



Sensoreal® PSP Alert™ Water: Rapid Test for detection of PSP toxins in Drinking Water

Product ID: ALRT-PSP-KIT-W

Relevance of Saxitoxin and PSP toxin Determination

Paralytic shellfish toxins (PSTs), including saxitoxin (STX), neosaxitoxin, and gonyautoxins, are potent neurotoxins produced by certain marine dinoflagellates and freshwater cyanobacteria during harmful algal blooms. These toxins interfere with normal nerve function and are the causative agents of paralytic shellfish poisoning (PSP). Human exposure is most commonly associated with the consumption of contaminated bivalve mollusks, such as mussels, oysters, and clams. Symptoms may range from tingling, numbness, headache, and muscle weakness to severe neurological effects, including respiratory paralysis, which can be life-threatening.

Although PST contamination has traditionally been associated with marine shellfish, STX and related toxins may also occur in freshwater sources used for drinking, recreation, and municipal water supplies. Toxin concentrations can vary depending on algal species, bloom conditions, water treatment, and environmental factors. Because routine monitoring of STX in freshwater is relatively recent, advisory values differ among regulatory authorities. The Washington State Department of Health has established a provisional drinking-water advisory level of 0.2 ppb (0.2 ng/mL), while the World Health Organization has established a guideline value of 3 ppb (3 ng/mL). Rapid screening methods can therefore support early detection, water-quality monitoring, and timely decisions regarding confirmatory testing and public-health precautions.

Validation Data

Test Sensitivity and Threshold:	The PSP Alert™ Water Test detects STX in drinking water, with a limit of detection (LOD) below 0.1 ppb (0.1 ng/mL). Results are classified as Low (<0.15 ppb), Medium (0.15–0.5 ppb), or High (>0.5 ppb). The Medium range includes the Washington State Department of Health provisional drinking-water advisory level of 0.2 ppb; samples at or above this level should be considered potentially unsafe pending confirmatory testing.
Selectivity:	The assay detects Saxitoxin and other PSTs to varying degrees.
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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1. General Description and Principle of the Method

Sensoreal PSP Alert™ Water Test is a rapid lateral flow immunoassay designed for the qualitative and semi-quantitative screening of saxitoxin (STX) and related paralytic shellfish toxin (PSTs) analogues in drinking water. Please refer to Section 6 C-E for information on the collection, preparation, and testing of different water samples. Where necessary, positive screening results may be confirmed using ELISA, HPLC, LC-MS/MS, or another appropriate reference method.

The assay uses a competitive immunoassay format. The prepared water sample is incubated with a lyophilized antibody–gold nanoparticle conjugate. If STX or a recognized analogue is present, it binds to the conjugate antibodies and reduces the amount of free antibody–gold nanoparticle complex available to bind at the test line. The mixture is then applied to the lateral flow cassette and migrates across a membrane containing immobilized STX–protein conjugate at the test line. Consequently, test-line intensity is inversely related to toxin concentration: higher toxin concentrations produce a fainter test line. A control line appears in all valid tests to confirm proper sample migration and assay performance. Results are objectively interpreted using the Sensoreal SensoRead™ scanner.

2. Safety

Discard samples according to local, state and federal regulations.

3. Storage

Store all PSP Alert™ Water Test components as specified on their respective labels.

- Test cassettes and diluent powder vials must be stored at temperatures specified in the label and should remain sealed until use to protect them from moisture and humidity.
- Lyophilized antibody conjugate vials may be stored frozen or as strictly specified on the product label. Keep vials sealed and do not open until ready to perform the assay.
- Store the additional buffer solution as directed.

Before testing, allow the test cassettes and reagents to reach room temperature. Protect all kit components from excessive heat and direct sunlight. Do not use components beyond their printed expiration date or if the packaging or reagents show signs of damage or deterioration.

4. Procedural Notes

- The PSP Alert™ Water Test is intended for detecting saxitoxin and related PSTs in drinking water. It is not validated for shellfish or other sample types.
- Follow all specified sample-preparation, incubation, and read times. Protocol deviations may affect test performance.
- Use clean, disposable pipette tips and fresh materials for each sample to prevent cross-contamination.
- Keep test cassettes and conjugate components sealed until immediately before use.
- Interpret results only with the designated Sensoreal SensoRead™ scanner and corresponding method settings.
- Dispose of samples and used kit components according to applicable institutional and regulatory requirements.
- Positive results leading to regulatory action should be confirmed by a recognized alternative quantitative method (e.g., HPLC-PCOX)

5. Limitations and Precautions

- The PSP Alert™ Water Test is intended for qualitative screening of STX and related PSTs in drinking water. Although common water constituents are not expected to interfere, matrix effects from unusual contaminants cannot be completely excluded. Hard and muddy particles if present must be removed.
- Improper storage, extreme temperatures, incorrect timing, or deviations from the procedure may produce inaccurate results.
- Pair test strips and conjugate reagents according to the lot IDs listed on the Certificate of Analysis (CoA) - they are quality-controlled in combination and must be used together. Allow samples and kit components to reach room temperature before testing. Keep cassettes and conjugate components sealed until use, and follow all specified sample-preparation, incubation, and read times (Section 6C-E).
- Use fresh disposable pipette tips and materials for each sample to prevent cross-contamination. Interpret results only with the designated Sensoreal SensoRead™ scanner.
- Positive samples can be confirmed by ELISA, HPLC-PCOX or other analytical methods.

Protocol Instructions

A. Kit Components

The PSP Alert™ kit includes the following components:

1. Lateral flow test strips (Cassettes)
2. Conjugate tubes (lyophilized antibody-gold nanoparticle)
3. Diluent powder tubes ("D")

B. Materials and Equipment Required (Not Provided)

1. Sensoreal's SensoRead™ Scanner (required for result interpretation)
2. Electronic timer
3. Measuring cylinder (10 mL)
4. Adjustable precision pipette covering volumes of 20–200 µL
5. Disposable pipette tips
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, Processing and Sample Analysis

1. Locate the Diluent powder tube ("D"). Using a graduated cylinder, add 5 mL of the drinking water sample. Shake or vortex vigorously until all powder dissolves (some frothing will appear). This is mixed solution D.
2. Using a pipette fitted with a new tip, transfer 140 µL of Solution D into the Conjugate vial containing the lyophilized antibody-conjugate pellet. Pipette the mixture up and down to achieve complete dissolution of the 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 a homogeneous light pink, let the vial sit uninterrupted at room temperature for exactly 10 minutes.
3. After the 10-minute incubation, transfer **all of the contents** of the Conjugate mix into the sample port of the LFA cassette.
4. Leave the cassette on a flat, horizontal surface. Set a timer and allow the assay to develop for exactly 15 minutes so the test and control lines can form.

D. SensoRead™ Scanner Analysis

1. Ensure the Sensoreal SensoRead™ scanner is turned on. 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 Water'
2. You will be prompted to identify the Lot being used. Either select an existing Lot from the on-screen list, or for a new Lot, press "Add New Lot" and scan the lot-specific QR code located on the LFA test pouch or the Certificate of Analysis (CoA). 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).

NOTE: The PSP Alert™ Water Test has been validated and optimized for finished drinking water containing low amounts of chlorine (< 0.5 ppm). Samples containing visible sediment or suspended particulates should be filtered using an appropriate syringe filter before testing, as these materials may interfere with assay performance. Contact Sensoreal for specific testing instructions before use.

E. Interpretation of Results

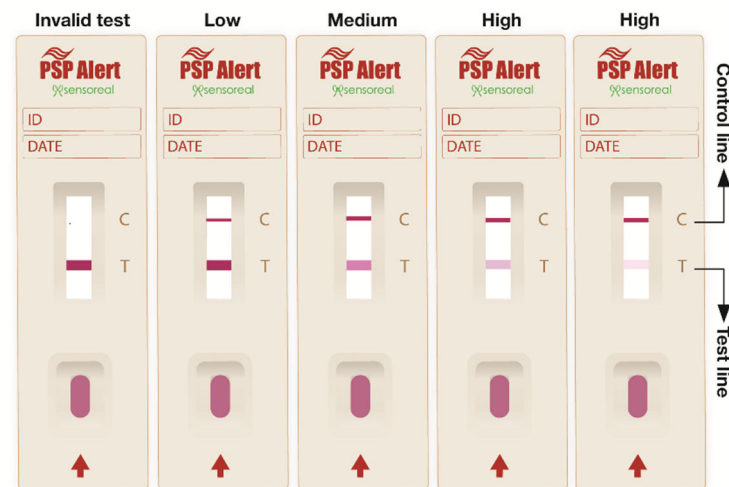
Assay results are determined by the SensoRead™ scanner through a digital analysis of the Test-to-Control (T/C) line intensity ratio. While the absolute intensity of the control line may fluctuate between runs, a visible control line must be present for the assay to be considered valid; the absence of 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 T/C ratio indicates STX and/or related PSP toxins above 0.5 ppb (0.5 ng/mL).

-Medium: The T/C ratio indicates an STX-equivalent concentration of 0.15–0.5 ppb (0.15–0.5 ng/mL).

-Low: The T/C ratio indicates an STX-equivalent concentration below 0.15 ppb (0.15 ng/mL).



Test Line	Control Line	Interpretation
Present	Absent	Invalid Test (Repeat Test)
Faint or Non-Visible	Visible	High: > 0.5 ppb (0.5 ng/mL)
Moderate Intensity	Visible	Medium: 0.15 – 0.5 ppb (0.15 – 0.5 ng/mL)
Equal to or More Intense than Control Line	Visible	Low: < 0.15 ppb (0.15 ng/mL)

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.

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