



Sensoreal® PSP Alert™ Rapid Test for detection of PSP toxins in Shellfish (Filter)

Product ID: ALRT-PSP-KIT

Relevance of Saxitoxin and PSP toxin Determination

Paralytic shellfish toxins (PSTs), including saxitoxin (STX) and its analogues (e.g., neosaxitoxin and gonyautoxins), are potent marine neurotoxins produced by certain dinoflagellates during harmful algal blooms (HABs). These toxins are the causative agents of Paralytic Shellfish Poisoning (PSP) in humans. Consumption of PST-contaminated bivalve mollusks can lead to a range of symptoms, from tingling and numbness to severe neurological effects, including respiratory paralysis, which can be life-threatening. PST exposure has also been associated with intoxication events in marine wildlife. Due to these significant health risks, regulatory authorities worldwide (including the United States, Canada, and Europe) require routine monitoring of bivalve shellfish. A strict maximum regulatory limit of 80 µg STX equivalents per 100 g of shellfish tissue (0.8 ppm) is enforced for harvest closures and market access control.

Validation Data

Test Sensitivity and Threshold:	PSP Alert™ is engineered with a conservative decision threshold of 65 µg STX equivalent per 100 g of shellfish tissue (0.65 ppm) to provide an added safety margin relative to the regulatory limit.
Selectivity:	The assay detects Saxitoxin and other PSP toxins to varying degrees.
Comparability with HPLC-PCOX:	In single-laboratory validation studies, the assay demonstrated 100% agreement with standard HPLC-PCOX reference methods for samples containing PSP toxins at or above the regulatory action level (80 µg STX eq/100g) in mussels. No false negatives were observed at or above the regulatory limit.
Cross-reactivity	Saxitoxin – 100% GTX 2&3 – 118.1% Neosaxitoxin – 86.4% GTX 1&4 – 78.1% GTX 5- – 15.4% C1/C2 toxins – 12.3% Decarbamoyl GTX 2&3 – 7.6%
General Limited Warranty:	The PSP Alert™ Rapid Test Kit is intended for research and pre-testing purposes only and is not a replacement for officially validated regulatory methods. Users are responsible for determining product suitability. Sensoreal Inc. provides no expressed or implied warranties and is not liable for indirect, incidental, or consequential damages.

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Instructions are effective as of (date): 2026-09-25

Version: 1.60

1. General Description and Principle of the Method

Sensoreal PSP Alert™ is a rapid lateral flow immunoassay (LFA) designed for the qualitative detection of paralytic shellfish toxins (PSP), mainly saxitoxin (STX) in bivalve mollusks. The assay operates on a competitive binding format and has been evaluated in mussels, oysters, scallops, geoduck, and multiple clam species, including razor, butter, Manila, and littleneck clams.

PSP toxins like STX are extracted from homogenized shellfish tissue using our proprietary aqueous extraction solution. The extract is then diluted and incubated with a lyophilized antibody-gold nanoparticle conjugate. If STX is present in the sample, it binds to the conjugate antibodies, reducing the amount of free antibody-gold complex available. The mixture is then applied to the lateral flow cassette and migrates across a membrane containing immobilized STX-protein at the test line. Consequently, the test line intensity is inversely proportional to the STX concentration (higher STX concentration = fainter test line). A control line will appear in all valid tests to confirm proper assay function. Results are objectively interpreted using the Sensoreal SensoRead™ scanner.

2. Safety

Treat all samples, extracts, and used test components as potentially contaminated with STX, other PSP toxins, and biological material. Wear appropriate PPE, including gloves, safety goggles, and a laboratory coat, during testing. The PSP Alert™ protocol uses an environmentally friendly aqueous extraction solution that can be safely discarded down the drain. Dispose of all samples and used test components in appropriate waste containers.

3. Storage

- Lateral Flow Test Strips (Cassettes): Store at the temperature specified on the label. Do not freeze. Keep cassettes in their original, sealed pouches until immediately prior to use to protect them from moisture and humidity.
- Antibody Conjugate Vials (Lyophilized): This is the only kit component that may be frozen. Store frozen or as strictly specified on the product label. Keep vials sealed and do not open until ready to perform the assay.
- Diluent Powder Vials: Store at the temperature specified on the label. Do not freeze. Keep sealed to protect from excess heat and moisture.
- Buffer Solution: Store as directed on the label.
- General Stability:** Protect all kit components from excess heat and direct sunlight. Do not utilize kit components past their printed expiration date or if they exhibit any signs of damage or deterioration.

4. Procedural Notes

- The PSP Alert™ test is optimized for analyzing freshly harvested bivalves, intact samples refrigerated for under 48 hours, or previously homogenized tissue kept frozen. Prior to beginning the extraction process, it is critical that all chilled or frozen samples are allowed to fully equilibrate to ambient room temperature.
- Unprocessed shellfish can be safely held under refrigeration (2–8°C) provided they will be tested within two days of harvest. If the testing timeline extends beyond this 48-hour window, the shellfish meat must be completely shucked, homogenized (as outlined in Section C), and stored at -20°C to ensure toxin stability prior to extraction.
- Please note that this protocol is exclusively validated for bivalve shellfish matrices. Any application to alternative sample types requires thorough independent validation by the user before routine testing is implemented.
- Follow the specified extraction, dilution, incubation, and read times exactly as detailed in Section D and E. Deviations from the protocol may adversely affect test performance.
- To avoid cross-contamination, use clean, disposable pipette tips and fresh extraction/dilution materials for each individual sample.
- Do not open the lateral flow cassettes or conjugate components until ready to initiate testing.
- Both visual and scanner-based interpretation are supported. Users may utilize the designated Sensoreal SensoRead™ scanner and its corresponding settings, or perform a manual visual interpretation of the results.
- Dispose of sample extracts, and used kit components in strict accordance with institutional, local, and regulatory environmental requirements.
- As with any screening technique, positive results leading to regulatory action or market closure should be confirmed by a recognized alternative quantitative method (e.g., HPLC-PCOX).

Protocol Instructions

A. Kit Components

The PSP Alert™ kit includes the following components:

1. Lateral Flow Test Strips (Cassettes)
2. Extraction solution ("E")
3. Conjugate Vials (lyophilized antibody-gold nanoparticle)
4. Diluent Powder Vials ("D")
5. Buffer Solution ("B")

B. Materials and Equipment Required (Not Provided)

1. Sensoreal's SensoRead™ Scanner (used for result interpretation)
2. Shellfish shucking tools (knife, etc.)
3. Blender for tissue homogenization, Analytical weighing balance, Electronic timer
4. Adjustable precision pipettes covering volumes of 20–200 µL and 100–1000 µL and disposable pipette tips
5. 15 mL conical tubes (for extraction and collection)
6. The use of test tube racks and a vortex mixer is recommended for operational ease; however, these components are not mandatory for the methodology.

C. Sample Collection and Processing

1. For each sample ID, shuck a representative population of 10 to 12 individual animals to obtain a minimum of 100 g of pooled shellfish tissue.
2. Thoroughly rinse the exterior of the shellfish with deionized or distilled water to remove extraneous debris, such as sand or mud.
3. Transfer the collected tissue to a sieve and allow it to drain to remove excess fluid.
4. Homogenize the tissue using an immersion blender (or equivalent mechanical blender) until a completely uniform, smooth consistency is achieved.

D. Toxin Extraction

1. Using a clean spatula and weighing balance, weigh exactly 2.5 g of the homogenized shellfish sample and transfer it into a 15 mL conical tube.
2. Add 9 mL of extraction solution to the conical tube containing the sample.
3. Cap the conical tube tightly and shake vigorously and incubate for 15 minutes.
4. Place a nylon mesh filter inside the silicone funnel and position the funnel over a clean 15 mL conical tube or suitable collection container. After incubation, pour the sample slurry through the filter and collect the filtrate. Use the collected filtrate for the subsequent assay steps.

E. Test Strip Sample Analysis Procedure

Ensure the Sensoreal SensoRead™ scanner is turned on and the correct lot QR code has been scanned prior to initiating the test.

1. Locate the Diluent powder tube ("D"). Using a pipette fitted with a new tip, add 2 mL of Buffer "B", vortex or shake vigorously to dissolve, then add 20 µL of the sample supernatant to Tube "D". Mix thoroughly by vortexing or pipetting up and down.
2. Using a pipette fitted with a new tip, transfer 70 µL of the Diluted Sample (from tube "D") into the Conjugate vial. Pipette the mixture up and down to achieve complete dissolution of the lyophilized pellet, ensuring that no red specks remain adhered to the interior walls of the tube. Once the pellet is fully dissolved and the solution is homogeneous, let the vial sit uninterrupted at room temperature for exactly 10 minutes.
3. After the 10-minute incubation, transfer 70 µL of the Conjugate mix into the sample port of the test cassette.
4. Leave the cassette on a flat, horizontal surface. Set a timer and allow the assay to develop for exactly 15 minutes.

F. SensoRead™ Scanner Analysis

1. After exactly 15 minutes of development, immediately insert the test cassette into the scanner slot of the SensoRead™ device. Follow the on-screen prompts: Select Cassette -> PSP Alert
2. You will be prompted to identify the batch being used. Either select an existing Lot from the on-screen list, or for a new Lot, press "Add New Lot" and scan the batch-specific QR code located on the LFA test pouch or the Certificate of Analysis. This QR code provides the system with integral calibration parameters required for accurate interpretation. (Note: Each Lot only needs to be scanned once; for subsequent tests with the same Lot, simply select it from the saved list).
3. Once the Lot is confirmed, enter the unique Sample ID using the on-screen keypad and press "Run Test". The device will immediately initiate the analysis process to receive the qualitative result (T/C ratio and classification).

G. Interpretation of Results

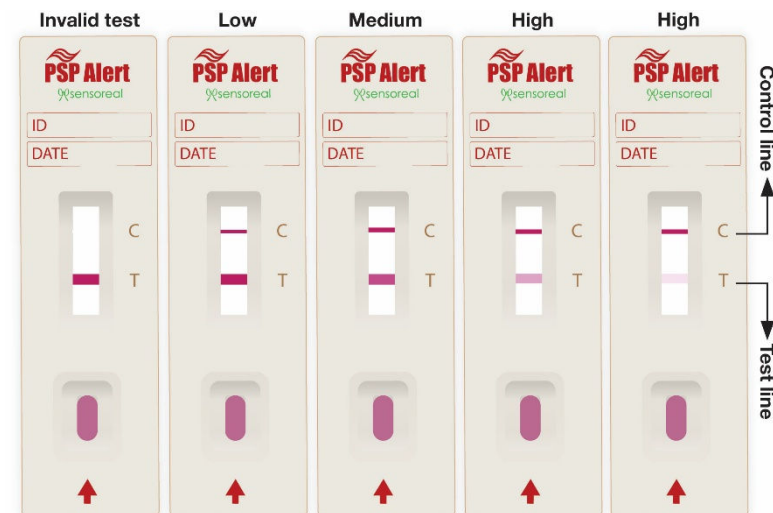
Assay results can be interpreted visually or digitally using the SensoRead™ scanner, which calculates the Test-to-Control (T/C) line intensity ratio. While the absolute intensity of the control line may fluctuate between runs, a visible control line must be present for the assay to be considered valid; the absence of a control line indicates an invalid result requiring a retest.

The SensoRead™ scanner provides an objective determination of line intensities for consistent interpretation, as well as a digital photographic record of all test strips.

-High: The scanner has detected STX and/or other PSP toxins at or above the **65 µg STX eq/100g** threshold. The scanner will flag this sample, indicating it has reached or exceeded the precautionary limit.

-Medium: The T/C ratio indicates concentrations between **25-65 µg STX eq/100g** threshold, and the sample is considered compliant.

-Low: The T/C ratio indicates concentrations is **<25 µg STX eq/100g** threshold, and the sample is considered compliant.



Test Line	Control Line	Interpretation
Present	Absent	Invalid Test (Repeat Test)
Faint or Non-Visible	Visible	High: $\geq 65 \mu\text{g STX eq/100g}$
Moderate Intensity	Visible	Medium: $25\text{--}65 \mu\text{g STX eq/100g}$
Equal to or More Intense than Control Line	Visible	Low: $<25 \mu\text{g STX eq/100g}$

Note: It is essential to perform the reading at the designated 15-minute mark. Determinations made using strips that have dried for more or less than the required time may be inaccurate, as chromatographic line intensities vary with drying time. To ensure a rigorous safety margin against the $80 \mu\text{g STX eq/100g}$ NSSP regulatory limit, the PSP Alert™ system is intentionally calibrated to a conservative early-warning threshold of the $65 \mu\text{g STX eq/100g}$.

For supplemental technical data or methodological assistance, please direct all inquiries to Sensoreal Technical Support at sales@sensoreal.com.