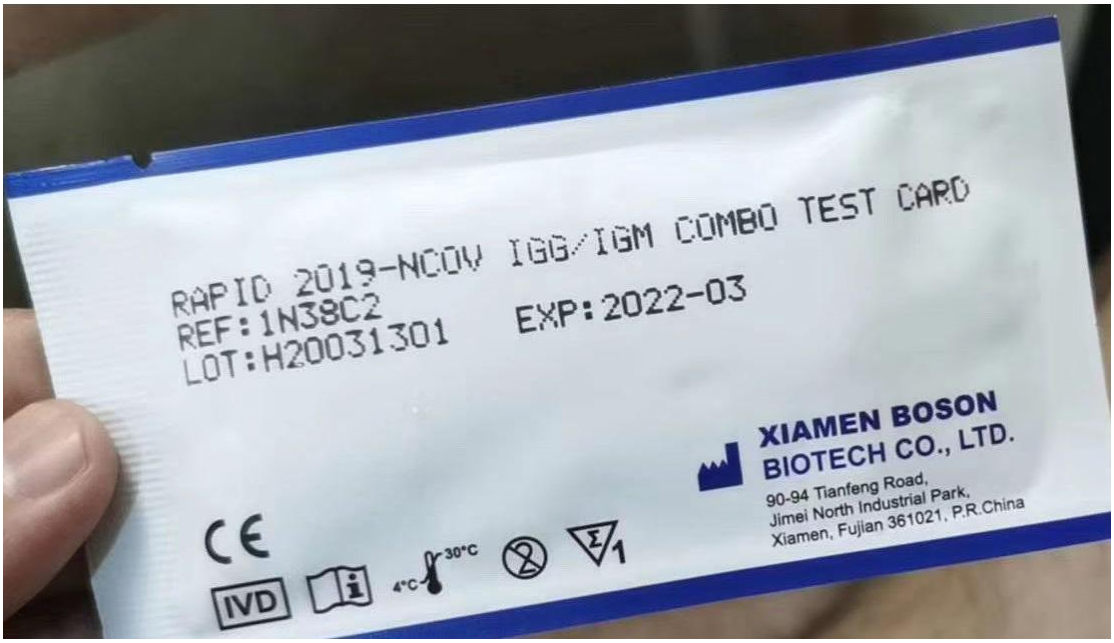
Add 2 drops of sample buffer (approximately 80-100µL) to well marked as "**S**".

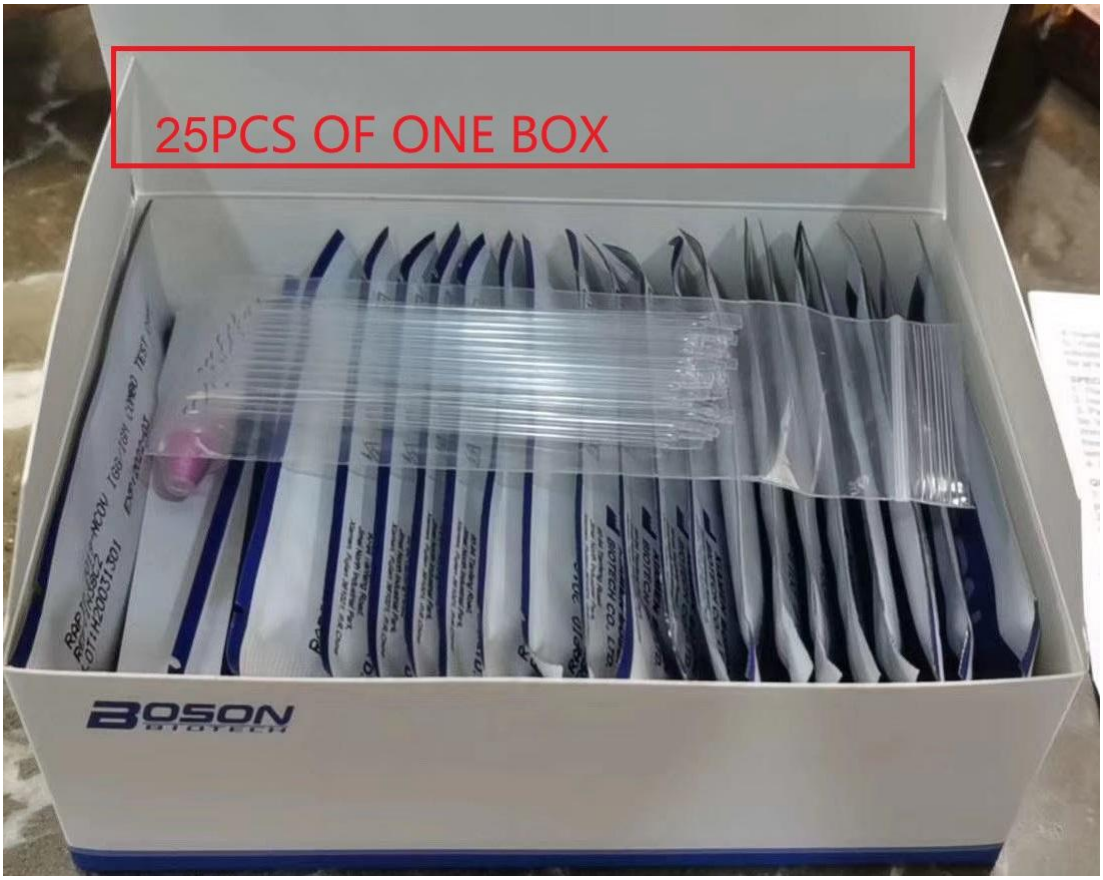
6



Read the result at 15 minutes. A strong positive sample may show result earlier.

Note: Results after 20 minutes may not be accurate.


RAPID 2019-NCOV IGG/IGM COMBO TEST CARD
REF:1N38C2
LOT:H20031301
EXP:2022-03
XIAMEN BOSON
BIOTECH CO., LTD.
90-94 Tianfeng Road,
Jimei North Industrial Park,
Xiamen, Fujian 361021, P.R.China
IVD
4°C
30°C
Σ 1


25PCS OF ONE BOX
BOSON