INSTRUCTION FOR USE

SENSI*Swab* kit

(Cat. nr. HU0030101 / HU0030102)

Swabbing Kit for the Application in Surface Contamination and Cleaning Control Monitoring

1. GENERAL INFORMATION

The **SENSI*Swab*** kit is an additional product to support monitoring surface contamination and cleaning control. It is especially designed and validated for the application of **SENSI*Spec*** and **SENSI*Strip*** test kits.
This instruction for use applies to the single kit for 5 swab tests (**Cat. nr. HU0030101**) or 10 x single kit for 50 swab tests (**Cat. nr. HU0030102**). Besides, the quantity all components and procedures are identical.

2. KIT CONTENTS

The kit contains consumables and reagents for modules of 5 or 10 x 5 tests. They have to be stored at 2-30°C. Expiry data are found on the labels of the bottles and the outer package.
Note: There is another expiry printed on the peel pouch of the swab. This refers to the sterility property of the devices which is not required for this application. Thus, this information must not be considered relevant.
Each module contains the following consumables and reagents:

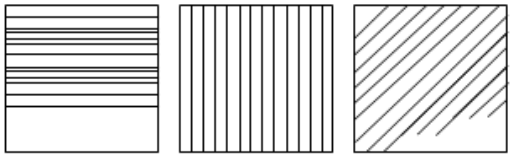
1) Swabs with break off tips, 5 pcs., individually packed.
2) Sample tubes and caps, 5 pcs.
3) Swabbing solution, 10 mL in dropper bottle, ready-to-use.

3. SWABBING PROCEDURE

Depending on the user's requirements either one of the following procedures can be applied.

DRY SURFACES → SEND SAMPLE TO AN EXTERNAL LAB

1) Mark out a 5x5 cm area or use swab directly on (e.g. uneven) area.
2) Moisten the swab with 5 drops of swabbing solution.
3) Swab marked area by using crosshatch (1. horizontally, 2. vertically, 3. diagonally) technique while rotating the tip.



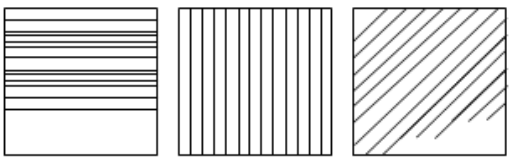
4) Place the swab into the tube and break off the tip.
5) Close the sample tube with cap tightly, label and send it to the lab.

WET SURFACES → SEND SAMPLE TO EXTERNAL LAB

Apply same method as described for dry surfaces, **without** prior need to moisten the swab.

DRY SURFACES → IN-HOUSE TESTING

1) Mark out a 5x5 cm area or use swab directly on (e.g. uneven) area.
2) Fill 1 mL swabbing solution into a sample tube using the dropper bottle.
   Note: Swabbing is only a qualitative or semi-quantitative method. Thus, using the tube's scale is sufficient.
   In case it is intended for **SENSI*Spec* ELISA**, use the respective sample buffer when available to receive most reliable results. For qualitative or semi-quantitative results, the provided swabbing solution is totally suitable.
3) Moisten the swab by dipping into the tube.
4) Swab the marked area by using crosshatch (1. horizontally, 2. vertically, 3. diagonally) technique while rotating the tip.



5) Place the swab into the tube and break off the tip.
6) Close the sample tube with cap completely to avoid any spillage.
7) Shake for 1 minute to release the sample from the swab.

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WET SURFACES → IN-HOUSE TESTING

Apply same method as described for dry surfaces, **without** prior need to moisten the swab.

4. ASSAY PROCEDURE

SENSI*Swab* kits are optimized for the use with Eurofins Technologies **SENSI*Spec* ELISA** or **SENSI*Strip* LFD** tests kits.
For use with ELISA test kits use 100 µL prepared sample according to the test kit instructions. For LFD apply dropper to the sample tube and add 300 µL into the incubation vial. Run the test according to the test kit instructions. As swabs can be used with multiple tests detecting various proteins, it is recommended to test within 4 hours to secure protein stability. For long term storage up to one week keep samples frozen at -20°C. Anyway, when shipping is intended (e.g. to a service lab) it is recommended to validate shipping conditions for the specific application.

5. LIABILITY

Gold Standard Diagnostics Budapest shall not be liable for any damages to the customer caused by the improper use of the kit and for any action undertaken as a consequence of results.
Gold Standard Diagnostics Budapest shall not be liable for the unsafe use of the kit out of the current European safety regulations.