

The Clinical Validity of the Mycotoxin Test conducted at RealTime Laboratories, Inc.

And

The Clinical Indications for Testing of and Treating of Mycotoxins.

By

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October 8, 2019.

Why are fungal and mycotoxin testing so important to patients and the physicians who treat them?

The benefits of the mycotoxin tests are far reaching in chronic unexplained disease. The physicians that use RealTime's tests tell the patients it is a toxicology test that complements heavy metals like lead or mercury, carbon monoxide exposure, and solvent exposure, all of which are neurotoxins. Since mold and damp environments are prevalent, it must be considered in chronic persistent neurological symptoms – especially fatigue and alteration of mental function. (Personal Communication).

Some people are very sensitive to molds and their secondary metabolites, mycotoxins. For these people, exposure to molds can lead to symptoms such as stuffy nose, wheezing, and red or itchy eyes, or skin.

Some people, such as those with allergies to molds or with asthma, may have more intense reactions.

Severe reactions may occur among workers exposed to large amounts of molds in occupational settings, such as farmers working around moldy hay (i.e. farmer's lung). Severe reactions may include fever and shortness of breath.

People with a weakened immune system, such as people receiving treatment for cancer, people who have had an organ or stem cell transplant, and people taking medicines that suppress the immune system, are more likely to get mold and thus, mycotoxin infestations. (mycotoxicosis).

What is the Clinical Validity of the test?

Mycotoxicoses are examples of “poisoning by natural means” and thus are analogous to the pathologies caused by exposure to pesticides or heavy metal residues. The **symptoms of a mycotoxicosis** depend on the type of mycotoxin; the amount and duration of the exposure; the age, health, and sex of the exposed individual; and many poorly understood synergistic effects involving genetics, dietary status, and interactions with other toxic insults.

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The severity of mycotoxin poisoning can be compounded by factors such as vitamin deficiency, caloric deprivation, alcohol abuse, and infectious disease status. In turn, mycotoxicoses can heighten vulnerability to microbial diseases, worsen the effects of malnutrition, and interact synergistically with other toxins.

What type of doctor should see patients who are concerned about mold exposure?

The patient should first consult a family or general health care provider who will decide whether the patient needs referral to a specialist. Such specialists might include an allergist who treats patients with mold allergies or an infectious disease physician who treats mold infections. If an infection is in the lungs, a pulmonary physician might be recommended. Patients who have been exposed to molds in their workplace may be referred to an occupational physician or an environmental physician specialist

What are the clinical indications for testing and possible treatment?

Microbial growth may result in greater numbers of spores, cell fragments, allergens, mycotoxins, endotoxins, β -glucans and volatile organic compounds in indoor air. The causative agents of the adverse health effects have not been identified conclusively, but an excess level of any of these agents in the indoor environment is a potential health hazard.

Microbial interactions and moisture-related physical and chemical emissions from building materials may also play a role in dampness-related health effects. Building standards and regulations for comfort and health do not sufficiently emphasize requirements for preventing and controlling excess moisture and dampness.

The prevalence of indoor dampness varies widely within and among countries, continents and climate zones. Indoor dampness is estimated to affect 10–50% of indoor environments in Australia, Europe, India, Japan, and North America. In certain settings, such as river valleys and coastal areas, the conditions of dampness are substantially more severe than the national average.

The amount of water available on or in materials is the most important trigger of the growth of microorganisms, including fungi, actinomycetes and other bacteria. Microorganisms are ubiquitous. Microbes propagate rapidly wherever water is available. The dust and dirt normally present in most indoor spaces provide water availability.

As the relationships between dampness, microbial exposure, and health effects cannot be quantified precisely, no quantitative, health-based guideline values or thresholds can be recommended for acceptable levels of contamination by microorganisms. Instead, it is recommended that dampness and mold related problems be prevented. When they occur, they should be remediated because they increase the risk of hazardous exposure to microbes and chemicals.

Well-designed, well-constructed, well-maintained building envelopes are critical to the prevention and control of excess moisture and microbial growth, as they prevent thermal bridges and the entry of liquid or vapor-phase water. Management of moisture requires proper control of temperature and ventilation to avoid excess humidity, condensation on surfaces and excess moisture in materials. Ventilation should be distributed effectively throughout spaces, and stagnant air zones should be avoided.

Building owners are responsible for providing a healthy workplace or living environment that is free of excess moisture and mold, by ensuring proper building construction and maintenance. The occupants are responsible for managing the use of water, heating, ventilation and appliances in a manner that does not lead to dampness and mold growth.

What are the treatment modalities for fungal disease and mycotoxicosis?

Attempting to treat clinical cases affected by mycotoxins can be beneficial to the patient if the treating physician knows what he/she is treating. However, if not chronic or severe, and caught early enough, the cases usually resolve when the source of toxicity is withdrawn, and the patients are given supportive therapy.

Physicians have used “binders” for toxin removal in the intestinal tract. Other physicians have used hyperbaric oxygen and/or antifungals for treatment of sinusitis and

mycotoxicosis, as well as for disseminated fungal disorders (See Attachment #1). Emphasis is made on ensuring the immune system is intact and strong because the mycotoxins play a major role in immunosuppression. Consequently, transplantation surgeons use a mycotoxin, Mycophenolic Acid (Brand names: Myfortic and Cell Cept) to induce immunosuppression in patients who require an organ transplant.

Supportive therapy includes supplementation for biochemical pathways such as Glutathione and others. Such supplements are chosen at the clinicians' discretion and their understanding of biochemical pathways which may be affected by environmental toxins. If the patient has a disseminated fungal disease, the clinician also can choose to use systemic antifungal therapy (See Attachment #1).

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Attachment #1

Antifungals used for systemic and local fungal infections. *

Amphotericin B - can be used iv for systemic infections or as a Nasal spray (diluted) with EDTA for biofilm Disruption and treatment of focal sinus infections

Caspofungin - iv only for candidemia and mucosal candidiasis

Fluconazole - iv or oral (used primarily for Coccidiomycosis and Cryptococcal meningitis)

Itraconazole - oral, can be used for thrush, esophageal candidiasis and prophylaxis for invasive aspergillosis and candidiasis

Posaconazole - oral candidiasis; used in oral candidiasis refractory to itraconazole

Voriconazole. - iv or oral. For Candidiasis or Fusariosis.

*from Merck Manual 2019.

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