Environmental Test Specifications

Background

Mycotoxins are small molecular weight toxic molecules produced by various species of mold, some of which inhabit water damaged homes or buildings. Many clinical symptoms and disease states have been associated with human exposure to mycotoxins. The RealTime Lab Mycotoxin Panel detects 15 different mycotoxins, as follows: Trichothecenes (Satratoxin G and H, Isosatratoxin F, Roridin A, E, H, and L-2, and Verrucarin A and J.), Ochratoxins (Ochratoxin A), Aflatoxins (Aflatoxin B1, B2, G1, and G2), and Gliotoxin (bis (methyl) gliotoxin)

Mycotoxins are particularly important because they are known to be highly toxic and are produced by species such as Stachybotrys ("black mold"), shown to be present in mold contaminated buildings.

Testing is done using competitive ELISA, a very sensitive and specific method for detection using antibodies prepared against the Mycotoxins.

References:

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- Intranasal Antifungal Therapy in Patients with Chronic Illness Associated with Mold and Mycotoxins: An Observational Analysis. Brewer, J.H., Hooper, D., and S. Muralidhar. Global J. of Med. Res. 2015. 15(1). 29-33
- Trichothecenes: From Simple to Complex Mycotoxins. McCormick, S.P., Stanley, A.M., Stover, N.A., and N.J. Alexander. Toxins. 2011. 3, 802-814

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Mycotoxin Panel

Assay Method: ELISA

Accuracy

Assay accuracy was evaluated by obtaining concentrated mycotoxin from an independent vendor, and the RTL Mycotoxin Panel was used to measure the concentration of each mycotoxin present within a range of dilutions specific for each assay. Measurements must be accurate within 20% of the expected value for samples measured in the assay specific ranges.

Assays	Tested Concentration Range (PPB)	Percent Error
Trichothecene	0.01 to 1.0	≤ 20.0
Ochratoxin	0.5 to 10.0	≤ 20.0
Aflatoxin	1.0 to 8.0	≤ 20.0
Gliotoxin	0.3 to 10.0	≤ 20.0

Precision/Reproducibility

Assay precision was determined by spiking a negative urine sample with a known amount of mycotoxin and testing ten replicates for each assay. Measurements must have a Coefficient of Variation (CV) of ≤ 20%.

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Gliotoxin	0.3 to 10.0	≤ 20.0

Linearity

The RTL Mycotoxin Assays are highly linear ($R^2 > 0.95$) over several orders of magnitude. The reportable ranges for the assays are as follows:

Assays	Present if ≥	Equivocal if between
Trichothecene	0.03 ppb	0.02-0.03 ppb
Ochratoxin	2.0 ppb	1.8-2.0 ppb
Aflatoxin	1.0 ppb	0.8-1.0 ppb
Gliotoxin	1.0 ppb	0.5-1.0 ppb

Sensitivity

The analytical limit of detection for the mycotoxin assays are as follows: Trichothecene is 0.01 ppb, Ochratoxin is 0.5 ppb, Aflatoxin is 1.0 ppb, and Gliotoxin is 0.3 ppb.

Specificity

The RTL Mycotoxin Panel is specific for the detection and measurement of 15 specific mycotoxins. Each assay is specific for the mycotoxins specified and do not cross react with any other mycotoxins in the same sample thus not yielding a false positive result.

Accreditation

RealTime Laboratories, Inc. is a CAP (#7210193) and CLIA (#45D1051736) accredited testing laboratory.