ABRAXIS® Cylindrospermopsin Method Detection Limit (MDL) Standard for Demonstration of Capability in Cylindrospermopsin Analysis
Product No. 300705

1. General Description
The ABRAXIS® Cylindrospermopsin Method Detection Limit (MDL) Standard is an analytical standard used for the demonstration of capability in the analysis of samples for the presence of Cylindrospermopsin.

2. Notes and Precautions
Method Detection Limit (MDL) studies may be required for:
- initial demonstration of capability (IDOC) for analysts who have not previously analyzed samples for the presence of Cylindrospermopsin
- annual demonstration of capability (DOC) for analysts who routinely analyze samples for the presence of Cylindrospermopsin
- verification of the acceptable performance of equipment used in sample analysis

Prior to use, ensure that the standard has not expired by verifying that the date of use is prior to the expiration date on thelabel.

3. Materials Provided
ABRAXIS® Cylindrospermopsin Method Detection Limit (MDL) Standard, 3 vials, each containing 1 mL of 0.1 ppb Cylindrospermopsin solution

4. Additional Materials
ABRAXIS® Cylindrospermopsin ELISA Kit (PN 522011)

5. Storage and Stability
The ABRAXIS® Cylindrospermopsin Method Detection Limit (MDL) Standard should be stored between 4-8ºC.
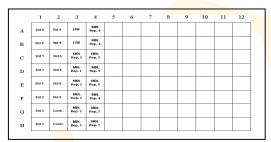
6. Safety Instructions
Discard according to local, state, and federal regulations.

7. Test Preparation
Allow the standard to warm to room temperature before use.

8. Procedure
Analyze seven replicate aliquots of the MDL standard in duplicate (a total of 14 wells) as samples, along with the appropriate calibrators and quality control standards, as described in the user's guide. For example, calibration standards,quality control standards, and the MDL standard should be pipetted into the wells of the microtiter plate as shown below:

	1	2	3	4	5	6	7	8	9	10	11	12
A	Std 0	Std 4	LRB	MDL Rep. 4								
B	Std 0	Std 4	LRB	MDL Rep. 4								
C	Std 1	Std 5	MDL Rep. 1	MDL Rep. 5								
D	Std 1	Std 5	MDL Rep. 1	MDL Rep. 5								
E	Std 2	Std 6	MDL Rep. 2	MDL Rep. 6								
F	Std 2	Std 6	MDL Rep. 2	MDL Rep. 6								
G	Std 3	Contr.	MDL Rep. 3	MDL Rep. 7								
H	Std 3	Contr.	MDL Rep. 3	MDL Rep. 7								

9. Evaluation of Results

The MDL is determined by multiplying the standard deviation of the ELISA results for the seven replicates by 3.143 (theStudent's t value for a 99% confidence interval and a standard deviation estimate with n-1 degrees of freedom for seven replicates):

$$MDL = (3.143)*(SD_R)$$

The MDL can also be determined using a spreadsheet macro available from Gold Standard Diagnostics upon request.

10. Acceptance Criteria

The following criteria must be met in order for the MDL study to be considered valid:
- the calculated MDL value is no more than ten times lower than the concentration of the MDL standard
- the calculated MDL value does not exceed the concentration of the MDL standard
- the calculated MDL value must not exceed the reporting limit of 0.05 μg/L (ppb)

11. For ordering or technical assistance contact:

Gold Standard Diagnostics   Phone: (215) 357 3911
124 Railroad Drive   Fax: (215) 357 5232
Warminster, PA 18974   Ordering: info.abraxis@us.goldstandarddiagnostics.com
WEB: www.abraxiskits.com   Technical Support: support.abraxis@us.goldstandarddiagnostics.com

Date this Technical Bulletin is effective: 09NOV2021   Version: 01