


# Saxitoxin Lateral Flow Kit

Shellfish · Rapid Test

Catalog Number: **AU2057-01**

**For Research Use Only. Not for use in Diagnostic Procedures.**

# 1. Introduction

Attogene's Saxitoxin Lateral Flow Kit for shellfish is a rapid, single-use cassette test that screens shellfish tissue for saxitoxin at a screening level of 50 ppb (50 µg/kg). A 1 g portion of homogenized tissue is extracted in 30 mL of water and passed through a syringe filter. The filtered extract is added to a tube of Sample Dilution Buffer with a fixed-volume pipette, mixed and added to a cassette. No pipettor or power is needed at the testing step.

The test is a competitive immunoassay (Figure 1). As the sample flows along the strip it picks up colloidal gold coated with an anti-saxitoxin antibody. The test line (T) carries a saxitoxin–BSA conjugate. If the sample contains no saxitoxin, the gold binds the test line and a red test line forms. Saxitoxin in the sample fills the antibody binding sites, so less gold binds the test line: the more saxitoxin in the sample, the weaker the test line. The control line (C) carries goat anti-mouse IgG and biotin–BSA. It captures the antibody–gold that passes the test line, together with streptavidin–gold that binds only to the control line. The control line is therefore faint when the test line is strong, and becomes stronger as the saxitoxin concentration increases.

**Important:** a weaker test line means MORE saxitoxin. Always read each sample against a negative control cassette run at the same time (Section 9).

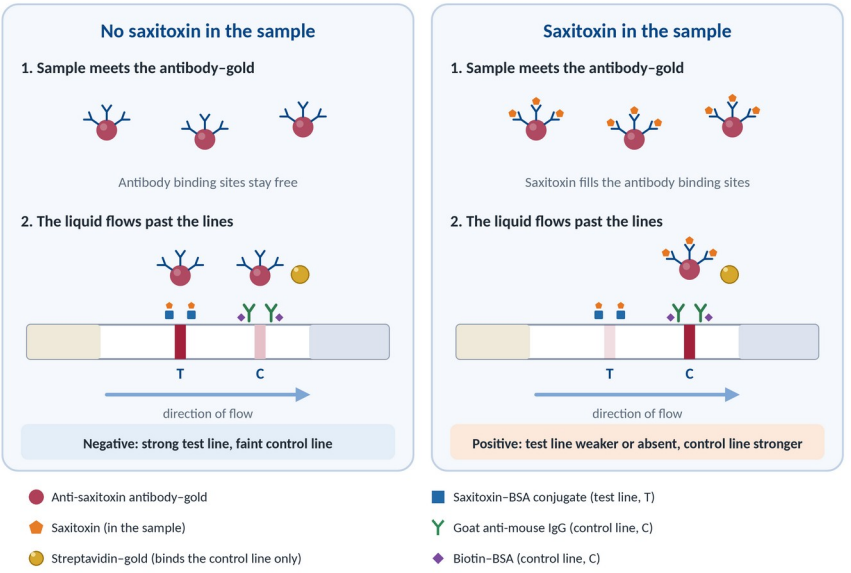



**Figure 1.** *Test principle. Left: with no saxitoxin, most antibody–gold binds the saxitoxin–BSA test line (T), so the test line is strong and the control line (C) is faint. Right: saxitoxin in the sample blocks the antibody, so the antibody–gold passes the test line and is captured at the control line; the test line is weaker or absent and the control line is stronger. Streptavidin–gold binds only the control line, so a control line forms on every cassette that ran correctly.*

## About Saxitoxin

Saxitoxins (STXs) are naturally occurring alkaloids produced by some marine dinoflagellates and by strains of several species of freshwater cyanobacteria. Saxitoxin is one of the most prevalent paralytic shellfish toxins (PSTs). It belongs to a family of potent neurotoxins with a molecular weight of about 300 Da, built on a tetrahydropurine ring system with a highly polar guanidinium group. During harmful algal blooms (HABs), saxitoxins accumulate in filter-feeding shellfish and can cause paralytic shellfish poisoning (PSP). The regulatory limit for PSP toxins in shellfish is 800 µg saxitoxin-dihydrochloride equivalents per kg of shellfish meat (80 µg per 100 g; 800 ppb), used by the US FDA and the EU. The kit responds mainly to saxitoxin and only partly, or not at all, to analogues such as the gonyautoxins and neosaxitoxin (neoSTX) (Table 4), so a result below 800 ppb does not rule out total PSP toxicity above the limit.

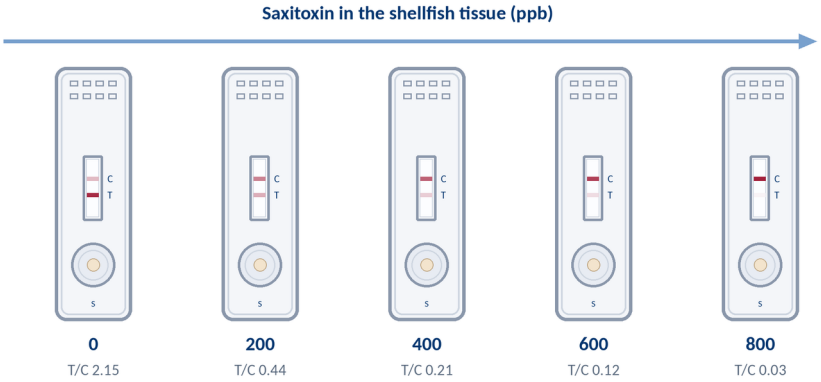



**Figure 2.** *Shellfish samples spiked with saxitoxin (0–800 ppb in the tissue), tested with AU2057-01 (reference data from the rev2 manual). The cassette images are redrawn from the lateral flow reader values (T/C = test line value ÷ control line value). The image is for illustration only and does not represent the performance of any particular lot.*

## Features & Benefits

- Screens shellfish tissue for saxitoxin at a screening level of 50 ppb (50 µg/kg).
- Results in 30 minutes; no instrument is needed for the visual result. A lateral flow reader can be used for numerical (T/C) readings.
- Every sample is read against its own negative control cassette.
- Extraction materials are in the kit; a blender, a balance and water are needed (Section 5).

## 2. Kit Contents

The kit contains the components listed in Table 1.

| Component | Quantity | Storage |
|---|---|---|
| **Saxitoxin Cassette, in a foil pouch with desiccant** | 24 | Room temp. |
| **Sample Dilution Buffer (10X), 30 µL per tube** | 12 tubes | Room temp. |
| **Negative Control (1X), 200 µL per tube** | 12 tubes | Room temp. |
| **Fixed-Volume Pipette, 200 µL** | 24 | Room temp. |
| **1 mL Syringe** | 12 | Room temp. |
| **Syringe Filter, 1.2 µm** | 12 | Room temp. |
| **Extract Collection Tube** | 12 | Room temp. |
| **Conical Tube, 50 mL** | 12 | Room temp. |
| **Manual** | 1 | — |

**Table 1.** *Kit contents.*

**Kit size:** 12 samples. Each sample uses two cassettes: one for the sample and one for its negative control. Each cassette is sealed in its own foil pouch with a desiccant. Extra Sample Dilution Buffer is available as an add-on (Section 13).

## 3. Product Specifications

Key specifications for experienced users and for setting up a lateral flow reader (Table 2).

| Parameter | Specification |
|---|---|
| **Format** | Single-use lateral flow cassette: sample port (S) and reading window, with C and T printed to the right of the window (Figure 3) |
| **Assay principle** | Competitive immunoassay: the test line weakens, and the control line strengthens, as the saxitoxin concentration in the sample increases. |
| **Reporter** | 40 nm colloidal gold conjugated to an anti-saxitoxin monoclonal antibody (mAb) |
| **Test line (T)** | Saxitoxin–BSA conjugate |
| **Control line (C)** | Goat anti-mouse IgG (GAM) and biotin–BSA. The GAM captures anti-saxitoxin mAb–gold that passes the test line; streptavidin–gold binds only to the control line. |
| **Samples** | Shellfish tissue (homogenized meat) |
| **Screening level** | 50 ppb (50 µg/kg) saxitoxin in the shellfish tissue |
| **Visual detection** | Sample test line lighter than the negative control test line: 50 ppb or above. No test line, or only a trace: about 800 ppb or above (the regulatory limit). |
| **Reader detection** | Set in the reader program; cut-offs can be tailored to the customer's requirements |
| **Sample preparation** | 1 g of homogenate extracted in 30 mL of distilled or deionized water and passed through a 1.2 µm syringe filter; 200 µL of filtered extract added to 30 µL of Sample Dilution Buffer (10X) |
| **Volume to cassette** | 200 µL of the buffered extract; 200 µL of Negative Control |
| **Time to result** | Read at 30 minutes |
| **Controls** | Negative Control supplied, 12 tubes per kit. Positive control not supplied. |
| **Cross-reactivity** | Strong response to saxitoxin (STX); moderate to gonyautoxins GTX2/3; weak to GTX1/4; little or none to neosaxitoxin (neoSTX), GTX5 and GTX6 (Table 4). |
| **Storage** | Cassettes in their sealed foil pouches, Sample Dilution Buffer and Negative Control at room temperature. Shelf life 18 months from the date of manufacture. |

**Table 2.** *Product specifications.*

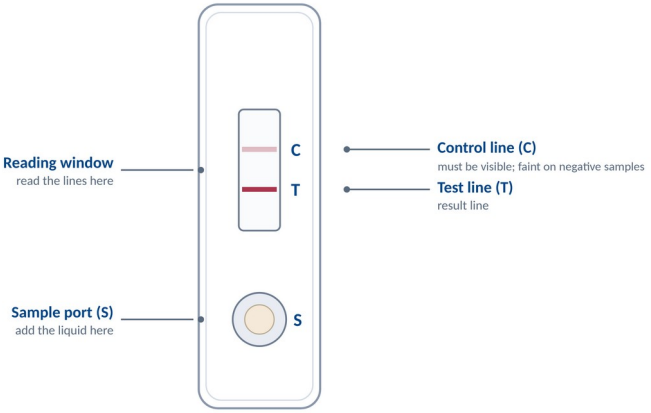



**Figure 3.** *Parts of the cassette. Add the liquid to the sample port (S) and read the lines through the window. The test line (T) is nearer the sample port than the control line (C).*

## 4. Storage and Stability

- Store the cassettes in their sealed foil pouches at room temperature. Open a pouch only when you are ready to run the test.
- Store the Sample Dilution Buffer and the Negative Control at room temperature.
- The kit is guaranteed for 18 months from the date of manufacture.
- Use the kit before the expiration date on the label.

## 5. Required Materials Not Supplied

- **Timer** – to time the run
- **Disposable gloves** – for sample collection and testing
- **Permanent marker – to label tubes and cassettes**
- **High-speed blender – to homogenize the shellfish tissue**
- **Balance (0.5–100 g) – to weigh the homogenate**
- **Distilled or deionized water – 30 mL per sample**

## 6. Precautions

- This kit gives screening results. Confirm positive results, and any result used for a regulatory decision, by ELISA, HPLC, LC-MS/MS or another conventional analytical method.
- Before use, check that the date of use is before the expiration date on the label.

- Saxitoxin is a potent neurotoxin. Wear gloves and other suitable protective equipment when you handle raw shellfish and extracts, and wash your hands after testing.
- The Sample Dilution Buffer and the Negative Control contain sodium azide as a preservative. Do not swallow them, and rinse any skin or eye contact with water.
- Use one Fixed-Volume Pipette for the Negative Control and a new one for the sample. Use a new conical tube, syringe, syringe filter, extract collection tube and Sample Dilution Buffer tube for each sample to avoid cross-contamination.
- Use only reagents from one kit lot; the components of a lot have been adjusted to work together.
- Do not use a cassette from a damaged pouch. Use each cassette once.
- Lay each cassette flat on a level surface and do not move it while the sample runs.
- Good laboratory practice: test a sample of known saxitoxin concentration (positive control, not supplied) with each kit lot to see the line intensity to expect.

## 7. Sample Collection and Storage

- Wear suitable personal protective equipment when you handle raw shellfish, and label each sample.
- Live shellfish can be stored at 4 °C for up to 2 days.
- Once the shellfish have been eviscerated, homogenize the tissue immediately or freeze it.
- Bring the cassettes, the Sample Dilution Buffer, the Negative Control and the extracts to room temperature before testing.

## 8. Procedure

### Before you start

- Bring the cassettes, Sample Dilution Buffer, Negative Control and samples to room temperature.
- Each sample needs two cassettes: one for the Negative Control and one for the sample.
- Wearing gloves, take the cassettes out of their pouches and lay them flat on a level surface. Label each cassette on the plastic (not on the window): “A” for the negative control and “B” with the sample name.

### A. Sample preparation (extraction)

1. Remove the shell from each shellfish and rinse the meat thoroughly with distilled or deionized water. Let the excess water drain off.
2. Homogenize the tissue in a high-speed blender for at least 120 seconds. Push tissue back into the blades if it sticks to the sides. A good homogenate is essential.
3. Weigh 1 g of homogenate into a 50 mL Conical Tube (Figure 4, step 1).
4. Add 30 mL of distilled or deionized water. Shake vigorously or vortex until all the tissue is suspended (step 2). A cloudy solution with bubbles is normal.
5. Draw the extract into the 1 mL Syringe until the plunger stops. Do not attach the filter yet (step 3).
6. Press the syringe firmly into the 1.2 µm Syringe Filter. Push the plunger to filter the extract into an Extract Collection Tube (step 4). The extract is ready to test.

### B. Negative control (run first)

1. Using a Fixed-Volume Pipette, transfer 200 µL of Negative Control into the sample port (S) of the negative control cassette (Cassette A), all at once. Start the timer (steps 5–6).

### C. Sample

1. Using a new Fixed-Volume Pipette, add 200 µL of filtered extract to a Sample Dilution Buffer tube (step 7).
2. Mix gently by pipetting up and down 3 times with the same pipette (step 7).
3. With the same pipette, transfer 200 µL of the buffered extract into the sample port (S) of the sample cassette (Cassette B), all at once. Note the time (step 8).
4. Leave both cassettes flat and undisturbed. Read each cassette 30 minutes after its liquid was added (step 9).
5. Read both cassettes by eye or with a lateral flow reader (Section 9).

**NOTE:** read each cassette 30 minutes after its liquid was added, and no later than 35 minutes. Compare the sample cassette with its negative control cassette side by side.




**Figure 4.** *Procedure overview (photos from the AU2057-01 Quick Reference Guide).*

## 9. Interpretation of Results

Read the sample cassette and its negative control cassette side by side. First check the control line (C), then compare the test line (T) of the sample with the test line of the negative control (Table 3 and Figure 5).

| Result | What you see | Meaning |
|---|---|---|
| **Invalid** | No control line (C) on the sample cassette or on the negative control cassette | The test did not run correctly. Repeat with new cassettes (Section 11). |
| **Negative** | Sample T line as strong as, or stronger than, the T line of the negative control | No saxitoxin detected (below 50 ppb) |
| **Low positive** | Sample T line visible but lighter than the T line of the negative control | Saxitoxin detected: 50 ppb (50 µg/kg) or above, below about 800 ppb |
| **Positive** | No sample T line, or only a trace (the C line is visible) | Saxitoxin at about 800 ppb (the regulatory limit) or above |

**Table 3.** *How to read the result. The control line is faint on the negative control and on negative samples, and becomes stronger as saxitoxin increases. A faint control line is normal: the result is valid as long as a control line is visible.*

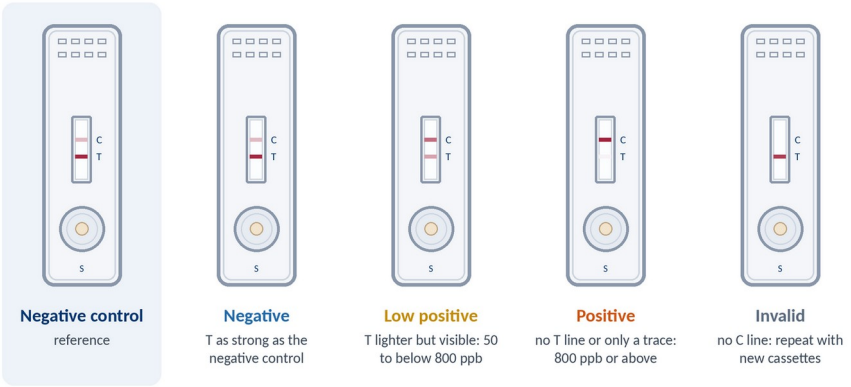



**Figure 5.** *Reading the result against the negative control.*

### Reading with a lateral flow reader

Calculate T/C (test line value ÷ control line value) for the sample and for its negative control, and compare the two. A lower T/C than the negative control shows saxitoxin in the sample. In the reference data (Figure 2), T/C fell from 2.15 at 0 ppb to 0.44 at 200 ppb, 0.21 at 400 ppb, 0.12 at 600 ppb and 0.03 at 800 ppb. DETEKT RDS-2500 readers supplied by Attogene are set up with a program dedicated to saxitoxin; its cut-offs can be tailored to the customer's requirements (see the STX Quick Reference Guide for the DETEKT Reader).

### Approximate concentrations (semi-quantitative)

To estimate concentration, test saxitoxin standards of known concentration (not supplied), prepared in extract of saxitoxin-free shellfish, alongside the samples, and compare the test lines. Do not use cassettes run earlier. Give standards as tissue-equivalent ppb (µg/kg): with 1 g in 30 mL, 800 ppb in the tissue is about 26.7 µg/L in the extract. The comparison works from 0 to about 800 ppb. To estimate a higher concentration, dilute the filtered extract with extract of saxitoxin-free shellfish, test it again and multiply the result by the dilution factor.

## 10. Limitations

- The test screens for saxitoxin; it does not give an exact concentration. Confirm positive results by a conventional analytical method (Section 12).
- The antibody responds most strongly to saxitoxin (STX). It responds partly to gonyautoxins GTX2/3, weakly to GTX1/4, and little or not at all to neosaxitoxin (neoSTX), GTX5 and GTX6 (Table 4). The test therefore does not measure total paralytic shellfish toxins as STX equivalents: a result below 800 ppb does not rule out total PSP toxicity above the regulatory limit. In a trial with naturally contaminated New Zealand shellfish, whose toxin profiles were dominated by gonyautoxins and C-toxins, the kit underestimated total PSP toxicity (Cawthron Institute, 2024).

| Compound (25 ppb) | T/C | Response |
|---|---|---|
| **Blank (no toxin)** | 5.71 | Reference |
| **Saxitoxin (STX)** | 0.12 | Strong |
| **Gonyautoxins GTX2/3** | 1.29 | Moderate |
| **Gonyautoxins GTX1/4** | 4.47 | Weak |
| **Neosaxitoxin (neoSTX)** | 5.54 | Little or none |
| **Gonyautoxin GTX5** | 8.34 | None |
| **Gonyautoxin GTX6** | 5.47 | None |

**Table 4.** *Response to related compounds, each at 25 ppb in running buffer (one cassette per level; Attogene R&D data, 11 Aug 2025). At 5 ppb, T/C was 0.39 for STX and 2.20 for GTX2/3. A lower T/C means a stronger response.*

## 11. Troubleshooting

Table 5 lists common problems and what to do.

| Observation | Likely cause | What to do |
|---|---|---|
| **No control line** | Too little liquid in the sample port, cassette moved or tilted during the run, or cassette exposed to moisture | Repeat with a new cassette from an undamaged pouch; add the full 200 µL at once and keep the cassette flat and still |
| **No test line on the negative control cassette** | Cassette damaged or expired, or the Negative Control was not added | Check the expiration date; repeat with new cassettes. If it happens again, contact Attogene |
| **Slow flow, liquid left in the port, or high background** | Particles in the sample | Make sure the extract was passed through the 1.2 µm Syringe Filter (Section 8, part A); repeat with a new filtered extract |
| **Sample and negative control hard to compare** | Cassettes read at different times or under different light | Read both cassettes side by side, under the same light, at 30 minutes |

**Table 5.** *Troubleshooting.*

## 12. Additional Analysis

If needed, confirm positive samples by ELISA, HPLC, LC-MS/MS or another conventional analytical method. The Attogene Saxitoxin (PSP) ELISA Kit (catalog number EL2048-02) can be used for this purpose. A lateral flow reader can be used to obtain numerical (T/C) readings from the visual result. Contact us with any questions.

## 13. Ordering Information

| Catalog no. | Description | Size |
|---|---|---|
| **AU2057-01** | Saxitoxin Lateral Flow Kit, Shellfish Rapid Test: 24 cassettes, Sample Dilution Buffer, Negative Control, syringes, syringe filters, extraction tubes, pipettes | 12 samples |
| **AU2057** | Saxitoxin Lateral Flow Kit, Freshwater, Field Use: 10 cassettes and sample bottles | 5 samples |
| **PN2194-2** | Sample Dilution Buffer (10X) add-on for AU2057-01, 30 µL per tube | 12 or 24 tubes |

**Table 6.** *Ordering information.*

### Add-ons

Extra Sample Dilution Buffer tubes for this kit can be bought separately, in a 12-pack or a 24-pack, from www.attogene.com. The AU2057 and AU2057-01 buffers are not interchangeable.

*For bulk cassettes, custom formats or other analytes, contact sales@attogene.com.*




## Contact Us

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Web: www.attogene.com

# 14. Quick Reference

## Procedure at a glance

| Step | Action |
|---|---|
| 1 | Bring everything to room temperature. Lay two cassettes flat per sample: “A” (negative control) and “B” (sample). |
| 2 | Extract: 1 g homogenate + 30 mL distilled or deionized water in the 50 mL tube; vortex; filter through the 1.2 µm Syringe Filter into an Extract Collection Tube. |
| 3 | Negative control: 200 µL of Negative Control into port S of Cassette A; start the timer. |
| 4 | With a new pipette, add 200 µL of extract to a Sample Dilution Buffer tube and mix 3 times. |
| 5 | Add 200 µL of the buffered extract to port S of Cassette B; note the time. |
| 6 | Leave flat; read each cassette 30 minutes after its liquid was added (no later than 35 minutes). |

## Reading the result (always against the negative control)

| Result | Sample cassette |
|---|---|
| **Invalid** | No C line (on either cassette): repeat |
| **Negative** | T line as strong as or stronger than the negative control: no saxitoxin detected |
| **Low positive** | T line visible but lighter than the negative control: 50 ppb or above, below about 800 ppb |
| **Positive** | No T line, or only a trace: about 800 ppb or above |

## Storage

- Cassettes, Sample Dilution Buffer and Negative Control at room temperature; open a cassette pouch only when ready to test.
- Use the kit before the expiration date on the label.

## Notes

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