RANDOX
FOOD DIAGNOSTICS

Ergot Alkaloid Analysis

Better Science, Safer Food

Ergot Alkaloids ELISA

Randox Food Diagnostics Ergot Alkaloids ELISA meets all current and planned future EU regulations applicable to the industry. Complying with Commission Regulation (EU) 2021/1399 for the lowest maximum levels of the 12 regulated ergot alkaloids applicable from January 2022, for cereal-based feed, wheat, rye, oats, barley and spelt and their milling products.

Ergot alkaloids are produced by a group of fungi known as the Claviceps species, the most significant being the C. purpurea. Ergot alkaloids are toxic to humans and animals and they are well known for causing a disease called "Ergotism". In most countries, grain that is contaminated with ergot is banned from human consumption and redirected for use as livestock feed.

Contaminated feed with toxic levels of ergot alkaloids has been found to affect the reproductive cycles of pigs, poultry and cattle, causing animals to terminate pregnancies. They also have been shown to impact upon digestive systems, resulting in under-performance in weight-gain for meat production.

Compliant

Compliant with the lowest proposed maximum levels mandated by new Commission Regulation (EU) 2021/1399, applicable from January 1st 2022.

Unrivalled

Unrivalled in the detection of low contamination levels. A Z-score -0.6 for multigrain baby food was obtained in the FAPAS proficiency test using Randox Ergot Alkaloids ELISA.

Accurate

Randox Ergot Alkaloids ELISA results show an excellent 100% correlation with the assigned concentration within BIPEA proficiency test scheme.

Evaluated

Evaluated by third-party laboratory (Wageningen Food Safety research (WFSR), 2019) and proven to be able to distinguish between negative and positive samples.

Validated

Validated according to Commission Regulation (EC) No 519/2014 as a semi-quantitative screening method for cereal-based feed, rye, wheat, oats, barley and spelt and their milling products.

Proficiency Testing

Randox Food Diagnostics are regular participants in proficiency testing schemes for mycotoxins, which provide an independent check of a laboratory's performance and ensures the delivery of quality results. FAPAS is the largest and most comprehensive analytical chemistry proficiency testing scheme in the food sector. The scheme has more than 2000 participants in over 100 countries. BIPEA is a European non-profit organization, gathering nearly 2500 laboratories in the world throughout 120 countries, it offers more than 150 regular proficiency testing programs.

The aim of both schemes are to get as close a score as possible on the Z-score scale, which is a perfect 0. Randox Food Diagnostics Ergot Alkaloids ELISA is approved to test the most affected type of cereal – Rye. Results from both independent proficiency test schemes show an excellent correlation with assigned concentrations.

FAPAS® - Food Chemistry Proficiency Test Report 22158

Ergot Alkaloids in Rye Flour (March – April 2019)

Analyte	Assigned Value Xα µg/kg	Number of Scores |z| ≤ 2	Total Number of Scores	% |z| ≤ 2
Ergocornine	18.4	23	26	88
Ergocorninine	7.11	21	21	100
Ergocristine	64.7	23	27	85
Ergocristinine	22.1	23	25	92
α-and-ß-Ergocryptine (sum)	Not issued	-	-	-
α-and-ß-Ergocryptinine (sum)	10	22	23	96
Ergometrine	15.6	21	24	88
Ergometrinine	2.3	12	15	80
Ergosine	10	21	25	84
Ergosinine	3.35	17	18	94
Ergotamine	26	22	27	81
Ergotaminine	7	17	19	89

FAPAS® Total Ergot Alkaloids Content: 186.56 µg/kg
Randox ELISA EA3491 Total Ergot Alkaloids Content: 176.4 µg/kg

BIPEA – Interlaboratory Comparisons Report – 99 – 5

Ergot and Datura Alkaloids, Rye, 02-299 (February 2021)

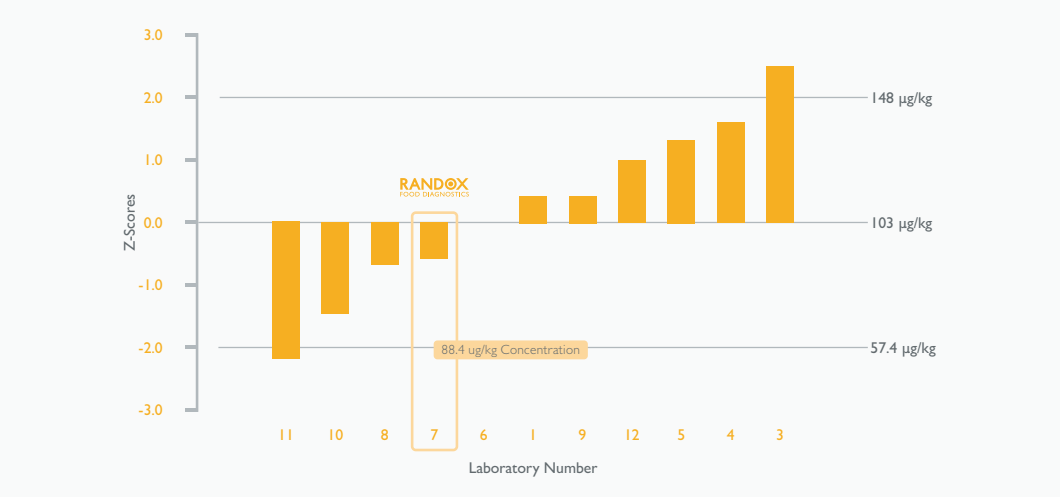
Criteria	Assigned Value µg/kg	Standard Deviation	Result	Z-Score
Sum of 12 Ergot Alkaloids	905	269	906	0.00

FAPAS® - Food Chemistry Proficiency Test Report 22163

Ergot Alkaloids in Baby Food (August – October 2019)

Randox Food Diagnostics Ergot Alkaloids ELISA has been proven to test accurately at low concentrations.

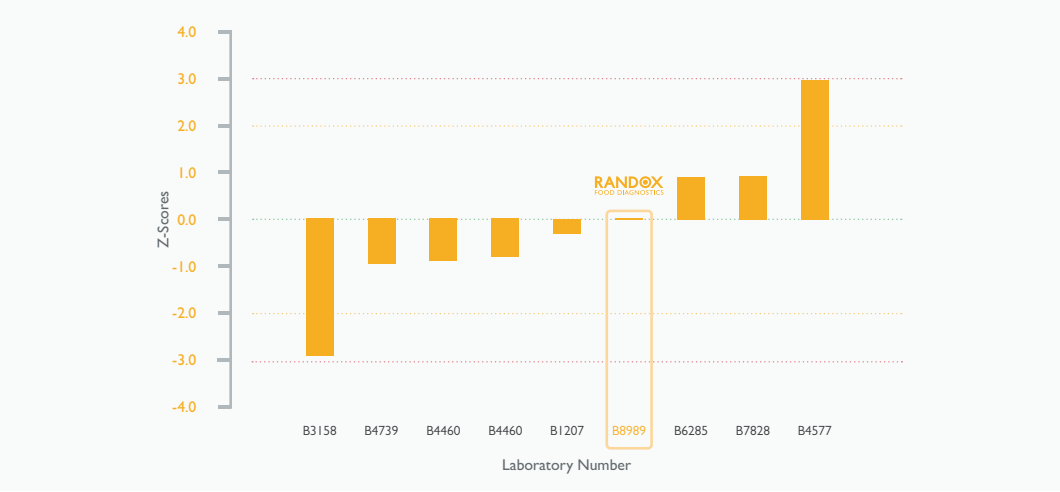
See below results for **baby food**, showing a Z-score of -0.6 within **FAPAS** Proficiency Test scheme.



BIPEA – Interlaboratory Comparisons Report – 99 – 53

Ergot and Datura Alkaloids, Rye, 02-299 (February 2021)

A perfect Z-score of 0.0 was obtained for a rye flour sample provided by BIPEA.



Validation

Randox Food Diagnostics Ergot Alkaloids ELISA is validated based on Commission Regulation (EU) No 519/2014 as a semi-quantitative screening method for cereal-based feed, wheat, rye, oats, barley and spelt and their milling products.

It is successfully assessed by fit-for-purpose approach based on Commission Regulation (EC) No 401/2006 as an approved method of analysis and is successfully assessed by fit-for-purpose approach based on Commission Regulation (EU) No 519/2014 for confirmatory method as an approved method for official control.

Randox Food Diagnostics Ergots Alkaloids ELISA has been evaluated by an EU Reference Laboratory to enable distinguishing between negative and positive samples. Randox's ELISA displayed **no false-negatives** and **no false-positives** in an evaluated study. Across all commercially available ELISA tests evaluated by the EU Reference Laboratory, Randox Food Diagnostics Ergot Alkaloids ELISA was the only test which showed good performance with cereal-based feed, wheat and rye sample types, including 11 matrices and a total of 24 samples.

Performance of ELISA Tests

Ref: Wageningen Food Safety research (WFSR), 2019

				Randox Food Ergot Alkaloids ELISA					
Matrix Type	ELISA Test Kit 1			ELISA Test Kit 2			ELISA Test Kit 3		
	P1	P2	P3	P1	P2	P3	P1	P2	P3
Cereals	+/-	NT	+/-	+	+	+	+/-	+/-	+/-
Feed	+	NT	-	+	+	+	+/-	+/-	+/-
Bread	NT	NT	NT	+	+	+	+	+	+

(+): Good performance: ELISA showed positive/negative result for samples positive/negative by LC-MS/MS. No false-positive or false-negative.

(+/-): Medium performance: ELISA showed one or more false-positive results (>LOQ by LC-MS/MS).

(-): Variable performance: ELISA showed at least one false-negative result for samples where EA content by LC-MS/MS is higher than ELISA's lowest calibration point.

NT: Not tested.

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