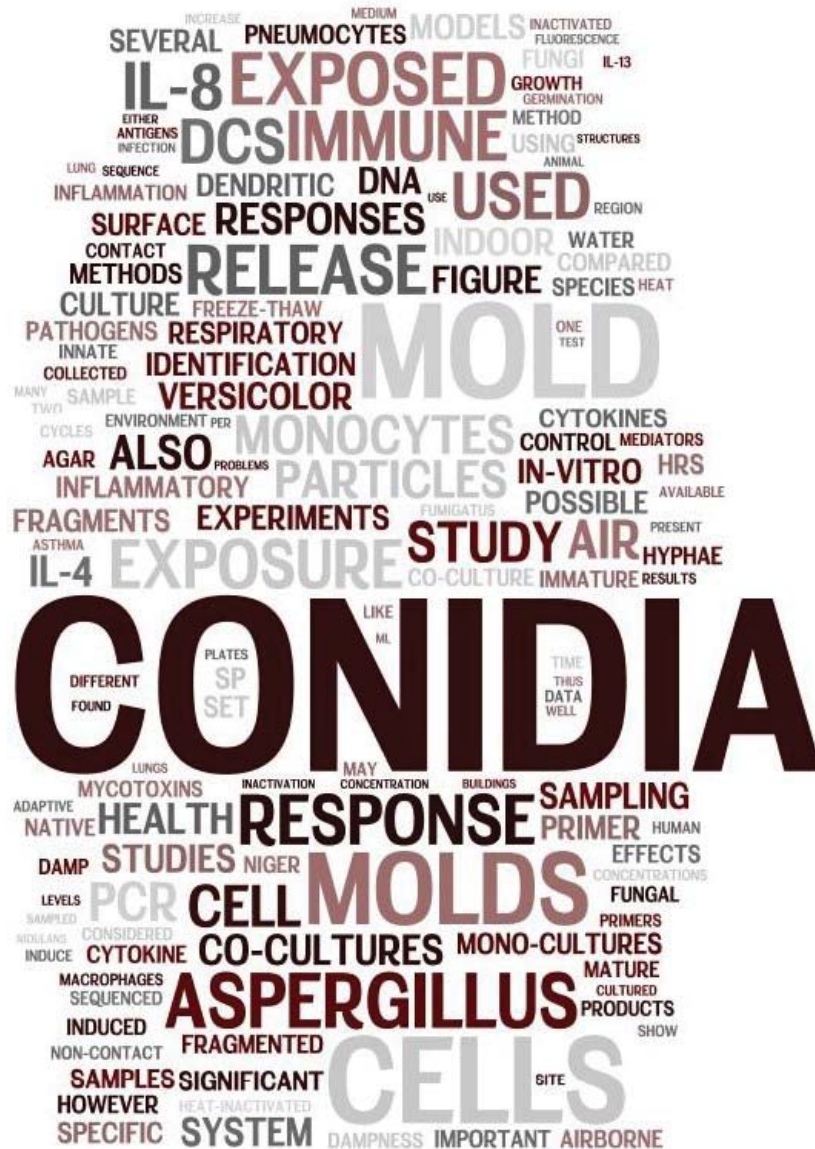


# Urine Testing For Mycotoxins

## Junk Science or Not?

by Gary Rosen, Ph.D.



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In *Proceedings of the 6th International Scientific Conference on Bioaerosols, Mold and Mycotoxins* Sept 6-9 2011:

Dr. Erwin Maertlbauer, a research scientist and expert on the subject of testing for Mycotoxins in foods was asked (see page 172 of *Bioaerosols*<sup>1</sup>):

*Question: “I have patients who come now with “mycotoxins test results” that they get from somewhere in Texas [Real Time Labs] in a lab that claims to be able to test for mycotoxins in human—such as in urine, hair or other body parts as an indicator of mycotoxin exposure from the indoor environment. Could you comment on this and what are your thoughts about this?”*

*Maertlbauer's response: “As far as I know, this laboratory offers testing for Aflatoxins, Ochratoxin and for Trichothecenes. And in regard to Trichothecenes, these are not specified. It remains unclear what a “positive” result means because there are hundreds of Trichothecenes. .. I would guess testing for Trichothecenes, except maybe for Deoxynivalenol (DON), does not make much sense to me. For several reasons: For example these chemicals have a very, very short half-time [half-life]. We do not know exactly how these are metabolized in humans, we do not know what metabolites to look for. And if you have a continuous exposure to DON in food, you will find DON in the urine or other samples. Same applies to Ochratoxin A mycotoxins.*

*“If you have a continuous exposure to Aflatoxin, you will find Aflatoxin in the serum or in tissue samples. We know that. But I doubt that this is related to indoor environment. In the majority of the cases I would say it's directly related to food intake.”*

Comment by Gary Rosen: So if mycotoxins measured in urine are actually from the food we eat why are so many doctors prescribing urine testing for mycotoxins and then when finding Aflatoxin, Trichothecene or Ochratoxin present create a panic about the indoor environment? And a panic for immediate treatment with toxin binders? That is the question we ask in the following review: *Urine Testing for Mycotoxins — Junk Science or Not.*

The review author (Dr. Rosen) firmly believes that elevated levels of mycotoxins in the indoor air can be harmful to mold sensitive individuals and that treatment of mycotoxin exposure with toxin binders (charcoal, cholestyramine, clays or algae cell walls ) under a doctor's care can play an important role in restoring the health of the exposed (mold sensitive) individual. The issue here is in regard to commercial mycotoxin testing — *Junk Science of Not?*

**The question is whether urine testing for mycotoxins is a useful tool or unproven i.e. Junk Science?**

## Urine Testing for Mold Toxins—Junk Science or Not?

**Background:** I'd like to review why I started looking into this issue, asking the question: Commercial mycotoxin testing (typically for Aflatoxin, Ochratoxin and Trichothecene) — Junk Science or Not?

First was the research presentation by Dr. Erwin Maertlbauer<sup>1</sup> at the 6th Annual Mold & Mycotoxins Conference in Saratoga NY several years back discussed on the previous page. Though he is a noted authority on testing for mycotoxins in food, his response is certainly one person's perspective and perhaps can be discounted.

Then last November 2014, I attended the World Mycotoxin Conference<sup>2</sup> in Vienna Austria. Top scientists from all over the world were there to present their studies on mycotoxins — how they impact health; how to test for them; how to reduce their levels in crops and in people, and many other topics. Dozens of researchers were discussing the latest advances in mycotoxin testing as well as comparing and evaluating the different types of mycotoxin testing methodologies. To make a long story short, the evidence I heard was all in favor of Maertlbauer's position, that currently available commercial urine testing for mycotoxins does not test for mycotoxins from the indoor environment but from trace levels of mycotoxins that are always present in the daily food we eat<sup>3</sup>.

Over the years I have visited homes of people that were found to have high levels of mycotoxins in their urine but were not being exposed to these toxins in their homes. It was suggested to me that large reservoirs of such toxins exist in the body from prior exposures which was why they were showing up in urine. But according to available research<sup>4</sup>, it is known that high levels of mold toxins are not typically stored but are quickly eliminated from body serums. DON, a trichothecene, for example is eliminated from the body in *hours* see table below.

**Some of the Experimentally-defined Half Lives of Certain Mycotoxins**

Toxin	Half Life	Reference
<b>Aflatoxin B1</b>	91.8 hr	Coulombe R.A. Jr. and Sharma R.P. (1985) "Clearance and excretion of intratracheally and orally administered aflatoxin B1 in the rat." <i>Food Chem Toxicol.</i> 23(9):827-830
<b>Deoxynivalenol (DON, vomitoxin)</b>	7.1 hr	Prelusky, D.B., Hartin, K.E., Trenholm, H.L., Miller J.D. (1988) Pharmacokinetic fate of 14C-labeled deoxynivalenol in swine. <i>Fundam Appl Toxicol;</i> 10(2):276-286

Out of the three mycotoxins tested for (Aflatoxin, Ochratoxin and Trichothecene), Trichothecene is the toxin of most concern because it is produced by the "toxic mold" *Stachybotrys*. Regarding Trichothecene (DON, T-2, Satratoxin etc), according to the U.S. Surgeon General Report<sup>5</sup>: "Regardless of the route of administration or the species of animal tested, the trichothecene mycotoxins were *rapidly metabolized* and excreted in urine and feces."

But all the patients with high levels of mold toxins in their urine are claimed<sup>6</sup> to be very poor at detoxing in general. Why were there high levels of (detoxified) mold toxins in their urine if they were bad at detoxing? Made no sense. More likely as Maertlbauer claimed the mold toxins in their urine were from daily intake of foods contaminated with trace amounts of mycotoxins. Low levels of mycotoxin contaminants in food is commonplace especially in the U.S. where government restrictions on mycotoxins contaminants in food is lax or non-existent vs the E.U. where six common mycotoxins are strictly regulated in both animal and human food.

I've carefully read several recently published papers<sup>7,8</sup> that were based on using Real Time Labs to analyze mycotoxins in urine. (I'll discuss the specifics later.) I had some questions about the papers and what appeared to be either errors or inconsistencies. I had emailed the authors of these papers, as well as the Journal that published the papers, for contact information on the reviewers to discuss these issues and ask my questions. I received no response at all from the Journal or from the lead authors. And I was told by one of the paper's secondary authors that I was considered, by the lead authors, to be arrogant for asking such questions and for doubting the integrity of the people involved. Please note — Lack of transparency is a hallmark of Junk Science.

I asked why no one else has ever reproduced their urine testing for mycotoxins procedures or results and was told that the techniques are proprietary and patent pending. Science *requires* that others are able to reproduce one's methods as well as results and if not — then it is Junk Science.

↓ See LA Times exposé on Real Time Labs ↓

The LA Times exposé on Dr. Hooper, President of Real Time Labs<sup>9</sup> ([www.latimes.com/local/la-me-kdday3dec07-story.html#page=1](http://www.latimes.com/local/la-me-kdday3dec07-story.html#page=1)) does not contribute to this reviewer's (Dr. Rosen's) confidence in the Real Time Lab procedures or results.

## Reproducibility & Peer Review

Science is not science unless another independent party can and does independently reproduce the testing and independently come up with the same results and conclusions. Beware of studies that are not peer reviewed; not independently verified (repeated) by others; and with outcomes that tend to benefit the authors, for example the lab doing the analysis or the doctors treating similar patients. Such studies are *often* Junk Science.

There have been many cases of Junk Science also called Pathological Science or Voodoo Science. See article at: [http://en.wikipedia.org/wiki/Pathological\\_science](http://en.wikipedia.org/wiki/Pathological_science).

## Analysis of Published Research

Studies by Joseph Brewer using Real Time Labs<sup>7,8</sup> (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3705282/> and <http://www.mdpi.com/2072-6651/6/1/66>) conclude that the toxins in the urine of people with Chronic Fatigue Syndrome are due to mold colonizing patient sinuses and that mycotoxins are actually causing CFS (therefore go immediately for treatment!). The three toxins tested for were Aflatoxin, Ochratoxin and Macrocylic Trichothecene. One of the three mold toxins found in urine in these same studies was Macrocylic Trichothecene — Satratoxin from *Stachybotrys* mold. The articles stated that it is known that:

- *Stachybotrys* does not grow on or in human tissue.
- Patients were no longer in water damaged homes. So there is no current exposure.

Furthermore, *Stachybotrys* toxins are not present in commercial foods. Therefore, if

- Not from food & not from growing in the body for example not growing in sinuses;
- Not stored in body fluids as the body starts to detox Satratoxin in minutes<sup>10</sup>; and
- Not from the environment as patients are no longer in the water damage home.

The only possible conclusion for finding *Stachybotrys* toxin in patient urine is that what is being measured is a false positive and that there is a major problem with the RTL measurements of toxins in urine.

It is widely known that the methods used by Real Time Labs to test for Satratoxin (which is a type of [trichothecene](#)<sup>11</sup>) cross reacts with other Trichothecenes that are very often found in food.

Trichothecenes are produced by *Fusarium*<sup>12</sup> mold that commonly contaminates corn, wheat, rice and barley. Such toxins are present in diets of all Americans and Europeans.

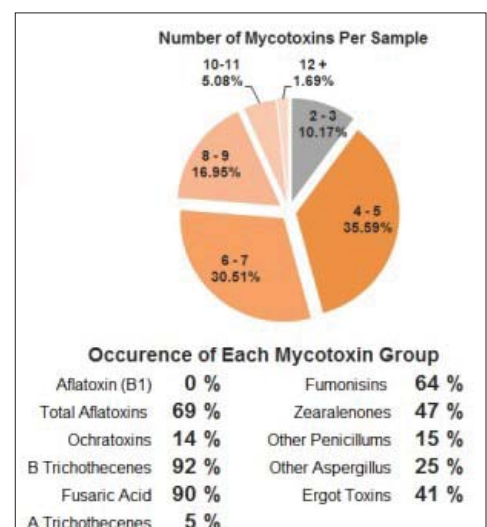
Trichothecenes are strictly regulated in foods produced or imported into the E.U.<sup>13</sup> but there is no such quality control or monitoring program in the U.S.

## Mycotoxins Commonly Found in Food

The Table to the right shows the number of mycotoxins present in U.S. corn (from Alltech.com web site.) Trichothecenes (typically from *Fusarium*) are in abundance.

Most likely this is the source of Trichothecene in RTL urine tests. Not from sinuses and not from being stored in the body and *not from indoor mold exposure*.

**All strong evidence of Junk Science status for urine testing for mold toxins.**



## Mycotoxins Commonly Found in Water Damaged Buildings

From research in *Mold and Mycotoxins in Indoor Environments— A Survey of Water Damaged Buildings*<sup>14</sup> see chart below:

The mycotoxins tested for and found in patient urine in the Brewer studies are the mycotoxins *least commonly* found in water damaged homes. But again the ones tested for are some of toxins most commonly found in foods. Why pick Aflatoxin, Ochratoxin and Satratoxin to test in urine? Nowhere in any of the research articles based on RTL urine analysis for mycotoxins is this question answered. Strong evidence of Junk Science status for urine testing for mold toxins.

*Journal of Occupational and Environmental Hygiene*, 6: 671–678  
Molds and Mycotoxins in Indoor Environment - A Survey in Water-Damaged Buildings.

### No. of Samples in the Indicated Building Material in Which Mycotoxins were Detected

	<b>Gypsum Board</b> n = 40	<b>Wood Based</b> n = 37	<b>Linoleum Flooring</b> n = 7	<b>Wallpaper</b> n = 6	<b>Other<sup>A</sup></b> n = 10
TRID (Trichodermol)	12	4	nd	2	3
VER (Verrucarol)	nd	3	nd	nd	nd
STRG (Sterigmatocystin)	2	3	nd	2	1
TRID, VER	8	5	nd	nd	2
TRID, STRG	3	1	nd	1	nd
VER, STRG	1	nd	nd	nd	1
STRG, AFLAB (Aflatoxin B1)	nd	nd	nd	nd	nd
TRID, VER, GLIO (Gliotoxin)	nd	nd	1	1	nd
TRID, VER, STRG	2	3	nd	nd	nd
TRID, VER, SATG/H (Satratoxin)	2	nd	nd	nd	nd
TRID, VER, SATG	1	nd	nd	nd	nd
TRID, VER, STRG, SATG/H	2	nd	nd	nd	nd
VER, STRG, SATG, SATH	nd	nd	nd	nd	nd

### Toxicology 101 in 30 Seconds or Less

When we are exposed to mold toxins from any source (indoor air or trace levels in food) our detox systems, typically via glutathione mediated detox<sup>15</sup> pathways, chemically modify the toxins into a derivative form that is readily excreted by the body. Detox of mold toxins in our blood is typically performed in the liver and kidneys. The biotransformed *toxin derivatives and not the original mycotoxins* are excreted in the stool and in urine.

According to the U.S. Surgeon General's report<sup>16</sup> on Trichothecene mycotoxin used as a bioweapon:

*“Four hours after swine received intravenous tritium-labeled T-2 toxin, glucuronide conjugates represented 63% of the metabolic residues in urine, and 77% in bile. The formation of glucuronide conjugates generally results in the elimination of toxicological activity of xenobiotics, which in certain species could represent a major route of detoxification of trichothecene mycotoxins.*

*In summary, then, very little of the parent trichothecene mycotoxin is excreted intact. Rather, elimination by detoxification of the toxin is the result of extensive and rapid biotransformation.”*

When a lab such as Alltech, EMSL<sup>17</sup> or other tests foods for mycotoxin contamination they have a relatively easy job. They purchase the lab equipment for the testing from commercial sources and they purchase the pure forms of the mycotoxins from established chemical supply houses. These pure forms of mycotoxins are then used to calibrate the equipment and run as simultaneous controls during analysis.

When Real Time Labs (RTL) is testing for Ochratoxin, Aflatoxin or Trichothecene in urine they cannot actually test for these toxins because these toxins never exist in urine. Only the detoxified (biotransformed) derivatives (also called metabolites) of these mycotoxins are present in urine. The detoxified derivatives of Ochratoxin, Aflatoxin or Macrocytic have different chemical properties and molecular weights from the original mycotoxins and as such do not consistently cross react with immunoassays<sup>18,19,20</sup> developed to detect the actual (non-detoxified) mycotoxins one is exposed to from either foods or moldy indoor environments.

So when you read in an article that tests for mycotoxins in urine by RTL where they claim that they purchased pure mycotoxins from such and such a source to calibrate their equipment ... there's a problem. They are using a completely different chemical to calibrate their systems than what they are attempting to measure in urine which is the biotransformed derivative of the toxin and not the original toxin ingested or breathed.

Furthermore, in the papers published by Brewer<sup>7,8</sup>, Real Time Labs uses (as explained in their papers) a different toxin — roridin and not satratoxin — to develop and calibrate their equipment for analysis of Satratoxin (which RTL calls Macrocytic Trichothecene.) How could they expect to have meaningful results?

Studies by leading researchers find that detection of mycotoxins in urine even with much higher end equipment than used by labs doing commercial urine testing are fraught with problems including false positives<sup>21</sup>.

There is no doubt that people are constantly being exposed to mycotoxins in the foods they eat which can account for finding detoxified mycotoxins in urine. Detoxified mycotoxins in urine when people are not being exposed to mold contaminated environments are *from consumption*.

High levels of detoxified mycotoxins are not present in urine as a result of being stored for long periods in the body from earlier mold exposure since the rate of mycotoxins detox from bodily fluids is hours or days and not months or years.

As mentioned, Trichothecenes in food are highly regulated in the E.U. but not regulated at all in the U.S. So we can expect some level of these mycotoxins to always be present in foods that are eaten and that if one's detox system is working well their detoxified derivatives would be present in urine (and stool.)

Finding mycotoxin derivatives in urine will generally mean that one's detox system is working well and these toxins are not being accumulated.

What does finding mold toxins derivatives in urine really mean *if* they are measured?

- Doesn't it mean that one's detox system is working well?
- Doesn't it mean that you are eating foods that contain mycotoxins (grains generally) and your body is doing its job of removing the toxins before they cause damage?
- Or, does it mean that you are in a water damaged/ mycotoxin infested home?

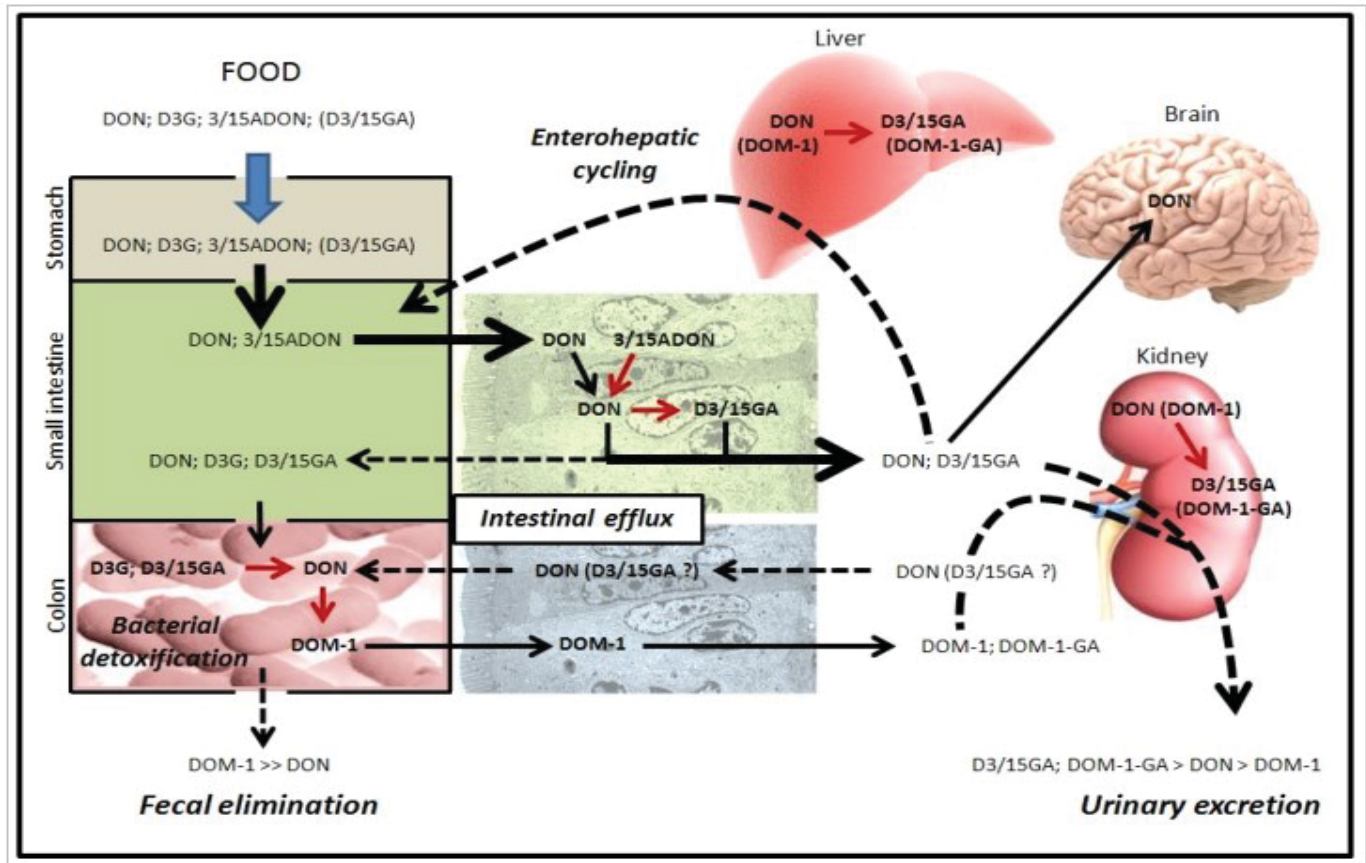
According to RTL: "People with HLA-DRBQ genetic makeups cannot make antibodies to mold toxins. Hence we cannot effectively remove these toxins from our body like other people." (<https://cdn.shopify.com/s/files/1/0245/5023/files/bombshell-bonus-chapter.pdf>)

- If people with that genetic makeup cannot detox well ... why is so much detoxified mold toxin showing up in their urine as a result of their ability to detox?

**All of these questions need to be answered otherwise studies using the RTL technique should be classified as Junk Science.**

## Metabolites of Trichothecenes

DON is the most common trichothecene in the food chain. A great deal is known about DON compared to other trichothecenes about how it is metabolized in the body and what its derivatives are<sup>21</sup>. See DON detox and excretion pathway below. Once in the gut, DON (another name for DON is Vomitoxin) is rapidly converted to less toxic derivatives by both gut microflora as well as the human body's detox pathways. Very little of the original DON trichothecene is excreted in the urine. Studies in humans has shown that 91% of the DON excreted in urine is glucuronide-DON, D15GA being predominantly found.<sup>22</sup>



Bottom line is that for Trichothecenes whatever is ingested is not what is excreted in either urine or fecal matter. The detoxification and conversion to metabolites that are readily excreted from the body is rapid. The same is also the case for Ochratoxin<sup>23</sup> and Aflatoxin<sup>23</sup>. Ochratoxin and Aflatoxin are not excreted by the human body. Only detoxed metabolites are excreted.

Therefore when RTL states they are testing for Trichothecene or Ochratoxin or Aflatoxin in urine and finding high levels, that is complete nonsense. Because if there was exposure to any of these three toxins either from the indoor environment or food they would not be present in urine, only derivatives would be present.

Calibrating test equipment using Trichothecene or Ochratoxin or Aflatoxin to test for the metabolites of Trichothecene or Ochratoxin or Aflatoxin makes no sense at all as the metabolites have vastly different chemical properties, molecular weights and binding ability to antibodies employed in the ELISA (immunoassay) testing performed by RTL.



## Mold Growth in Sinuses

In the ground breaking Mayo Clinic study *The Diagnosis and Incidence of Allergic Fungal Sinusitis*, Ponikau et al<sup>23</sup> have analyzed the fungal growth in sinuses of 210 patients with chronic fungal sinusitis. The molds and yeasts colonizing the sick patient's sinuses are listed on the right.

The remarkable feature of this list is not only how many different molds and yeasts can and do grow in sinuses, but that there is:

- No correlation between mold growing in sinuses and the molds producing toxins that are tested for in commercially available urine testing for mycotoxins.

Commercial urine testing for mycotoxins tests (Real Time Labs) tests for:

- Aflatoxin (from *A. flavus*)
- Ochratoxin (from *A. ochraceus*)
- Satratoxin — Macrocytic Trichothecene (from *Stachybotrys*.)

From the list on the right, the occurrence of Aflatoxin producing mold is relatively small in terms of the percentage of persons infected by *A. flavus*.

Neither *A. ochraceus* nor *Stachybotrys* were found in any of the 200+ patients with Chronic Sinusitis.

The latest research by Ponikau et al<sup>24</sup> finds that chronic rhinosinusitis (CRS) is a disease that affects 14.2% of the US adult population and the release of mycotoxins is NOT a factor in CRS.

Table 1. Number of Organisms (in Alphabetical Order) Recovered From Patients With Chronic Rhinosinusitis (N=210) and Percentage of Patients Colonized With the Species

<i>Acremonium</i>	5 (2.4%)
<i>Alternaria</i>	93 (44.3%)
<i>Arachniotus citrinus</i>	3 (1.4%)
<i>Arthrographis kalrae</i>	1 (0.5%)
<i>Aspergillus</i>	62 (29.5%)
<i>A. flavus</i>	8
<i>A. fumigatus</i>	17
<i>A. glaucus</i>	6
<i>A. nidulans</i>	1
<i>A. niger</i>	5
<i>A. terreus</i>	2
<i>A. versicolor</i>	15
<i>A. versiforme</i>	1
<i>Aspergillus</i> species*	7
<i>Aureobasidium</i>	8 (3.8%)
<i>Beauveria</i>	2 (1.0%)
<i>Bipolaris</i>	2 (1.0%)
<i>Candida</i>	45 (21.4%)
<i>C. albicans</i>	31
<i>C. krusei</i>	1
<i>C. lipolytica</i>	1
<i>C. lusitanae</i>	1
<i>C. parapsilosis</i>	9
<i>C. tropicalis</i>	1
<i>Candida</i> species*	1
<i>Chaetomium</i>	3 (1.4%)
<i>Chrysosporium</i>	2 (1.0%)
<i>Cladosporium</i>	82 (39.0%)
<i>Cryptococcus</i>	4 (1.9%)
<i>C. albidus</i>	1
<i>C. laurentii</i>	2
<i>Cryptococcus</i> species*	1
<i>Curvularia</i>	2 (1.0%)
<i>Epicoccum</i>	12 (5.7%)
<i>Exophiala jeanselmei</i>	2 (1.0%)
<i>Fusarium</i>	34 (16.2%)
<i>Geotrichum</i>	10 (4.8%)
<i>Gliomastix</i>	1 (0.5%)
<i>Monilia</i>	3 (1.4%)
<i>Mucor</i>	4 (1.9%)
<i>Nigrospora</i>	1 (0.5%)
<i>Oidioendron</i>	1 (0.5%)
<i>Paeclomyces</i>	5 (2.4%)
<i>Papularia</i>	4 (1.9%)
<i>Penicillium</i>	91 (43.3%)
<i>Phoma</i>	2 (1.0%)
<i>Pithomyces</i>	14 (6.7%)
<i>Pseudallescheria boydii</i>	1 (0.5%)
<i>Rhinochadiella</i>	3 (1.4%)
<i>Rhizopus</i>	5 (2.4%)
<i>Rhodotorula</i>	4 (1.9%)
<i>R. minuta</i>	2
<i>Rhodotorula</i> species*	2
<i>Saccharomyces cerevisiae</i>	1 (0.5%)
<i>Saghamala</i>	1 (0.5%)
<i>Scotlecobasidium</i>	1 (0.5%)
<i>Scopulariopsis</i>	3 (1.4%)
<i>S. brumptii</i>	1
<i>Scopulariopsis</i> species*	2
<i>Trichoderma</i>	8 (3.8%)
<i>Trichophyton</i>	2 (1.0%)
<i>T. rubrum</i>	1
<i>Trichophyton</i> species*	1
<i>Trichosporon beigeli</i>	1 (0.5%)
<i>Ustilago</i>	13 (6.2%)
Total No. of organisms	541

\*Subclasses not available.


Recent claims by J. Brewer<sup>6,7</sup> using Real Time Labs for mycotoxin analysis of urine, that high levels of Aflatoxin (from *A. flavus*), Ochratoxin (from *A. ochraceus*) and Trichothecene (from *Stachybotrys*) measured in urine are due to toxins produced by mold growing in sinuses would appear to be completely unfounded based on this major Mayo clinic study.

An explanation needs to be provided as to why conclusions from the J. Brewer/ Hooper papers are contrary to work by researchers at the Mayo clinic — otherwise J. Brewer/ Hooper work should be classified as Junk Science.

## RTL Mycotoxin Panel Reports

Below we show two RTL Mycotoxin Panel Reports posted at SponaugleWellness.com:

- The Real Time Labs Mycotoxin Panel Report on the top is for patient Laurie prior to treatments for mold toxin removal.
- Pre-detox results are negative for Ochratoxin, slightly elevated for Aflatoxin and very high for Trichothecene group.
- The Real Time Labs Mycotoxin Panel Report below is for patient Laurie after treatments for mold toxin removal. Post-detox results are negative for OT & AT and still highly elevated for Trichothecenes.
- What is interesting is that in all the earlier papers published by RTL they discuss measuring Macrocytic Trichothecene (MT) which is the toxin from the toxic indoor mold Stachybotrys (also called Satratoxin) but in this very recent report they say Trichothecene group which means any Trichothecene and not only MT.
- This is an important distinction as Trichothecenes as a group are widely found in diet but MT (Satratoxin) is not found in diet but found only in water damaged homes.



**MYCOTOXIN PANEL REPORT FORM**  
07/29/2014

RealTime Laboratories, Inc  
4100 Fairway Drive, Ste 600  
Carrollton, TX 75010  
Phone: 1-972-492-0419  
Fax: 1-972-243-7759  
Website: www.realtimelab.com  
Email: info@realtimelab.com  
CLIA #: 45D1051736  
CAP #: 7210193  
TaxId#: 45-0669342

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**Patient:** Laurie  
**Patient Date of Birth:**  
**Date of Receipt:** 07/29/2014  
**Date of Report:** 07/29/2014  
**Ordering Physician:** Marvin Sponaugle  
 Florida Detox  
 32815 US Highway 19N, Palm Harbor, FL 34684-3123

**Accession No:** 143530  
**MRN:**  
**Date of Service:** 07/28/2014  
**Specimen:** Urine

**Procedure Type**

Ochratoxin A - Procedure by ELISA  
 Aflatoxin Group - Procedure by ELISA  
 Trichothecene Group - Procedure by ELISA


**Results:**

Code	Test	Specimen	Value	Result	Negative if less than	Equivocal if between	Positive if greater or equal
E8501	Ochratoxin A	Urine	0 ppb	Negative	1.8 ppb	1.8-2.0 ppb	2.0 ppb
E8502	Aflatoxin Group	Urine	1.29 ppb	Positive	0.8 ppb	0.8-1.0 ppb	1.0 ppb
E8503	Trichothecene Group	Urine	82.63 ppb	Positive	0.18 ppb	0.18-0.2 ppb	0.2 ppb

Director Signature \_\_\_\_\_

Tests such as this should be used only in conjunction with other medically established diagnostic elements (e.g., symptoms, history, clinical impressions, results from other tests, etc). Physicians should use all the information available to them to diagnose and determine appropriate treatment for their patients.  
 Disclaimer: This test was developed and its performance characteristics determined by RealTime Lab. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

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**MYCOTOXIN PANEL REPORT FORM**  
08/08/2014

RealTime Laboratories, Inc  
4100 Fairway Drive, Ste 600  
Carrollton, TX 75010  
Phone: 1-972-492-0419  
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Website: www.realtimelab.com  
Email: info@realtimelab.com  
CLIA #: 45D1051736  
CAP #: 7210193  
TaxId#: 45-0669342

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**Patient:** Laurie  
**Patient Date of Birth:**  
**Date of Receipt:** 08/06/2014  
**Date of Report:** 08/08/2014  
**Ordering Physician:** Marvin Sponaugle  
 Florida Detox  
 32815 US Highway 19N, Palm Harbor, FL 34684-3123

**Accession No:** 144381  
**MRN:**  
**Date of Service:** 08/4/2014  
**Specimen:** Urine

**Procedure Type**

Ochratoxin A - Procedure by ELISA  
 Aflatoxin Group - Procedure by ELISA  
 Trichothecene Group - Procedure by ELISA

**Results:**

Code	Test	Specimen	Value	Result	Negative if less than	Equivocal if between	Positive if greater or equal
E8501	Ochratoxin A	Urine	0 ppb	Negative	1.8 ppb	1.8-2.0 ppb	2.0 ppb
E8502	Aflatoxin Group	Urine	0 ppb	Negative	0.8 ppb	0.8-1.0 ppb	1.0 ppb
E8503	Trichothecene Group	Urine	3.12 ppb	Positive	0.18 ppb	0.18-0.2 ppb	0.2 ppb

Director Signature \_\_\_\_\_

Tests such as this should be used only in conjunction with other medically established diagnostic elements (e.g., symptoms, history, clinical impressions, results from other tests, etc). Physicians should use all the information available to them to diagnose and determine appropriate treatment for their patients.  
 Disclaimer: This test was developed and its performance characteristics determined by RealTime Lab. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

## **The Real Time Labs Mycotoxin Panel Report pre-detox urine test.**

Date of service: 7/28.

Date of Receipt 7/29.

Date of Report 7/29.

The report shows a one day turn around time. (That's good.)

Two mycotoxins (Aflatoxin and Trichothecene) are indicated to be elevated urine. But what does the Real Time Labs Mycotoxin Panel Report pre-detox test prove?

- That Laurie is detoxing well?
- That she is eating food with a large amount of Trichothecene and some Aflatoxin in it?
- That she is in a mold contaminated home?

## **The Real Time Labs Mycotoxin Panel Report post-detox urine test.**

Date of service: 8/4.

Date of Receipt 8/6.

Date of Report 8/8.

The report shows a four day turn around time. (Not so good.)

One mycotoxin (Trichothecene) is now indicated to be elevated urine. There is no longer any Aflatoxin present. But what does the Real Time Labs Mycotoxin Panel Report post-detox test show/prove?

- That Laurie is now detoxing poorly as there are less toxins in her urine?
- Is this result now good with Trichothecene levels (3.12 ppb) in urine 17 times acceptable levels?
- That she now has changed her diet and is not eating food with Trichothecene in it?
- That she has been in treatment staying in a hotel and no longer exposed to Trichothecenes whereas earlier she was in a mold toxin contaminated house?

Or is the only difference that the lab samples for the second test took 4 days to analyze instead of 1 day and the toxins broke down in the three extra days so the testing is not valid?

What does the lab results showing reduction in mycotoxins in urine mean? Certainly hard to say. What one wants to know is if the reduction in mycotoxins in Laurie's blood has any correlation with reduction of symptoms. That's really what we care about.  
Is the treatment making Laurie better?

## **Measuring Outcomes of Toxin Binding Treatment — VCS Deficit**

In regard to patient Laurie, the toxin binding treatment for mold toxins has (allegedly) dramatically decreased the levels of toxins in urine, especially Trichothecene.

One would certainly like to see in addition to reduction of toxins in urine, that symptoms resulting from mold toxin exposure are being relieved or reduced as the result of clearing the majority of the toxins from the body. However due to the number of organs affected by mycotoxins such as Trichothecene, this can be a complex undertaking as explained in the review *Mycotoxins*.<sup>26</sup>

*“The symptoms produced by various trichothecenes include effects on almost every major system of the vertebrate body; many of these effects are due to secondary processes that are initiated by often poorly understood metabolic mechanisms related to the inhibition of protein synthesis.”*

However we do know from the Surgeon General report<sup>11</sup> that exposure to trichothecene mycotoxins results in neurological impairment. Neurological impairment can be tested for quite easily and cheaply using Visual Contrast Sensitivity (VCS) testing. VCS testing is part of a panel of neurobehavioral tests recommended by the Agency for Toxic Substances and Disease Registry for use in community studies of residents exposed to neurotoxins.<sup>27, 28</sup>

And from research by Dr. Kenneth Hudnell when working for the EPA<sup>29,30</sup>, Visual Contrast Sensitivity<sup>31</sup> (VCS) deficit testing can be an effective tool for tracking the success of toxin binding therapy on biotoxin exposed individuals.

The U.S. Center for Disease Control<sup>32</sup> (Sept 2010) study *Comparison of Mold Exposures, Work-related Symptoms, and Visual Contrast Sensitivity between Employees at a Severely Water-damaged School and Employees at a School without Significant Water Damage* found:

*“significantly lower visual contrast sensitivity test results [impairment] for AFSHS [the name of the water damaged school] compared with WHHS [the name of the control — not water damaged building] employees,”*

*“Persons reporting one or more lower respiratory symptoms [from being in the moldy building] had significantly lower mean VCS values at all spatial frequencies than those reporting no lower respiratory symptoms”*

- Visual Contrast Sensitivity (VCS) Testing is easy and cheap (can be done on the internet but we recommend that it be done under doctor supervision).
- VCS can be used to track the success of toxin binding therapy on biotoxin exposed individuals.
- VCS testing has been validated by the CDC for measuring mold exposure.

So why isn't VCS testing being used here to answer the questions:

- Is the treatment making Laurie better?
- Is there a correlation between reduction of mycotoxins in urine and neurological impairment?

VCS testing is low cost, simple and easily available (Internet) and with confirmation of its validity by the CDC. It is not clear to me why patients that are spending a fortune on detox and urine testing for mycotoxins would not take a series of VCS tests before, during and afterwards to, if not validate the procedure, at least provide another vector as to the effectiveness of the detox beyond basing success solely on urine analysis of mycotoxins.

I am not sure why. Makes no sense.

Caution on VCS testing: VCS testing has been used to document subclinical neurobehavioral effects in persons exposed to neurotoxins and has recently been reported to be affected by exposure to water-damaged buildings. VCS tests are considered superior to visual acuity tests for detecting visual loss. Visual acuity tests (similar to the tests done by optometrists when ordering eyeglasses) generally detect refractive disorders, whereas VCS tests may detect visual changes due to chemical exposures even though visual acuity is normal (e.g., 20/20).

VCS can be affected by a number of factors including age, hypertension, diabetes, head injury, alcohol consumption; and various eye conditions such as cataract, glaucoma, LASIK and other eye surgery. VCS testing should be done under doctor supervision.

## Measuring Outcomes of Toxin Binding Treatment — Mold Problems in Homes

In regard to patient Laurie, as noted, the toxin binding treatment for mold toxins has (allegedly) dramatically decreased the levels of toxins in urine especially Trichothecene.

- ◆ But was the original elevation in urine from food intake or from indoor environmental exposure?
- ◆ Did the indoor environment actually contain elevated levels of toxin producing molds?
- ◆ Specifically, was the indoor environment tested to see if Aflatoxin, Ochratoxin or Trichothecene producing molds were present?

Treatment for mold related illness due to environmental exposure should never be performed without FIRST assessing/ testing the indoor environment. This is relatively simple and easy to do and not costly compared to the cost of treatment, accommodations, meals, missed work, etc.

Visual inspection for water damage as well as assessment for visible mold is important and recommended, however, two factors: Mold Odor & DNA-based ERMI testing<sup>33,34,35,36,37,38</sup> have been found in combination to be the most reliable methods for determining mold exposure. And *exposure* is what we care about.

DNA-based ERMI (Environmental Relative Moldiness Index) testing can be used to accurately and reliably determine if there are elevated levels of Aflatoxin, Ochratoxin or Trichothecene producing molds in the indoor environment. If molds producing these toxins are not present in the indoor environment then finding any of these three toxins in urine at elevated levels has nothing to do with the indoor environment as mycotoxins are not stored in bodily fluids from earlier exposure. If high levels of mycotoxins are found in urine and if the indoor environment is not problematic, the toxins are from food and their excretion (in urine and stool) is a normal process and signifies that one's detox system is working well.

Traditional ERMI testing collects settled dust or carpet dust for analysis. There are certain limitations to sampling accumulated floor dusts. In our experience and in the experience of others<sup>39,40,41</sup> collecting either indoor air samples for ERMI analysis or dust from the home's air filter for DNA analysis is preferred to collecting carpet or floor dust.

Why? Because health related mold exposure is from mold spores and fragments in the indoor air one breathes and not necessarily from (perhaps 10 year old) carpet with embedded mold that was perhaps dragged in on dirty shoes.

Such ERMI sampling (air and/or air filter dust) should be conducted along with mold odor and visual inspection especially of the AC, AC closet, ducting to provide the most reliable method for evaluating the indoor environment for mold exposure.

Once the problem is properly assessed, remediation is typically straightforward and relatively inexpensive except in very old homes.

Once an environment is assessed to be problematic, in many cases properly fixing the indoor environment, which can usually be done in a few days, returns the individual to health with limited or no medical treatment.

No doubt many mold sensitive or immuno-compromised individuals will need treatment under doctor supervision to regain their health; but it is a certainty —

If the environment continues to be mold contaminated, no matter how brilliant the doctor, the patient will never return to health.

## Conclusions

Specialty research labs throughout the world do have the capability to accurately and reliably test for mycotoxin metabolites in urine<sup>42,43,44</sup>. But what these research labs do and how they do it bears little to no resemblance to the proprietary procedures used by Real Time Labs.

Commercial urine testing for mold toxins is it junk science? YES we think it is. Others<sup>45</sup> including the CDC agree<sup>46</sup>.

See attached recent CDC bulletin dated Feb 2015: *Use of Unvalidated Urine Mycotoxin Tests for the Clinical Diagnosis of Illness*.

So do *you* think commercial urine testing for mold toxins is junk science? Before answering, I ask you again to read through the LA Times Exposé on Hooper (President of Real Time Labs) that was referred to earlier on page 4.

**[www.latimes.com/local/la-me-kdday3dec07-story.html#page=1](http://www.latimes.com/local/la-me-kdday3dec07-story.html#page=1)**

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## Morbidity and Mortality Weekly Report (MMWR)

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# *Notes from the Field: Use of Unvalidated Urine Mycotoxin Tests for the Clinical Diagnosis of Illness — United States, 2014*

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## *Weekly*

**February 20, 2015 / 64(06);157-158**

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In February 2014, CDC's National Institute for Occupational Safety and Health received a request for a health hazard evaluation from a union representative in an office building. A female employee reported the onset of symptoms involving multiple organ systems upon returning to work after a prolonged absence. The employee searched the Internet for descriptions of symptoms matching hers, found a laboratory offering "toxic mold testing" direct to consumers, and submitted a urine sample, despite the absence of musty odors and signs of fungal growth in her office. The laboratory reported "positive" concentrations of two mycotoxins: ochratoxin at 2.8 parts per billion (ppb) and tricothecenes at 0.4 ppb. The laboratory cutoff for "positive" was  $\geq 2.0$  ppb for ochratoxin and  $\geq 0.2$  ppb for tricothecenes. The interpretation accompanying the laboratory report said the results "revealed that you have an unusual level of that mycotoxin(s) present in your body."

The laboratory referred the employee to a clinic specializing in "medical treatment for mold exposure and mold illness," where she was examined, diagnosed with mold toxicity, and prescribed an antifungal medication. Antifungal medications are used to treat fungal infections, not illnesses caused by toxins produced by fungi. Also prescribed were dietary modification (eating only canned chicken and white rice for 3 days) and several nonstandard medical treatments (e.g., bowel evacuation or hydrocolonic irrigation, cupping therapy, and ionic nasal spray).

Two consultants, one hired by the building manager and one by the employee, carried out destructive testing (removal of drywall, carpet, and ceiling tiles) in the employee's office. No evidence of water damage or significant fungal growth was found. The cost to the building manager exceeded \$25,000. The employee remained convinced that mold exposure occurred in the workplace. Some coworkers, aware of the destructive testing and the urine mycotoxin testing, began to attribute nonspecific symptoms to workplace mold exposures.

The laboratory mentioned its Clinical Laboratory Improvement Amendments (CLIA) certification on its reports and noted that the urine mycotoxin testing was not approved by the Food and Drug Administration (FDA). CLIA regulations require any laboratory that performs testing on patient specimens to have an appropriate CLIA certificate and to meet applicable quality and analytic standards to ensure accurate and reliable test results.\* CLIA regulations, however, do not address the clinical validity of testing (i.e., the accuracy with which the test identifies, measures, or



predicts a patient's clinical status).<sup>†</sup> FDA clearance or approval of a test provides assurance that the test has adequate analytical and clinical validation and that it is safe and effective.<sup>§</sup> There is no FDA-approved test for mycotoxins in human urine.

During the past 10 years, CDC's National Institute for Occupational Safety and Health has received many requests for workplace evaluations based on the results of unvalidated laboratory tests purported to diagnose occupational and environmental illnesses caused by exposure to fungi (including molds). Using unvalidated laboratory tests to diagnose work-related illness can lead to misinformation and fear in the workplace; incorrect diagnoses; unnecessary, inappropriate, and potentially harmful medical interventions; and unnecessary or inappropriate environmental and occupational evaluations (1,2).

Mycotoxins are metabolites of some fungi that can cause illness in humans and animals, primarily after ingestion of contaminated foods. Low levels of mycotoxins are found in many foods; therefore, mycotoxins are found in the urine of healthy persons (3,4). Mycotoxin levels that predict disease have not been established. Urine mycotoxin tests are not approved by FDA for accuracy or for clinical use.

CDC does not recommend biologic testing of persons who work or live in water-damaged buildings nor routine environmental sampling for mold (5,6). To identify possible mold contamination, visual inspection is the first step. To inspect the interior of walls and other difficult-to-examine spaces, a borescope can be inserted through a small hole. Moisture meters can measure moisture in building materials such as carpet, wallboard, wood, brick, and concrete. Identification and elimination of sources of moisture and cleaning or replacement of contaminated materials is essential.


Persons using direct-to-consumer laboratory tests that have not been approved by FDA for diagnostic purposes and their health care providers need to understand that these tests might not be valid or clinically useful. Additional information about molds and their health effects is available at <http://www.cdc.gov/mold/faqs.htm#mold>.

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§ Additional information available at 21 U.S.C. §§360c, 360e and 21 CFR 814.20, 860.7.

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