H. Additional Analysis

If necessary, positive samples can be confirmed by ELISA, HPLC or other conventional methods. These services are available from commercial analytical laboratories (list of analytical laboratories available upon request).

Importance of Saxitoxin Determination

Saxitoxin is one of the "paralytic shellfish poisons (PSP), produced by several marine dinoflagellates and fresh water algae. Contamination of water sources has been associated with harmful algal blooms throughout the world. In man, PSP causes dose-dependent perioral numbness or tingling sensation and progressive muscular paralysis, which can result in death through respiratory arrest.

Humans and other animals may be exposed to Saxitoxin through ingestion of contaminated water, through drinking or during recreational activities in which water is swallowed. Due to the potential for serious harm and even death, many countries are expanding monitoring programs to include Saxitoxin and are establishing regulations regarding the amount of Saxitoxin in drinking and recreational waters.

Performance Data

Test sensitivity: The PSP (Saxitoxin) Strip Test will detect Saxitoxin at 0.2 ng/mL (ppb) or higher in freshwater (2.0 ppb or higher in seawater). At this level, the test line exhibits moderate intensity. At levels greater than 3 ng/mL (ppb) (30 ppb in seawater) the test line is not visible.

Selectivity: The assay recognizes Saxitoxin and other PSP toxins to varying degrees:

Cross-reactivities:

Saxitoxin	100% (per definition)
Decarbamoyl STX	43%
GTX 2&3	19%
Lyngbyatoxin	14%
Neosaxitoxin	3%

Samples: A sample correlation between the PSP (Saxitoxin) Strip Test and ELISA methods showed a good correlation.

General Limited Warranty: Eurofins Abraxis warrants the products manufactured by the Company against defects and workmanship when used in accordance with the applicable instructions for a period not to extend beyond the product's printed expiration date. **Eurofins Abraxis makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose.**

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PSP (Saxitoxin) Strip Test

eurofins | Abraxis

Immunochromatographic Strip Test for the Detection
of Saxitoxin in Seawater, Drinking Water and Recreational Waters

Product No. 520044 (5 Test), 520045 (20 Test)

1. General Description

The PSP (Saxitoxin) Strip Test for Water is a rapid immunochromatographic test, designed for use in the qualitative/semi-quantitative screening of Saxitoxin in seawater, drinking water and recreational waters (please see Section 7. Sample Collection and Handling, for information on testing various water types). The PSP (Saxitoxin) Strip Test provides qualitative/semi-quantitative test results. If necessary, positive samples can be confirmed by ELISA, HPLC or other conventional methods.

2. Safety Instructions

Discard samples according to local, state and federal regulations.

3. Storage and Stability

The PSP (Saxitoxin) Strip Kit should be stored between 2-30°C. The test strips, test vials, and water samples to be analyzed should be at room temperature before use. The reagents may be used until the last day of the month as indicated by the expiration date on the box.

4. Test Principle

The test is based on the recognition of Saxitoxin by specific antibodies. The toxin conjugate competes for antibody binding sites with Saxitoxin that may be present in the water sample. The test device consists of a vial containing specific antibodies for Saxitoxin labeled with a gold colloid and a membrane strip to which a conjugate of the toxin is attached. A control line, produced by a different antibody/antigen reaction, is also present on the membrane strip. The control line is not influenced by the presence or absence of Saxitoxin in the water sample and, therefore, should be present in all reactions.

In the absence of toxin in the water sample, the colloidal gold labeled antibody complex moves with the water sample by capillary action to contact the immobilized Saxitoxin conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. The formation of two visible lines of similar intensity indicates a negative test result, meaning the test did not detect the toxin at or above the cut-off point established for the toxin. If Saxitoxin is present in the water sample, it competes with the immobilized toxin conjugate in the test area for the antibody binding sites on the colloidal gold-labeled complex. If a sufficient amount of toxin is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the toxin conjugate, therefore preventing the development of a colored line. If a colored line is not visible in the test line region, or if the test line is lighter than the control line, Saxitoxin is present at a level of concern. Semi-quantitative results can be obtained by comparing the sample test strip appearance to the appearance of test strips from solutions of known Saxitoxin concentrations (control solutions). Concentrated Saxitoxin standards, which can be used to prepare Saxitoxin controls, are available through Eurofins Abraxis (PN 300590).

5. Limitations of the PSP (Saxitoxin) Strip Test, Possible Test Interference

Numerous organic and inorganic compounds commonly found in water samples have been tested and found not to interfere with this test. However, due to the high variability of compounds that might be found in water samples, test interferences caused by matrix effects cannot be completely excluded.

Mistakes in handling the test can also cause errors. Possible sources for such errors include:
Inadequate storage conditions of the test strip, too long or too short incubation times, extreme temperatures during the test performance (lower than 10°C or higher than 30°C), use of the test with water samples which have not been preserved properly (see Section 6. Warnings and Precautions, and Section 7. Sample Collection and Handling).

The test is designed for use with fresh and seawater samples. The PSP (Saxitoxin) Strip Test provides a semi-quantitative/qualitative test result. Use another more quantitative analytical method such as ELISA or instrumental analysis to obtain a confirmed quantitative analytical result. Apply good judgement to any test result, particularly when preliminary positive results are observed.

6. Warnings and Precautions

-Use only the Saxitoxin test strips and reagents from one kit lot, as they have been adjusted in combination.
-Water samples must be preserved using the Sample Preservation Vials included in the kit before analyzing with the PSP (Saxitoxin) strip test. Use of the PSP (Saxitoxin) test strips with samples, which have not been treated with the reagents contained in the Sample Preservation Vials, **will produce inaccurate results** (see Section 7. Sample Collection and Handling, for information on collecting water samples for evaluation of Saxitoxin content). Use of sample preservation reagents other than those described in this user's guide may also produce inaccurate results.
-All reagents and samples should be allowed to reach room temperature before testing.
-Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date on the label.
-For test strips packaged in a desiccated vial, the vial should be kept completely closed except for opening to remove test strips. When re-closing, snap lid firmly.
-Avoid cross-contamination of water samples by using a new sample vial and disposable pipette for each sample.
-Use reasonable judgment when interpreting the test results.
-Results should be interpreted within 5-10 minutes after completion of the test.

7. Sample Collection and Handling

-**Fresh water samples must** be preserved at the time of collection (see Section E. Sample Preservation Procedure, below) to prevent degradation of Saxitoxin, which will produce inaccurate (biased low) sample results. The use of the PSP (Saxitoxin) test strips with samples which have not been treated with the reagents contained in the Sample Preservation Vials **will produce inaccurate results**.

-**Chlorinated water samples** must be treated (quenched) with **sodium thiosulfate** at 0.1 mg/mL at the time of collection to remove residual chlorine. Each chlorinated water sample should be collected in a clean container, then immediately treated with sodium thiosulfate to neutralize chlorine. Immediately after quenching, the sample should be transferred to a Sample Preservation Vial following the procedure described in Section E. Sample Preservation Procedure, below.

-**Seawater samples** or brackish water samples must be diluted 1:10 in deionized or distilled water prior to sample preservation. For example, mix 1 mL of the seawater samples with 9 mL deionized or distilled water. Mix well, and proceed to sample preservation (see Section E. Sample Preservation procedure, below). The results must be multiplied by a factor of 10 when interpreting results to account for the dilution. Biased (inaccurate) sample results will occur if the factor is not applied.

-The Sample Preservation Vials are amber glass containers which contain dried sample preservation reagents. The use of other types of containers will result in degradation of Saxitoxin due to the lack of preservation reagents, producing inaccurate (falsely low) results.

-Preserved samples can be stored refrigerated (4-8ºC) for up to 28 days. Samples which must be held for greater than 28 days should be stored frozen.

A. Materials Provided

1. PSP (Saxitoxin) test strips in a desiccated container
2. Sample preservation vials
3. PSP Sample Diluent, dropper bottle
4. 3 mL graduated disposable pipettes
5. Conical test vials containing conjugate pad
6. Disposable transfer pipettes
7. User's guide

B. Additional Materials (not provided with the test)

1. Timer
2. Saxitoxin standard, Eurofins Abraxis PN 300590, for the preparation of control solutions which can be analyzed with samples to obtain semi-quantitative sample results (see Section C. Controls, below)
3. Distilled or deionized water
4. Sodium thiosulfate
5. Glass or plastic sample containers (required for quenching chlorinated water samples or performing dilutions, if necessary)

C. Controls

It is a good laboratory practice to use positive and negative controls to ensure proper test performance. Water samples containing known quantities of Saxitoxin (positive and negative controls) should be analyzed with each lot of test strips to provide a reference for line intensity to be expected. Control samples should be preserved in the same manner as samples, using the Sample Preservation Vials, in order to produce accurate results. Analysis of control samples which have not been treated with the reagents in the Sample Preservation Vials will produce inaccurate positive and negative control sample results.

D. Test Preparation

1. Allow the reagents and preserved water sample to reach room temperature before use.
2. Remove the number of test strips required from the package. The remaining strips are stored in the tightly closed desiccated container.

E. Sample Preservation Procedure

Samples must be treated with sample preservation reagents at the time of collection to prevent loss of Saxitoxin:

1. Using a new 3 mL graduated disposable pipette for each sample, draw the sample to the 3 mL line (graduation mark slightly below the bulb) and add to an appropriately labeled amber glass Sample Preservation Vial.
2. Tightly cap the vial and shake thoroughly for 30 seconds to mix. Allow the vial to sit at room temperature for 5 minutes. Shake thoroughly to mix and repeat this step one time. Sample is now ready for testing or storage at 4°C for later testing.

F. Procedure

Samples must be preserved at the time of collection using the reagents contained in the Sample Preservation Vials provided in the kit according to the procedure described in Section E. Sample Preservation Procedure, before proceeding to the analysis procedure listed below. Samples which are not preserved appropriately will produce inaccurate results.

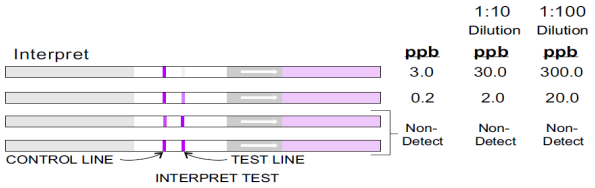
1. Using a new disposable transfer pipette for each sample, transfer 3 drops (approximately 100 µL) of the preserved water sample (from Section E, above) to the appropriately labeled conical test vial, which holds a dried pad containing gold conjugate.
2. Using the sample diluent dropper bottle, transfer 3 drops (approximately 100 µL) of PSP (Saxitoxin) sample diluent to each conical test vial prepared in step 1.
3. Close the conical test vial and shake for 30 seconds or until the gold conjugate is completely dissolved from the pad, turning the solution purple/pink and the pad holding the conjugate has little to no color remaining.
4. Incubate the conical test vial at room temperature for 10 minutes.
5. Insert the test strip (arrows down) into the conical vial. Be sure the test strip is fully inserted into the bottom of the vial and the conjugate pad does not interfere with the flow of sample onto the test strip membrane.
6. Allow the test to develop for 10 minutes.
7. Remove the test strip. Lay the strip flat and allow to continue developing for 5 additional minutes.
8. Read the results visually or with a reader within 5-10 minutes of removal from the conical vial (Step 7), as explained below in section G, Interpretation of Results.

G. Interpretation of Results

Sample concentrations are determined by comparison of the intensity of the test line to the intensity of the control line on the same test strip. Although control line intensity may vary, a visible control line must be present for results to be considered valid. Test strips with a test line which is darker than or of equal intensity to the control line indicate a result which is below the limit of detection of the test. Test strips with a visible test line which is lighter than the control line indicate a result which is ≥ 0.2 ppb and ≤ 3 ppb. Test strips with little to no test line visible (only the control line is visible) indicate a result which is ≥ 3 ppb. Results should be determined within 5-10 minutes of removal from the conical vial after completion of the strip test procedure. Determination made using strips which have dried for more or less than the required time may be inaccurate, as line intensities may vary with drying time. NOTE: Multiply the values in the table to account for any dilutions made during sample collection. Biased (inaccurate) sample results will occur if the dilution factor is not applied. For example, seawater values must be multiplied by a factor of 10 to account for the 1:10 dilution in Section 7, Sample Collection and Handling. The range for seawater is 2 ng/mL (ppb) to 30 ng/mL (ppb).

Control Line	***Test Line***	***Interpretation***
No control line present	No test line present	Invalid result
Control line present	Very light intensity or no test line present	≥3 ng/mL (ppb)
Control line present	Test line intensity ≥control line	≤0.2 ng/mL (ppb)

* Please note that the illustration is intended for the demonstration of test line to control line intensity only. Results should not be determined by comparing the intensity of test lines from test strips to the test line intensity of the illustration, as the overall intensity of test strips may vary slightly with different lots of reagents. To obtain semi-quantitative results in the range of 0-3 ppb, it is recommended that solutions of known Saxitoxin concentration (control solutions) be tested concurrently with samples. Sample test line intensities can then be compared with control solution test line intensities, yielding approximate sample concentrations. Do not use strips run previously to determine semi-quantitative sample concentrations, as test line intensities may vary once strips are completely dry.



Alternately, test strips can be interpreted using the AbraScan test strip reader (PN 475025B), which provides objective determination of line intensities for consistent interpretation of results as well as a digital photographic record of all test strips.

For sample screening requiring a higher concentration range (greater than 0.2 – 3 ppb) or for retesting of samples which exceed the standard assay detection range (≥ 3 ppb) that require a more definitive result, samples can be diluted prior to addition to the Sample Preservation Vials. The detection range of the strip test kit is then determined by multiplying the standard concentration range by the dilution factor of the samples. For example, a sample which is being screened for Saxitoxin content up to 20 ppb would be diluted 1:10 in distilled or deionized water (1 mL of sample into 9 mL of distilled or deionized water), before being transferred into the Sample Preservation Vial as described in section E, Sample Preservation Procedure. Analysis of the sample will result in control and test lines similar to the 3 ppb test strip pictured above. An additional 1:10 dilution of the sample will result in a 1:100 dilution of the 20 ppb sample, producing test strip results similar in appearance to the 0.2 ppb test strip pictured above. Further dilution of the sample would be outside of the detection range of the strip test and will produce a negative result.