INSTRUCTION FOR USE

SENSI*Strip* Food Allergen Rapid Test Strip-Shellfish

(Cat. nr. HU0030092)

GOLD STANDARD DIAGNOSTICS

1. BRIEF INFORMATION

Allergy to shellfish, including arthropods (e.g., crabs, prawns, shrimps) and mollusks (e.g., snails, oysters, scallops, squid) will have symptoms like fainting, palpitation, induced skin rash and asthma, if severe, will result in allergic shock. **SENSI*Strip* Shellfish Food Allergen Rapid Test** is an immunochromatographic test for the detection of shellfish in food. All reagents required for the test are included in the test kit. Results are interpreted visually. This test is suitable for the detection of unknown ingredient or ambiguous labeling in processed food. **SENSI*Strip* Shellfish Food Allergen Rapid Test** can be used with **SENSI*Strip* Swab Kit** (Product Number: HU0030098) to validate and verify allergen cleaning regimes in manufacturing and analytical environment. This test is also suitable for food quality control in food processing plants specifically with inbound goods, processing stages and final product.

***Detection limit:**
<u>0.1 ppm</u> shrimp extraction protein.

***Specificity:**
The test strips can react with shellfish and may also positively react with other organism belonging to the phylum Arthropoda, such as insects and arachnids.
No cross-reaction with casein, soy, gluten, buckwheat, egg, fish, peanut or almond.

2. REAGENTS PROVIDED

Each test kit contains

1) Rapid test strip — 20 pouches
2) Buffer — 65 mL, 1 bottle
3) Instruction manual — 1 manual
4) Supplies:
   - 1.5 mL Microcentrifuge tube — 20 pcs
   - 4 mL Sample tube — 20 pcs
   - Scoop — 20 pcs
   - Dropper — 20 pcs
   - Tubes Rack — 2 pcs

3. EQUIPMENT/ MATERIALS REQUIRED (NOT PROVIDED)

- 20 – 200 µL and 1,000 µL Pipetmans (or can be replaced by droppers provided).
- Accurate weighing scale.
- Grinder or homogenizer.
- Timer.
- Vortex mixer (if available).
- **SENSI*Strip* Swab Kit** (Product Number: HU0030098) (20 pieces).
- Clean water.

4. STORAE INSTRUCTIONS

- Store the test kit between 2 to 30 degrees Celsius.
- Keep away from direct sunlight.
- Do not freeze.

5. WARNINGS AND PRECAUTIONS FOR USERS

1) SENSI*Strip* products are for food testing and *In Vitro* diagnostic use only, not for human use.
2) SENSI*Strip* products contain non-toxic buffers. To maintain test accuracy, please keep bottle upright to prevent leakage.
3) SENSI*Strip* Rapid Tests are designed as a one-use test. Please do not re-use test strip.
4) SENSI*Strip* Rapid Tests are very sensitive to humidity, which could render the test strips useless. Please keep the test strips away from humidity.
5) SENSI*Strip* Rapid Tests are designed for screening purposes only. If analysis of ingredients is required, please send the sample to your local laboratory for further analysis.
6) To ensure test accuracy, please do not use expired test strips or omit the following steps include weighing samples or operating by pipetmans.
7) Airborne shellfish powder and dirty equipment can lead to shellfish contamination of the test strip and affect the results. In order to avoid cross-contamination during the operation, please clean equipment and surfaces with 75% ethanol before operating and wear gloves while performing the test to ensure detection accuracy.
8) All samples require dilution with the buffer in this kit. Do not test the sample directly with the test strip.
9) Highly concentrated samples and food samples containing high level of polyphenols (e.g. coffee, tea, wine, chocolate etc.), high fat volume (e.g. peanut butter, oil etc.) or heavy food colouring (e.g. soya sauce) will affect the results of the tests.
10) If the sample is too viscous or concentrated, it is recommended to increase the dilution factor of the sample with the buffer in this kit before testing.
11) Please complete the test procedure in 30 minutes.

6. PREPARATION OF SAMPLES

6.1 For liquid food/ drinks:

Measure 50 µL of sample with 450 µL buffer into a 1.5 mL microcentrifuge tube and mix well (the dilution factor here is 1/10).

6.2 For solid food:

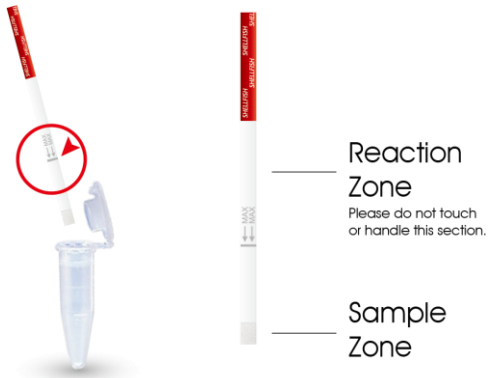
1) Weigh 0.3 g of sample (grind finely) or fill the sample up with scoop provided and then level it off.
2) Add with 3,000 µL buffer into a 4 mL sample tube (the dilution factor here is 1/10).
3) Vortex/ mix for 30 seconds.
4) Leave sample mixture to settle for 1 minute.
5) Measure 500 µL (or 15 drops by dropper) of the sample mixture supernatant into a 1.5 mL microcentrifuge tube.

6.3 Environmental swab test:

1) Transfer 500 µL (or 15 drops by dropper) of buffer into a 1.5 mL microcentrifuge tube.
2) Wet the cotton swab in the **SENSI*Strip* Swab Kit** with clean water.
3) Swab the sample with the pre-wetted cotton swab. (A sampling surface area of 100 cm^2 is recommended.)
4) Place the cotton swab in the 1.5 mL microcentrifuge tube making sure to immerse the cotton swab head in the buffer.
5) Gently agitate the cotton swab in the buffer for at least 30 seconds. (Please avoid spilling the buffer.)
6) Remove the cotton swab from the 1.5 mL microcentrifuge tube and leave the tube to rest for 1 minute.

7. TEST IMPLEMENTATION

1) Open the alu-pouch and take out the test strip. (Please handle the coloured sticker portion only and avoid contact with the reaction zone).
2) Insert the test strip into the 1.5 mL microcentrifuge tube.



Note: Do not allow liquid height to exceed the arrows

8. RESULTS AND SENSITIVITY

8.1 Wait 15 minutes for the results. Please read the results immediately without further manipulation.

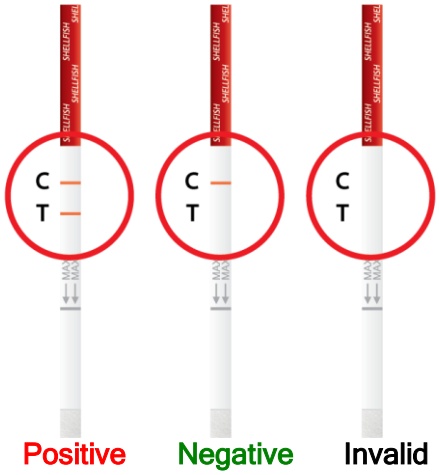
8.2 Result analysis

- **Positive result: two colored bands** (the C and T red test bands) are visible within the reaction zone.
- **Negative result: one colored band** (the C red test band) is visible within the reaction zone.
- **Invalid result: no colored band** is visible within the reaction zone, the test is considered invalid.

*Please check the following:

A. If the test strip packaging is damaged.
B. If the test strip is damp.
C. If the sample is too viscous or concentrated.

Please retest with a new test strip.



***NOTE:**

- **Please read test results within 30 minutes to ensure optimum accuracy.**
- **"Hook effect": Highly concentrated samples overload the test strip and weak band(s) will be visible.**

8.3 Sensitivity calculation

- Sample after dilution, a dilution factor will need to be considered.
- If the sample is further diluted, a dilution factor will need to be considered.

9. 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.

SENSIStrip Shellfish – QUICK GUIDE

A. Materials Needed:

	Liquid Sample	Solid Sample	Environmental Swab Test
4 mL Sample Tube	●	●	
1.5 mL Microcentrifuge Tube	●	●	●
Pipetmans or Droppers	●	●	●
Scoop		●	
Swab (Optional)			●

B. Preparation of Samples:

Liquid Sample

1. Transfer **450 µL** Buffer
2. **50 µL** Liquid Sample + **450 µL** Buffer
3. Vortex or Mix

Solid Sample

1. **0.3 g** Solid Sample (Grind Finely) + **3.000 µL** Buffer
2. Vortex or Mix — 30 s
3. Settle Down — 1 min
4. Pipette **500 µL** Sample Mixtures Supernatant to 1.5 mL Tube

Environmental Test

1. Transfer **500 µL** Buffer
2. Wet the Swab with Clean Water
3. Swab the Sampling Surface — 100 cm^2 is Recommended
4. Agitate the Swab for 30 sec — 30 s
5. Remove the Swab and Settle Down — 1 min

C. Strip Testing and Result Analysis:

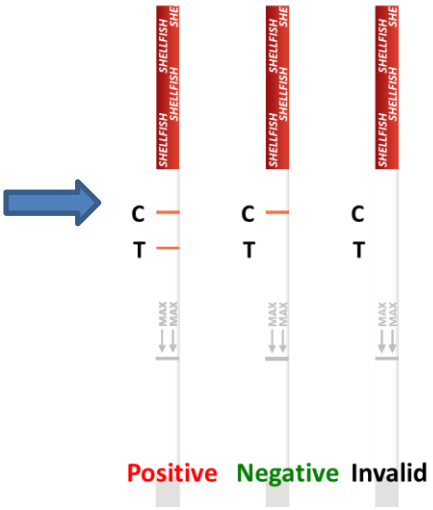
1. Remove Strip from Package



2. Insert Test Strip into Tube

Do Not Allow Liquid Height to Exceed the Arrows

15 min



Positive result: **two colored bands** (the C and T red test bands) are visible within the reaction zone.
Negative result: **one colored band** (the C red test band) is visible within the reaction zone.
Invalid result: **no colored band** is visible within the reaction zone, the test is considered invalid.

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