Comments on the CDC's "Notes from the Field: Use of Unvalidated Urine Mycotoxin Tests for the Clinical Diagnosis of Illness – United States 2014.

Key points:

1. **Does the RealTime Mycotoxin Test detect the presence of mycotoxins in patient's urine?** Yes. This has been verified by CAP and CLIA validation of our test.

2. **Do we claim that the results of our test are diagnostic for any illness?** No. But we have over 1000 medical professionals that use the test and treat patients exposed to mold and mycotoxins. Not because we say they are ill, but because the doctor's know they are. Our test results are used as just part of a clinical diagnosis.

3. **Is the RealTime Labs Mycotoxin Test FDA approved?** No. It is an LDT (Laboratory Determined Test). There are many such "non-FDA approved tests and we never claim that it is approved.
   http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm

4. **Are Mycotoxins Hazardous to your Health?** Absolutely. See the following from government and/or world health organizations:
   a. **NIH, National Cancer Institute web site:** "*Which cancers are associated with exposure to aflatoxins? Exposure to aflatoxins is associated with an increased risk of liver cancer.*" *https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/aflatoxins*

   b. **CDC, Centers for Disease Control and Prevention. Aflatoxin:** *"Aflatoxin is a fungal toxin that commonly contaminates maize and other types of crops during production, harvest, storage or processing. Exposure to aflatoxin is known to cause both chronic and acute hepatocellular injury."*
   https://www.cdc.gov/nceh/hsb/chemicals/aflatoxin.htm

   c. **U.S. Department of Health and Human Services 14th Report on Carcinogens (RoC)** *lists Aflatoxin as Known to be a Human Carcinogen and Ochratoxin A as Reasonably Anticipated to be Human Carcinogen.*
   https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf

d. **Food and Drug Administration Compliance Policy Guide Sec. *683-100 states:*** *"Aflatoxins are toxic by-products of mold growth on certain agricultural commodities. Since their discovery in the early 1960's, aflatoxins have been shown to be carcinogenic to laboratory test animals. In 1969, FDA set an action level for aflatoxins at 20 ppb for all foods, including animal feed, based on FDA's analytical capability and the agency's aim of limiting aflatoxin exposure to the lowest level possible."*

e. **CDC Centers for Disease Control and Prevention. Case Definition: Trichothecene Mycotoxin states:** *"The trichothecene mycotoxins are a group of toxins produced by multiple genera of fungi."* They later state: *"Systemic symptoms can develop with all routes of exposure (especially inhalation) and might include weakness, ataxia, hypotension, coagulopathy and death."* *https://emergency.cdc.gov/agent/trichothecene/casedef.asp*

f. **World Health Organization (WHO) Guidelines for Indoor Air Quality: Dampness and Mould states:** *"Microbial growth may result in greater numbers of spores, cell fragments, allergens, mycotoxins, endotoxins, B-glucans and volatile organic compounds in indoor air. The causative agents of 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."* *http://www.euro.who.int/__data/assets/pdf_file/0017/43325/E92645.pdf?ua=1*

g. **World Health Organization (WHO) in its publication: Mycotoxins: Children's Health and the Environment** defines mycotoxins as *"Natural products produced by fungi that evoke a toxic response when introduced in low concentrations to higher vertebrates by a natural route."* Note: There is no definition of what *"low concentration"* means. Also, humans are *"higher vertebrates" and inhalation is a "natural route"* *http://www.who.int/ceh/capacity/mycotoxins.pdf*

5. **Can mycotoxins in urine come from the foods we eat, as mentioned in the CDC paper?** Certain mycotoxins like aflatoxins and ochratoxins contaminate certain raw foods and can be detected in the finished foods. The government regulates the permissible levels for various food. If someone eats/drinks these products, it is possible to detect mycotoxins in the urine. Yes, However:
   a. The levels detected (per the paper cited by the CDC), are 400 X lower than our minimum level of detection for Aflatoxin and 60+ X lower than our minimum level of detection for Ochratoxin.
   b. The organisms that produce Trichothecene Mycotoxins (i.e. Stachybotrys)

do not contaminate food, so Trichothecenes would not be detected in the urine from ingestion of food and/or drink.

6. In paragraph 1 of the CDC paper, the last line reads: “The interpretation accompanying the laboratory report said the results “revealed that you have an unusual level of mycotoxin(s) present in your body”. That is not our wording or our lab. We simply state whether the mycotoxin is present or not, at our level of detection.

7. The second paragraph of the CDC paper which starts with “The laboratory referred the employee to a clinic specializing in “medical treatment for mold exposure and mold illness……is also referring another other lab.

8. **Given the hazards of mycotoxins (in the words of the government sources above), should patients be informed of exposure and allow them and their health care provider to determine the need for health interventions? We believe the answer to this is Yes.**