INSTRUCTION FOR USE

SENSI*Strip* Total Soy Protein 20/5 Tests

(Cat. nr. HU0030132/HU0030172)

Lateral-flow Device for the Determination of Soy Protein in Food and as Cleaning Control Monitoring

Sensitivity for food matrix	2.5 ppm
Sensitivity for swabbing	0.007 µg/cm^2
Sensitivity for rinse water	0.33 mg/L

1. GENERAL INFORMATION

Soy (Glycine max) belongs to the legumes. With 39% the fraction of proteins in soybeans is very high. Many of these proteins are known for being allergenic, such as Gly m1, Glycinin, Kunitz-Trypsin-Inhibitor and Gly m4 which are known to be cross-reactive to birch pollen allergen Bet v1. For this reason, soy represents an important food allergen. For soy allergic persons, hidden soy allergens in food are a critical problem. Already very low amounts of soy can cause allergic reactions, which may lead to anaphylactic shock in severe cases. Because of this, soy allergic persons must strictly avoid the consumption of soy or soy containing food. Partly undeclared addition of soy as an additive in many foods is of particular importance. Cross-contaminations, mostly as a consequence of the production process, represents another problem. The chocolate production process is a representative example. For this reason, sensitive detection systems for soy residues in foodstuffs are required. Soy represents a food which may exist in multiple conditions and processing states. This has to be covered by the analytical method.
The **SENSI*Strip* Total Soy Protein Lateral Flow Device** represents a sensitive detection system and is particularly capable of detecting soy protein residues in food matrices, rinse water and swabs.

2. PRINCIPLE OF THE TEST

The **SENSI*Strip* Total Soy Protein** test is based on the principle of immunoassay. Soy protein containing sample is given into a reaction vial containing an activation reagent. After 3 minutes incubation at room temperature a test strip is placed into the reaction vial. The sample migrates along the nitrocellulose membrane by capillary forces. Along its way it releases gold nanoparticles conjugated to anti-soy-antibodies. For positive samples a red line is formed when the liquid reaches the test line area. In case of negative samples, no line is formed. In any case, above the test line area a red control line appears, indicating the validity of the test. The test is evaluated after another 5 minutes.

3. PRECAUTIONS

Full compliance of the following good laboratory practices (GLP) will determine the reliability of the results:

1) Store the kit at 2-8°C.
2) Do not use the kit after its expiry date.
3) Prior to beginning the assay procedure, bring all samples and reagents to room temperature (20-25°C).
4) Extraction buffer should be mixed by gentle inversion or swirling prior to use. Do not induce foaming.
5) Once the assay has been started, all subsequent steps should be completed without interruption and within the recommended time limits.
6) Replace caps in all the reagents and samples immediately after use.
7) Use separate disposable consumables for each transfer of sample to the reaction vial in order to prevent cross-contamination.
8) Do not mix components from different batches.
9) Do not use reagents after the expiration date.

NOTE: The swab sampling device included in this kit may be supplied as sterile with a sterility expiration date printed on the device. However, this kit does not require a sterile sampling device, there-fore the swab sterility expiration date does not affect the kit expiration date and can be disregarded.

4. KIT CONTENTS

The kit contains components and reagents for 20 tests or 5 tests. They have to be stored at 2-8°C. Expiry dates are printed on the labels of the reagent containers and the outer package.

Gold Standard Diagnostics Budapest Kft.
Fóti út 56 A Ép., Budapest, Hungary
https://www.goldstandarddiagnostics.com/contacts

Content	20-strip	5-strip
Test Strips, in tube with desiccant stopper	20 pcs	5 pcs
Reaction vials	20 pcs	5 pcs
Extraction tubes with caps	20 pcs	5 pcs
Extraction Buffer, 60 mL, ready-to-use.	1 pcs	1 pcs
Disposable Pipettes, 0.3 mL	21 pcs	6 pcs
Disposable Pipette, 3 mL	1 pcs	1 pcs
Disposable Spatulas	20 pcs	5 pcs
Swab Sticks	20 pcs	5 pcs
Evaluation Card	1 pcs	1 pcs
Tubes and vials racks	by kit box	by kit box
QR-Code for evaluation with RapidScan ST5 lateral flow strip reader	1 pcs	1 pcs

5. EQUIPMENT AND MATERIALS (NOT PROVIDED)

1) *RapidScan ST5* lateral flow reader for quantitative evaluation (optional)

6. SAMPLE PREPARATION

Due to the high risk of cross-contamination, all applied instruments like applicator, mortar, vials etc. have to be **cleaned thoroughly** before and after each sample. Allergen proteins adhere very strongly to different surfaces. In certain cases, they can resist common dishwasher cleaning. To identify possible cross-contamination caused by previous extractions it is strongly recommended to note the sequence of the extractions for pattern recognition.

Chocolate and other products with high polyphenol content tend to show reduced results. To overcome this effect a special extraction additive can be ordered separately (HU0030100).

6.1 Solid samples / Liquid samples

1) Homogenize the sample using appropriate methods depending on its specific nature (e.g. grind, crush, mix).
2) *Solid samples:* Transfer one spatula of the sample to an extraction tube. Alternatively, in order to increase precision, weigh out 0.2 g of sample into an extraction tube.
   Liquid samples: Transfer a half spatula of sample liquid to the extraction tube. Alternatively, in order to increase precision, pipette 0.2 mL of sample into an extraction.
3) Add 3 mL of ready-to-use extraction buffer to the sample by using the disposable 3 mL pipette.
4) Close the extraction tube with a cap and shake for 1 minute.
5) Let the solid remain in the sediment. Depending on the nature of the samples, this might take 1-2 minutes. Alternatively centrifuges at 2000 g or higher.
6) Remove cap and transfer 0.3 mL of sample supernatant into a reaction vial using a disposable 0.3 mL pipette.

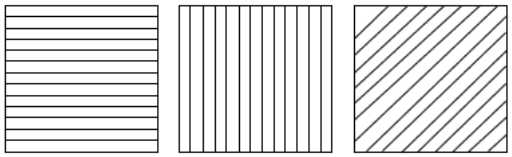
6.2 Rinse water

1) In case of strong acidic or basic rinse solution adjust the pH of the sample to 7 (+/- 0.5).
2) Transfer 0.3 mL of dilution buffer into a dilution tube using one of the disposable 0.3 mL pipettes.
3) Transfer 0.3 mL of rinse sample into the extraction tube using a second disposable 0.3 mL pipette.
4) Mix the two liquids by applying the same pipet as in step 3.
5) Transfer 0.3 mL of mixture to a reaction vial applying the same pipet as in step 4.

6.3 Swabbing samples

DRY SURFACES

1) Mark out 5x5 cm area or use swab directly on (e.g. uneven) area.
2) Transfer 1 mL of ready-to-use extraction solution into an extraction tube by using the disposable 3 mL pipette.
3) Moisten a swab by dipping into the tube.
4) Swab 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 extraction tube with a cap and shake for 1 minute to release the sample from the swab.
7) Remove cap and transfer 0.3 mL of sample supernatant into a reaction vial using a disposable 0.3 mL pipette.

WET SURFACES

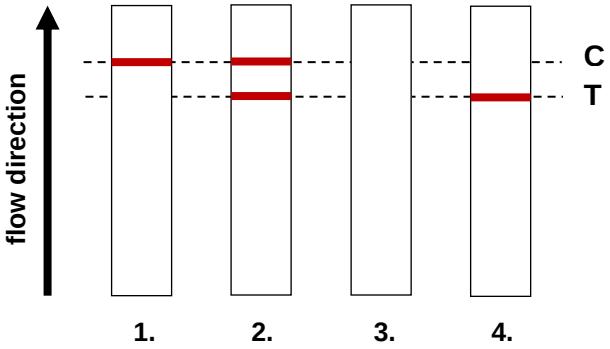
Apply the same method as described for dry surfaces without prior need to moisten the swab.

7. ASSAY PROCEDURE

1) Prepare samples as described above.
2) After transfer of the sample to the incubation vial, add cap and shake for 15 seconds. Make sure that the biotinylated antibody is completely dissolved.
3) Incubate for 3 minutes.
4) Remove the cap and place one strip into the vial. For proper strip orientation make sure that the arrows on the cover foil point downwards.
5) Incubate for 5 minutes.
6) Remove the strip from the vial and evaluate immediately.

8. EVALUATION

SENSI*Strip* lateral-flow devices are evaluated according to the following scheme:



1. **Negative:** visible control (C) line, no test (T) line
2. **Positive:** visible control (C) and test (T) lines
3. **Invalid:** neither control (C) and test (T) lines visible
4. **Invalid:** no control (C) line and visible test (T) line

For better distinguishing between negative, borderline and positive samples a colour card for evaluation is provided with the kit. The intensity of the test line has to be compared with the different increments of the colour card. Results lower than increment 3 should be treated as negative. Results according to increment 3 or higher should be treated as positive. Since the increments of the colour card are ranging up to 10 a semi-quantitative evaluation is also possible. This can be improved by taking into account the results stated in the validation report of the product.

In addition, a quantitative evaluation (2.5-50 ppm) in combination with the *RapidScan ST5* lateral flow reader is possible. For further information please contact Gold Standard Diagnostics Budapest.

9. PERFORMANCE

9.1 Sensitivity

LOD (total soy protein) of the SENSIStrip lateral-flow test is 2.5 ppm for food matrix, 0.33 mg/L for rinse water and 0.007 µg/cm^2 for swab samples applying the procedure above.

NOTE 1: Sensitivity may vary depending on the matrix and processing of a complex food mixture. For achieving reliable results each matrix should be validated prior to routine testing.
NOTE 2: The kit is not suitable for the detection of soy-derived lecithin.

9.2 Cross-reactivity

For the following foods not cross-reactivity could be detected:

Adzuki bean	Cow's milk	Onion
Almond	Cumin	Oyster
Apricot	Curcuma	Paprika
Barley	Dill	Pea
Bean, white	Duck	Peach
Bovine	Egg	Peanut
Bovine gelatine	Ewe's milk	Pecan
Brazil nut	Fennel	Pepper
Buckwheat	Fenugreek	Pine nut
Caraway	Flaxseed	Pistachio
Cardamom	Garden cress	Poppy seed
Carob bean	Garlic	Pork
Carrot	Gliadin	Potato
Cashew	Goat's milk	Pumpkin seed
Cayenne	Guar gum	Radish
Celery	Hazelnut	Rice
Cherry	Horseradish	Rye
Chestnut	Kidney bean	Sesame
Chia	Kiwi	Shrimp
Chicken	Lamb	Split peas
Chickpea	Leek	Sucrose
Chilli	Lentil	Sunflower seed
Cinnamon	Lupin	Thyme
Clove	Macadamia	Tomato
Cocoa	Milk powder	Turkey
Coconut	Mustard, yellow	Walnut
Cod	Nutmeg	Wheat
Corn	Oats	White cabbage

9.3 High-dose-hook Effect

Reduced or absent signals can occur in case of very high concentrations. The test gives valid results up to a concentration of 25000 ppm for food samples, according 67 µg/cm^2 for swabs and 3333 mg/L for rinse water samples.

9.4 Additional Performance Data

Additional data can be found in the corresponding validation report of the product, which can be inquired at Gold Standard Diagnostics Budapest.

10. 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 the results.
Gold Standard Diagnostics Budapest shall not be liable for the unsafe use of the kit out of the current European safety regulations.