



United States
Department of
Agriculture

Agricultural
Marketing
Service

Federal Grain Inspection Service
Technology and Science Division
10383 North Ambassador Drive
Kansas City, MO 64153

DATE: October 23, 2023

TO: Mr. George Papageorgiou
Prognosis Biotech SA
Larissa, Greece 41335

Dear Mr. Papageorgiou:

I am pleased to inform you that the Bio-Shield ZON 5 ELISA using the BYONNOY 96 Absorbance has been approved by the Federal Grain Inspection Service (FGIS) for the quantitative determination of zearalenone in corn (including dent or field corn, corn meal, corn flour, cracked corn, corn grits or polenta, and corn screenings), wheat (including whole grain wheat flour, wheat middlings, wheat red dog flour 2nd clear, and wheat screenings), barley (with hull, including malting barley), malted barley (including malted barley flour), hulled barley (including hullless barley), buckwheat, corn germ, corn starch, corn/soy blend, sweet corn, distillers dried grain w/solubles, oats (whole oats with hull), rapeseed, brown rice, milled rice (including brewer's rice and glutinous rice), rough rice, rye (or rye berries, including whole grain rye flour, rye meal, cracked rye, rye chops), white rye flour, white wheat flour, sorghum, and soybean (including whole soybean and full-fat soy flour). The Certificate of Conformance, FGIS 2024-181, is enclosed along with the evaluation data contained in Attachment I.

If you have any questions about the performance verification, please contact Dr. Ajit Ghosh at (816) 702-3817 or by e-mail at Ajit.K.Ghosh@usda.gov. For questions regarding FGIS policies on test kit evaluations, please contact me at (816) 702-3811 or by e-mail at Thomas.A.Weber@usda.gov.

Sincerely,

Thomas A. Weber, Chief, Analytical Chemistry Branch
Technology and Science Division

Enclosure: COC FGIS 2024-181

Attachment: Attachment I – Summary of Verification Data for Test Kit (2023229QN)



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**Attachment I - Summary of Verification Data for Test Kit (2023229QN)
Zearalenone in Corn**

BYONNOY 96 Absorbance

<u>100 ppb Level</u>		<u>1000 ppb Level</u>	
Analyst	Reading	Analyst	Reading
1	111	1	778
1	115	1	939
1	121	1	897
1	128	1	982
1	129	1	865
1	133	1	1080
1	127	1	1090
2	111	2	781
2	98.9	2	753
2	84.7	2	745
2	99.1	2	863
2	89.8	2	764
2	80.2	2	796
2	110	2	785
3	116	3	870
3	113	3	869
3	105	3	1010
3	107	3	899
3	115	3	975
3	109	3	963
3	91.2	3	772
Total Out-of-Range	0		0
Acceptable Ranges	$CRV \pm 2*0.25*CRV$		$CRV \pm 2*0.20*CRV$

CRV – Certified Reference Value