ABRAXIS® Microcystins Method Detection Limit (MDL) Standard for Demonstration of Capability in Microcystins Analysis

Product No. 300700

1. General Description

The ABRAXIS® Microcystins Method Detection Limit (MDL) Standard is an analytical standard used for the demonstration of capability in the analysis of samples for the presence of Microcystins and Nodularins as described in *Ohio EPA Total (Extracellular and Intracellular) Microcystins-ADDA by ELISA Analytical Methodology*.

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 Microcystins
- annual demonstration of capability (DOC) for analysts who routinely analyze samples for the presence of Microcystins
- 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 the label.

3. Materials Provided

Microcystins Method Detection Limit (MDL) Standard, 3 vials, each containing 1.5 mL of 0.4 ppb Microcystin-LR solution

4. Additional Materials

ABRAXIS® Microcystins/Nodularins-ADDA ELISA Kit (PN 520011 or PN520011OH) or ABRAXIS® Microcystins/Nodularins-DM ELISA Kit (PN 522015)

5. Storage and Stability

The Microcystins Method Detection Limit (MDL) Standard should be stored between 2-8ºC.

6. Safety Instructions

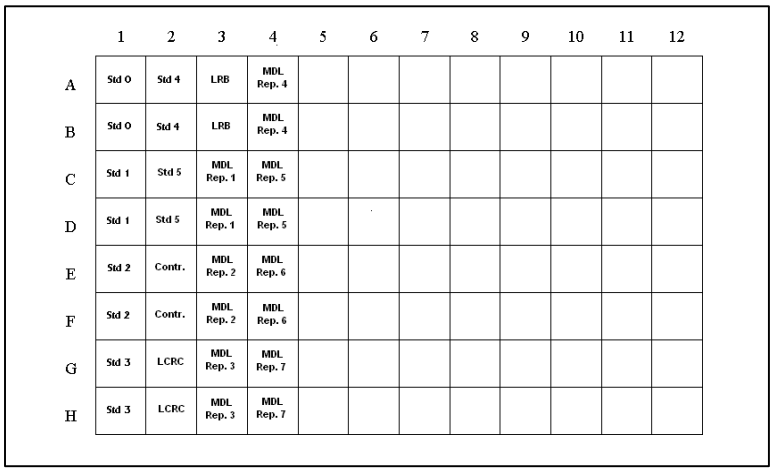
Discard according to local, state, and federal regulations.

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 appropriate user's guide. For example, if analyzing with the ABRAXIS® Microcystins-ADDA or ABRAXIS® Microcystins-DM ELISA kits, 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	Contr.	MDL Rep. 2	MDL Rep. 6								
F	Std 2	Contr.	MDL Rep. 2	MDL Rep. 6								
G	Std 3	LCRC	MDL Rep. 3	MDL Rep. 7								
H	Std 3	LCRC	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 (the Student's t value for a 99% confidence interval and a standard deviation estimate with n-1 degrees of freedom for seven replicates):

$$MDL = (3.143)*(SDR)$$

The MDL can also be determined using a spreadsheet macro available from Eurofins Abraxis 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
- if following the reporting limit guidelines as described in *Ohio EPA Total (Extracellular and Intracellular) Microcystins-ADDA by ELISA Analytical Methodology*, the calculated MDL value must also be less than the required reporting limit of 0.3 µg/L (ppb).

11. For ordering or technical assistance contact:

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