

Product Description

COV-Hygien Xpress On-Site Detection Kit for surfaces

Intended Use

The kit is designed for hygiene monitoring of environmental surfaces
 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

Performance evaluations

Kit performances will vary primarily with the type of surface that is sampled and to a lesser extent with the swabbing technique.

The data presented hereafter is a compilation of independent evaluations intended to provide indications of the detections limits achievable with the COV-Hygien kits.

Complete kit

The kit performances were evaluated by swabbing deposits of recombinant NP which was obtained lyophilized, then rehydrated in water.

Kits were used according to manufacturer’s instructions

Table 1: summary of evaluation results

(*)	Stainless Steel	Plastic	Wood	Glass/Ceramic
Evaluation 1	0,6 ng	0,3 ng	0,6 ng	–
Evaluation 2	2 ng	2 ng	> 2 ng	2 ng
Evaluation 3	0,54 ng	0,27 ng	0,54 ng	–
Evaluation 4	< 1 ng	< 1 ng	–	< 1 ng

*The Evaluation reports are available for download : [coronavirus-diy-detection-on-surfaces](https://www.biomire.com/coronavirus-diy-detection-on-surfaces)

Unless otherwise indicated, all strip results presented hereafter were obtained after sampling of 25 cm² (4 sq inch) and were interpreted by observation after 15 minutes of reaction. Observed limits of detection are expressed in ng of protein per 10µL of deposit.

Detection strip

During the development phase, the performances of the strips were evaluated after 100µL of prepared samples were diluted with 100µL of COV-Hygien buffer prior to immuno-detection with the strips.

Limits:

- Protein detection: results may vary with recombinant protein sequence, expression system, purification and storage
- Virus detection : results may vary with cell line infected, culture media composition and in particular the presence of serum, as well as lysis conditions

Protein detection

Preparation

During the development phase, the analytical performance was performed on 2-fold serial dilutions of recNP-2. The limit of detection (LOD) was defined as the last dilution that tested positive (15 tests, 2 independent readers)

Performance

The assay was shown to have a detection level down to 250 pg/mL.

Virus detection

Preparation

SARS-CoV-2 passage 3 (SARS-CoV-2-Iso_01-Human-2020-02-07-Swe, accession no/GenBank no. MT093571) was cultured on Vero E6 cells. The titer was determined using a plaque assay, with a fixation of cells at 72 hpi. All experiments involving isolates of SARS-CoV-2 were performed at the Biosafety Level 3 Laboratory at the Public Health Agency of Sweden (Folkhälsomyndigheten, Stockholm, Sweden).

During the development phase, the analytical performance of the assay was performed using a 2-fold serial dilution of the virus (in viral culture medium) in parallel with titrating the same virus preparation on Vero E6 cells (by plaque assay)

Performance

The assay was shown to have a detection level down to 5×10^3 pfu/mL,

Specificity

Cross-reactivity other viruses was evaluated with nasopharyngeal samples and/or from virus culture supernatants.

The results are presented hereafter

Table 2: Immuno-detection strip specificity

Viruses	Result	Bacteria	Result
Influenza A	neg	Acinetobacter baumannii	neg
Influenza B	neg	Haemophilus influenzae	neg
Respiratory Syncytial Virus (RSV)	neg	Klebsiella pneumoniae	neg
Respiratory Adenovirus	neg	Legionella pneumophila	neg
Parainfluenza	neg	Moraxella catarrhalis	neg
Rhinovirus	neg	Mycoplasma pneumoniae	neg
Metapneumovirus	neg	Nocardia asteroides	neg
Enterovirus	neg	Pseudomonas aeruginosa	neg
Coronavirus HKU1	neg	Staphylococcus aureus	neg*
Coronavirus OC43	neg	Streptococcus pneumoniae	neg
Coronavirus 229E	neg	Streptococcus pyogenes	neg
Coronavirus NL63	neg		
Coronavirus SARS-CoV	pos	Fungus	Result
Coronavirus SARS-CoV-2	pos	Aspergillus niger	neg

*Staphylococcus aureus was found positive at high bacteria concentrations (10e9 cfu/mL).
No false-positive results were obtained when testing samples from known S. aureus infected individuals.

Remarks:

The detection of SARS-CoV virus on surfaces is dependent on the surface characteristics and swabbing technique. In particular recovery of viral proteins by swabbing porous or absorbant surfaces such a raw wood, paper or cloth may be significantly lower than for hard and smooth surfaces such as plastic, glass or metal.

Observations after 30' of reaction result in test lines slightly more intense when protein concentration is close to the LOD, which may facilitate interpretation.

Evaluations suggests that results may be improved by applying the following 3 step swabbing technique:

1. Dampen the area to control with buffer imprignateg swab in one direction, wait 10 seconds
2. Rotate swab 1/3 of a turn and swab in a direction 90° to the first one
3. Rotate swab 1/3 of a turn and swab in a direction 45° to the first 2 directions

Evaluation suggests an alternative 2 step technique for swab preparation, which is applicable and some user may prefer:

1. Soak the swab tip in 3 drops of buffer in a clean tube. Swab the control surface(s)
2. Insert 12 drop in the tube, dip the swab tip and shake to re-suspend the deposit

References:

- Evaluation 1: [Evaluation of COV-Hygien Xpress On-SiteDetection Kit](#) - CHROMagar
- Evaluation 2: [Study of the use of a new immunochromatographic test strip for Detection on surfaces of protein specific to CORONAVIRUS SARS-CoV-2](#) - QSA Conseil
- Evaluation 3: [COV-Hygien Xpress Swabs](#) - CHROMagar
- Evaluation 4: - [Viral detection testing for surfaces](#) - Hylabs
- Study 1: Front. Med., 08 May 2020 ; <https://doi.org/10.3389/fmed.2020.00225>
- Study 2: Journal of Clinical Microbiology Jun 2020, JCM.00977-20; DOI: [10.1128/JCM.00977-20](https://doi.org/10.1128/JCM.00977-20)