

Recreational Water Sample Preparation for 8 PPB Screening Range Using the ABRAXIS® Cylindrospermopsin Strip Test

1. Intended Use

For the screening of Cylindrospermopsin in freshwater recreational water samples at 8 ppb. Samples requiring regulatory action should be confirmed by ELISA, HPLC, or other conventional methods.

2. Materials and Reagents Required

ABRAXIS® Cylindrospermopsin Strip Test Kit (PN 500030 [20T]; PN 500029 [5T]) Disposable graduated pipettes (calibrated at 1 mL) 20 mL glass vials with Teflon-lined caps Distilled or deionized water

3. Notes and Precautions

This procedure is intended for the screening of recreational water samples at 8 ppb. Samples must be diluted as described below prior to lysis and analysis as described in the ABRAXIS® Cylindrospermopsin Strip Test user's guide (section E, Procedure) in order to obtain accurate results. Dilution of samples after use of the ABRAXIS® QuikLyse^{TM*} reagents provided in the ABRAXIS® Cylindrospermopsin Strip Kit (rather than dilution before lysis, as described below) will produce inaccurate results. (*ABRAXIS® QuikLyse^{TM*} reagents may be used in a method of U.S. Patent 9,739,777.)

- The ABRAXIS® Cylindrospermopsin Strip Test is intended for use with fresh water samples only. Analysis of brackish or sea water samples will produce inaccurate results due to matrix interference.
- The ABRAXIS® Cylindrospermopsin Strip Test provides only preliminary qualitative test results. Use another, more quantitative, analytical method such as ELISA or instrumental analysis to obtain a confirmed quantitative analytical result.
- 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.
- The test strips are packaged in a desiccant vial. The vial should be kept completely closed except for opening to remove test strips. When re-closing, ensure lid is completely sealed.
- Avoid touching or bending the membrane on the test strip.
- Avoid cross-contamination of samples by using a new conical vial and disposable pipette for each sample.
- Use only ABRAXIS® Cylindrospermopsin Strip Test reagents from one kit lot, as they have been adjusted in combination.
- It is good laboratory practice to use positive and negative controls to ensure proper test performance. Samples which do not contain Cylindrospermopsin (negative controls) as well as samples containing known quantities of Cylindrospermopsin (positive controls) should be analyzed with each lot of test strips to provide a reference for line intensity to be expected.

4. Sample Collection and Handling

Collect water samples in glass containers and store refrigerated for up to 5 days. If samples must be held for greater than 5 days, samples should be stored frozen.

5. Test Preparation

Allow the test strips, conical vials, and samples to reach room temperature before testing.

6. Procedure

For screening samples at 8 ppb, samples must be diluted as described below prior to lysis and analysis using the ABRAXIS® Cylindrospermopsin Strip Test in order to obtain accurate screening results. To dilute water samples prior to screening:

- 6.1 Label 20 mL glass vials for each sample to be tested.
- 6.2 Using a 1 mL graduated disposable pipette, add 4 mL of distilled or deionized water to each of the previously labeled 20 mL glass vials (i.e., transfer 1 mL four times for a total of 4 mL of distilled or deionized water).

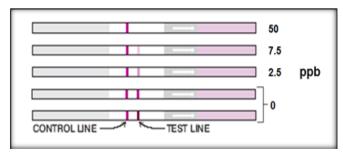
- 6.3 Using a new 1 mL graduated disposable transfer pipette for each sample, transfer 1 mL of the appropriate water sample to the appropriate labeled vial.
- 6.4 Cap the vial tightly and shake for 10-20 seconds to mix.
- 6.5 Samples are ready for screening at 8 ppb using the ABRAXIS® Cylindrospermopsin Strip Test.

7. Interpretation of Results

For samples prepared as described above, screening 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 indicates a result which is below the limit of detection of the test. Test strips with a test line which is lighter than the control line indicates a result which is ≥ 2.5 ppb. Test strips with no test line visible (only the control line is visible) indicates a result which is ≥ 50 ppb. Results should be determined within 5-10 minutes 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.

Control Line	<u>Test Line</u>	<u>Interpretation</u>
No control line present	No test line present	Invalid result
Control line present	No test line present	>50 ng/mL (ppb)
Control line present	Moderate to equal intensity test line present	Between 0 and 50 ng/mL (ppb)

The appearance of test strips may also be compared to the illustration below to determine approximate sample concentration ranges. 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 0-50 ppb, solutions of known Cylindrospermopsin concentration (control solutions) must 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.



8. Additional Analysis

If necessary, positive samples can be confirmed by ELISA, HPLC, or other conventional methods.

9. For ordering or technical assistance contact:

Gold Standard Diagnostics Horsham 124 Railroad Drive Warminster, PA 18974 Web: www.abraxiskits.com

Fax: (215) 357-5232
Ordering: <u>info.abraxis@us.goldstandarddiagnostics.com</u>
Technical Support: <u>info.abraxis@us.goldstandarddiagnostics.com</u>

Phone: (215) 357-3911

Version: 02

Date this Technical Bulletin is effective: 11MAR2024