# Romer Labs Check Sample Survey (CSS)

## Deoxynivalenol and Zearalenone and Ochratoxin A in Wheat

## (CSSMY026-M24161DZO)

*March – June 2024*

**Deoxynivalenol (DON)** is a mycotoxin produced by fungi of the *Fusarium* genus, particularly *Fusarium graminearum*. This mycotoxin occurs in grains such as wheat, corn, barley, oats, and rye. DON is highly toxic, levels above 1 ppm are considered potentially harmful to swine. Pet foods prepared with corn contaminated with DON have been involved in acute toxicities. DON is a known immunosuppressant and may cause kidney problems. Humans are thought to exhibit a similar vomiting syndrome when consuming DON-contaminated grain.

**Zearalenone (ZON)** is also produced by *Fusarium* species. It mainly occurs in grains and cereal products. ZON is not acutely toxic but is a problem because of its estrogenic effects on mammals. The negative effects on reproductive systems make it a concern in animal husbandry. Only a few countries have imposed recommended levels for this mycotoxin in animal feed, but it is often tested to prevent losses in animal husbandry. As with all mycotoxin tests, sampling is the most crucial step ensuring reliable results.

**Ochratoxin A (OTA)** - produced by different _Aspergillus_ and _Penicillium_ species - is one of the most-abundant food-contaminating <u>mycotoxins</u>. Human exposure can occur through consumption of contaminated food products, particularly contaminated <u>grain</u> and <u>pork</u> products, as well as <u>coffee</u>, <u>wine grapes</u>, and <u>dried grapes</u>. The toxin has been detected in the animal tissues and organs, including e.g. human <u>blood</u> and <u>breast milk</u>.

As part of its integral service approach Romer Labs offers a Check-Sample-Survey (CSS) for mycotoxins. The objective of the Romer Labs CSS is to provide an interlaboratory comparison study of DON, ZON and/or OTA analysis in wheat and a platform for laboratories to assess the effectiveness and accuracy of their test methods as part of their internal analytical quality management.

The Romer Labs CSS aims to industry- and service labs that perform mycotoxin analysis on a routine basis. The method employed for analysis is up to the participating laboratory.

Each participant will receive a foil sachet containing approximately 60 g of homogeneous and characterized test material. The foil sachet must be re-sealed properly after usage and stored at 2-8 °C.

**Methods and Results:**

Participants should treat the test material as if it was a sample for routine analysis, i.e., they can use the analytical method of their choice. Participating laboratories will be asked to provide information on the employed method. This information is subsequently presented in the final report of Romer Labs Check Sample Survey.

The on-time submission of results in the specified units (ppb=µg/kg) and before the submission deadline is part of Romer Labs CSS. Results must be submitted online via the website:

https://engage.romerlabs.com/don-zon-ota-m24161dzo-2024

Participating laboratories should report the results after analyzing their common number of replicates. Individual replicate values shall not be reported. Results reported in a semi-quantitative manner as "less than" or "more than" a specific value, together with qualitative results, will be collated and listed in the Romer Labs CSS report, but they cannot be included in the statistical analysis.

Kindly consider that **only one result per participant (per analyte)** can be accepted. Where appropriate, i.e., for GC or HPLC analyses, results should be reported corrected for recovery.

**Performance Assessment and Statistical Evaluation:**

Performance assessment and statistical evaluation will be done for the reported results of DON, ZON and OTA, provided that sufficient, satisfactory results are submitted.

The object of the statistical procedure employed is to obtain a simple and transparent result which the participant and other interested parties can readily interpret.

The following statistical parameters will be calculated based on the submitted data. Formulas and results will subsequently be disclosed in the report.

- Assigned Value (X):

  The assigned value X (the best estimate of the true concentration of the analyte) will be set as the consensus of the results submitted by the participants. To derive this consensus, the following procedures will be used: removal of non-valid data, calculation of the robust mean and uncertainty assessment.

  The procedure is straightforward, and the robust mean will be the most appropriate measure of central tendency of participants' results.

- Target Standard Deviation ($\sigma_P$) for the Test:

  The value of $\sigma_P$ determines the limit of satisfactory performance in the Romer Labs Check Sample Survey. It is set at a value that reflects best practice for the analysis in question. The standard deviation of reproducibility ($RSD_R$) found in collaborative studies is generally considered as an appropriate indicator of the best agreement that can be obtained between laboratories.

- z-Score:

  The z-score relates the error in the result to the target standard deviation ($\sigma_p$) which is set ahead of the test and reflects 'best practice' or fitness for purpose.

The performance assessment of the participating laboratories in the Romer Labs CSS is expressed in the standardized form of a z-score.

In a normal distribution only about 1 out of 20 results will be outside a range of two standard deviations from the mean hence Romer Labs CSS z-scores of $|z| \leq 2$ are considered to be satisfactory. If a participant receives a z-score outside the range $|z| \leq 2$, it is much more likely that this is due to poor performance rather than it being a "good" result that just happens to be at the extremes of the distribution.

A z-score within the satisfactory range does not automatically classify participants as "competent". The results from the Romer Labs CSS should be seen as one of several tools that enable participants to evaluate their performance.



The Normal Distribution
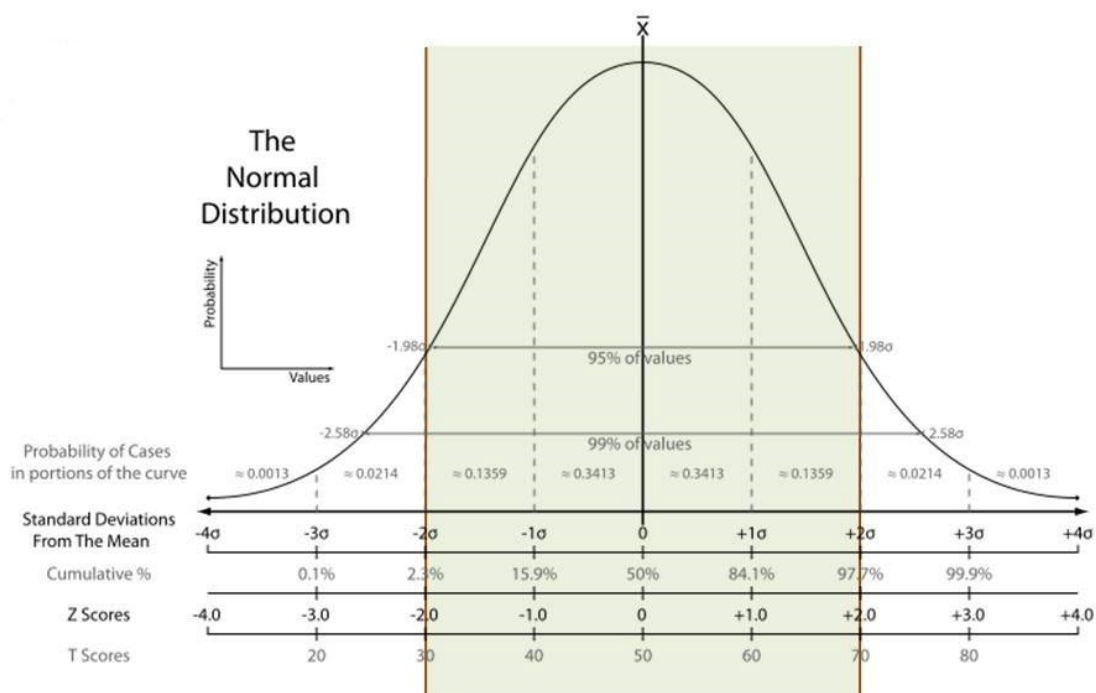
**Timeline of the survey (CSSMY026-M24161DZO):**

- Material available for ordering: March 2024 *(item number 10002324)*

- Submission deadline for results: May 17th, 2024

- Distribution of reports to participants: Beg of June 2024

**<u>Confidentiality of Participant Information:</u>**

All information held by Romer Labs about participants of the Romer Labs Check Sample Survey, including their z-scores, is confidential and will not be disclosed to anyone unless explicitly agreed by the participant for a particular purpose. To preserve this confidentiality participants of the Romer Labs Check Sample Survey will receive a report with anonymized data/results. These laboratory code numbers used in the report are assigned in order of receipt of the results from the participants.

Although Romer Labs is part of dsm-firmenich, all other companies that are part of this group do not have access to Romer Labs Check Sample Survey participants' details.