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

Unless otherwise indicated, all strip results presented hereafter were obtained after sampling of 25 cm^2 (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
Influenza A	neg
Influenza B	neg
Respiratory Syncytial Virus (RSV)	neg
Respiratory Adenovirus	neg
Parainfluenza	neg
Rhinovirus	neg
Metapneumovirus	neg
Enterovirus	neg
Coronavirus HKU1	neg
Coronavirus OC43	neg
Coronavirus 229E	neg
Coronavirus NL63	neg
Coronavirus SARS-CoV	pos
Coronavirus SARS-CoV-2	pos

Bacteria	Result
Acinetobacter baumannii	neg
Haemophilus influenzae	neg
Klebsiella pneumoniae	neg
Legionella pneumophila	neg
Moraxella catarrhalis	neg
Mycoplasma pneumoniae	neg
Nocardia asteroides	neg
Pseudomonas aeruginosa	neg
Staphylococcus aureus	neg*
Streptococcus pneumoniae	neg
Streptococcus pyogenes	neg

Fungus	Result
Aspergillus niger	neg

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 higher 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 immunochromatrographic 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