Instructions for Use

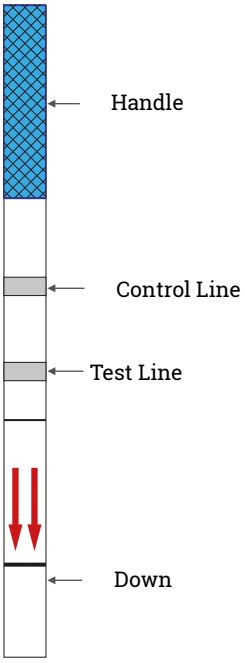
I. INTRODUCTION

The Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) responsible for the Coronavirus disease 2019 (COVID-19) first emerged in December 2019 in China. The emergence of the new SARS-CoV-2 coronavirus and its rapid dissemination in all continents has led to high concern at the local and international health authorities level, in the scientific community and in the media and population. As of 11 March 2020, WHO declare the disease as a pandemic. SARS-CoV-2 cause diseases of the respiratory tract leading to severe pneumonia in fragile patients, with most of the fatal cases in the elderly population. In the absence of vaccine and specific treatment, the containment of the epidemics rely also on rapid identification and disinfection of potentially contaminated surfaces. This strategy is based on the availability of rapid detection test to be performed on site. The detection of the antigen are the most suitable tests for traces detection of the virus.

The kit is designed for hygiene monitoring of environmental surfaces or research use
It is based on the detection of a specific antigen: the SARS-CoV-2 nucleocapsid protein (NP). It is not intended to determine if the virus is infectious. Not for diagnostic use

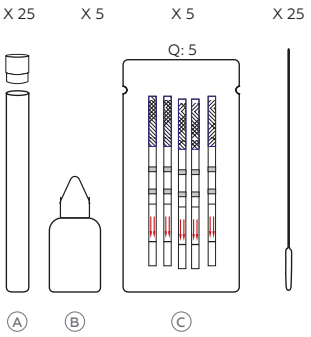
II. PRINCIPLE OF THE TEST

This test is ready to use and is based on a membrane technology with colloidal gold nanoparticles. A nitrocellulose membrane is sensitized with monoclonal antibodies directed against SARS-CoV-2 highly conserved nucleoprotein antigen. Another monoclonal antibody is conjugated to colloidal gold nanoparticles. The conjugate is immobilized on a membrane. This test is aimed to the detection of SARS-CoV-2 collected in swabs. When the swab sample extracted solution comes into contact with the strip, the solubilised conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-SARS antibody adsorbed onto the nitrocellulose strip. If the sample contains SARS-CoV-2, the conjugate–SARS-CoV complex will remain bound to the anti-SARS-CoV-2 antibody immobilized onto the nitrocellulose. The result is visible within 15 minutes in the form of a red line that develops on the strip. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.



III. REAGENTS AND MATERIALS

1. COV-Hygien Xpress strips.
   The strips come in pouches of 5 strips with a desiccant.
2. Dilution buffer (3,5 mL). Saline solution buffered to
   pH 7.5 containing Tris, EDTA, NaN3 (<0,1%) (x5)
3. The tubes, swabs and stoppers come in zip-locked
   plastic bags
4. Cardboard tube holder(s)
5. Labels & marker* (*in SARS SWB 05 only)



IV. SPECIAL PRECAUTIONS

- Avoid touching nitrocellulose with your fingers.
- Wipe the sampled surfaces after testing, to remove traces of buffer
- Never use reagents from another kit
- If strips are stored in a container, the container must be resealed as soon as the necessary number of strips for the operation has been removed, as the strips are sensitive to humidity. Make sure that the desiccant bag is present.
- Light green lines indicate immunoreagents adsorption sites. Green colour disappears during the test
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.
- To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line indicated under the arrows printed on the sticker.

V. WASTE DISPOSAL

Dispose of in accordance with biosecurity legislation.
Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

VI. STORAGE

- An unopened kit may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging.
- The strips remain stable for 15 weeks after pouch opening if they are kept closed at between 4 and 30°C and in a dry environment.
- Avoid freezing strips and buffer.

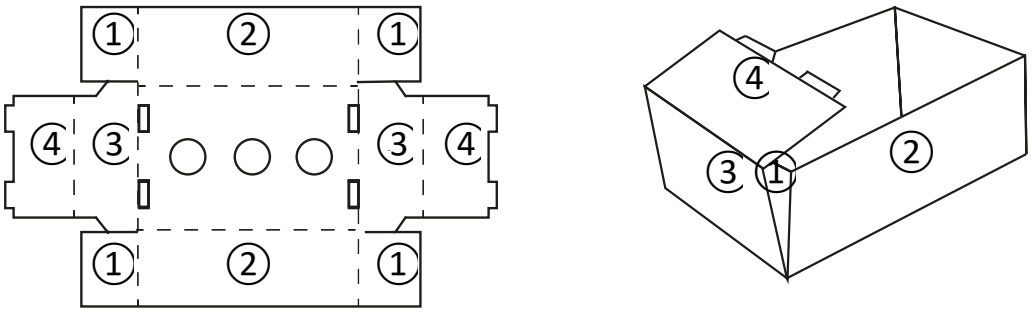
VII. SAMPLES HANDLING AND COLLECTION

Samples to be tested should be obtained and handled by standard methods for the collection of environmental sample swabs. Samples must be tested as soon as possible after collection.
Using of Flocked or Foam Swabs is recommended, although other other swabs for analytical sampling may be used.
Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

VIII. PROCEDURE

PREPARATIONS OF THE TEST

Fold rack as shown



Allow kit components, in unopened packaging, and sample to reach room temperature (15-30°C) before performing a test. Once opened, run the test immediately.

- Indicate a unique test identification (UDI) on a label. Place the label on the upper part of the tube. The label must be positioned such that the control and test lines remain visible when the strip is inserted in the tube
- Record the UDI, date, time and the location name or number. Place the marked test tube in a rack.

SPECIMEN PREPARATION PROCEDURE FOR SURFACE SAMPLING

- Add 15 drops (about 320 µL) of the buffer in the tube
- Immerse the swab in the tube to get it moisten by the buffer
- Wring the swab tip to remove excess buffer: pull the swab out of the buffer 2/3 of the way up the tube, gently apply the tip against the tube inner wall, and rotate the tip against the surface. No buffer droplet should hang from the tip before swabbing.
- Pass the swab on the surface to be tested
- Immerse again the swab in the tube.
  Shake the tube back and forth 10 times, stir the swab and squeeze it against the tube wall to maximize the sample extraction
- Discard the swab according to biosecurity requirements.
- Wipe the sampled surfaces after testing, to remove traces of buffer
- Insert one strip COV-Hygien Xpress strip, arrows down. Start timing, for 15 minutes.
- Positive results may be reported sooner the moment the test and control lines become visible.
- Do not take the appearance of new lines into account after 30’ reaction time is passed.
- The result must be read on still wet strip.
- After reading, discard the tube with the strip according to biosecurity requirements.

SPECIMEN PREPARATION PROCEDURE FOR LIQUID SAMPLES

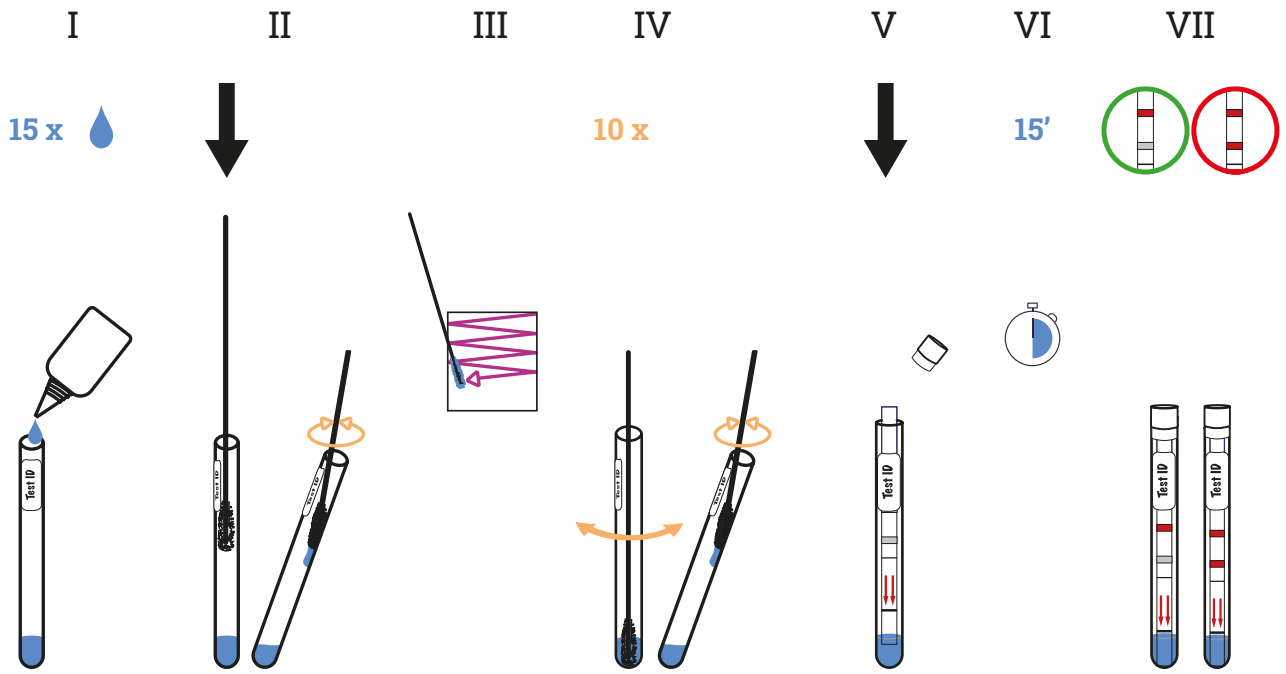
For research use, where the sample is in a liquid format.

- Insert 100µl of the sample in the tube

- Insert 100µl of the Cov-Hygien Xpress buffer to the tube
- Vortex or shake the tube back and forth 10 times
- Discard the used components according to biosecurity requirements.
- Insert one strip COV-Hygien Xpress strip, arrows down. Start timing, for 15 minutes.
- Positive results may be reported sooner the moment the test and control lines become visible.
- Do not take the appearance of new lines into account after 30' reaction time is passed.
- The result must be read on still wet strip.
- After reading, discard the tube with the strip according to biosecurity requirements.

Note: not recommended for viscous samples or samples with high salt concentrations since these characteristics may interfere with the test.

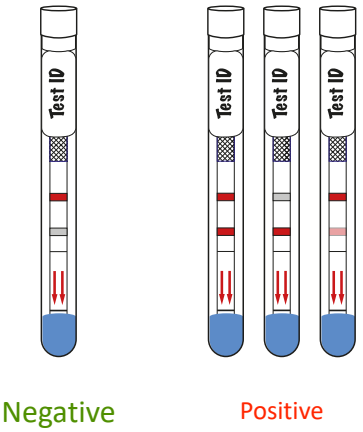
PROTOCOL DIAGRAM



IX. INTERPRETING RESULTS

The results are to be interpreted as follows:

- Negative test result: a reddish-purple line appears at the Control line (C) position (upper line). No other band is present.
- Positive test result: a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens found in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result. In addition, a reddish-purple band at the Control line (C) appears or not (see caution).
- Invalid test result: The absence of a Control line indicates a failure in the test procedure. Any reddish-



purple line (C), even weak, should be considered as valid.

Caution: The control line indicates that the migration occurred up to the top of the strip. It validates a negative result. In case of a strong positive result, the control line may not appear. Nevertheless if the test line is positive it should be regarded as a real positive.

Note: a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.

X. PERFORMANCE

The Limit Of Detection will vary primarily with the surface type and sampling technique and secondarily with the protein or virus source
• Viral detectability after sampling: down to 5 10^3 pfu/mL
• Recombinant protein detectability after sampling: down to 0,3 ng/mL

No cross-reaction with the following viruses: Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), Respiratory Adenovirus, Parainfluenza, Rhinovirus, Metapneumovirus, Enterovirus, Coronavirus HKU1, Coronavirus OC43, Coronavirus 229E, Coronavirus NL63

XI. LIMITS OF THE KIT

The test is qualitative and cannot predict the quantity of antigens present in the sample.

A positive test does not rule out the possibility that other viral or bacterial pathogens may be present.

XII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem or if performances do not correspond with those indicated in this package insert:
1. Record the kit batch number
2. If possible, keep the sample in the freezer during the complaint management
3. Contact BioMire (contact@biomire.solutions) or your local distributor