Introduction

The COV-Hygien Xpress kits are intended for use in hygiene monitoring applications for the detection of SARS-CoV 2 proteins on surfaces, after sanitation to monitor the procedure effectiveness and/or prior to sanitation as a rapid screening method.

In most screening situations, high-touch surfaces such as smartphones, office equipment and furniture, handles etc. most of the test results are expected to be negative.
After cleaning and disinfection, test results are expected to be systematically negative.

As a consequence of such a high percentage of negative results, it may be necessary and is recommended to check from time to time that the kits and testing technique are effective in detecting the virus antigen.

This note introduces the use of COV-Hygien Xpress Control Protein as a positive control for the verification of the detection strips, the swabbing and the hygiene test protocol.

Application Description

The use of Control Protein with COV-Hygien Xpress On-Site Detection Kit serves the following purposes:

- Training: to familiarize users with positive results
- Verification: to check the detection strip or the complete kits perform correctly
- Spiking: to assess the technique Limit-Of-Detection (LOD) for a given surface and swabbing technique

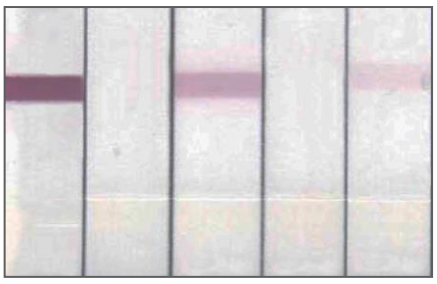
This document is designed to facilitate the verification that the kit and sampling technique are effective and may provide general guidance but does not constitute a Quality Control Procedure.
Not for diagnostic use

Necessary Material

- COV-Hygien Xpress kits for surfaces
- COV-Hygien Xpress Control Protein
  Each vial contains approximatively 20 ng Protein (the control proteins are produced by genetically modified microorganisms and are not from viral origin)
- A micropipette for dispensing 100µl of liquid
- Chlorine-free water such as purified, ultrapure or mineral bottled water
- COV-Hygien Xpress Instructions For Use (available in 6 languages here)

Markers

- The recommended sample volume for a COV-Hygien Xpress test is 250µl per tube, with a minimum per tube of 120µl
- Dependent on the volume of re-dissolution, one vial provides the necessary amount of protein for 1-2 strong, 2-4 medium, 4-8 weak positive results.
- The reading is recommended after 30 minutes because the signals are then more stable, which facilitates the comparison between results.



Strong, Medium and Weak Positive results

Protein reconstitution protocols

Preparation of the protein

- Set the re-suspension volume at 300-350 µl, which results in a protein concentration of 60ng/ml (or adjust to your specific study objective with re-suspension with 250µl - 1 000µl)
- Add that volume of water to one vial
- Close the vial and shake gently until the micro pellet of protein is dissolved
- The resulting solution concentration in Control Protein is approximatively 20 - 80 ng/ml

Verification of strips

Follow the general instruction provided in the kit I.F.U and in section VIII, the chapter « SPECIMEN PREPARATION PROCEDURE FOR LIQUID SAMPLES »

- Replace « 100µl of sample » by 100µl of reconstituted Control Protein
- Proceed with the detection as indicated in the I.F.U
- A strong test line should be visible after 30 minutes

Verification of kits

Follow the general instruction provided in the kit I.F.U and in section VIII, the chapter « SPECIMEN PREPARATION PROCEDURE FOR SURFACE SAMPLING », modified as follows:

- In a COV-Hygien Xpress tube, insert 10 drops of buffer
- Immerse a COV-Hygien Xpress swab tip entirely in reconstituted Control Protein
- Transfer the swab to the tube containing 10 drops of buffer
- Shake gently & wring the swab tip on the tube edge. Repeat 2 more times
- Proceed with the detection as indicated in the I.F.U
- A clear test line should be visible after 30 minutes

Surface spiking: verification of the overall technique

Spiking may be useful for:

- Training, to demonstrate positive results, to practice sampling from surfaces such as smartphones, bank notes, control panels etc., to practice identifying contaminated objects randomly mixed with non-contaminated objects
- To approach the Limit-Of-Detection of the kits on a given surface, for a given sampling pattern
- To support cleaning and sanitation efficacy

Recovery of deposits from a surface depends primarily on the surface material (metal and raw wood, smooth or rough surfaces are more or less amenable to swabbing).
Recovery also depends on the swabbed surface, swabbing pattern (linear or an area) and swabbing technique.
The following indications may need to be adjusted after observation of initial results.

Protein deposits

- For a strong signal, take 100µl of protein at 60 ng/ml with the pipette. For an average signal take 50µl of protein at 60 ng/ml with the pipette.
- Place the protein in approximatively ten droplets and until the pipette tip is empty, on a 5x5 cm (2 x 2 inch) surface
- Spread the droplets on the surface using the pipette tip
- Leave to dry (between 30 and 60 minutes)
- Proceed with the detection as indicated in the I.F.U

Surface spiking: monitoring virus decay

Surface spiking may be used to indicate the long lasting effect of special virucidal material, coating or treatments on-site.

However, it should be noted that a technology may be very effective in destroying viruses yet not have much effect on the virus proteins. In this case the test results may appear similar before and after treatment and not reflect the performance of the decontamination technology that is deployed.

As an example, a protocol suggestion that can be completed with 1 box of 25 kits and 3 vials of Control Protein is shown below.

	Reference surface		Anti-viral surface	
	« High » concentration of protein	« Average » protein concentration	« High » concentration of protein	« Average » protein concentration
T0: as soon as the deposit is dry	Comparable results, preferably all positive			
T1: after 4 hours of contact	Small decrease expected		Sharp decline expected (weaker or no signal)	
T2: after 12-24 hours of contact	Small decrease expected		Sharp decline expected (weaker or no signal)	
T0-T2 & each duplicate result = 24 tests or T0-T1 & each result in triplicate = 24 tests or T0-T1 & 3 protein concentrations = 24 tests				