



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: February 27, 2023

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

Dear Mr. Papageorgiou:

I am pleased to inform you that the Bio-Shield Total 5 ELISA using the BYONNOY 96 Absorbance has been approved by the Federal Grain Inspection Service (FGIS) for the quantitative determination of aflatoxins in corn (including dent or field corn, corn meal, corn flour, cracked corn, corn grits or polenta, and corn screenings), barley (with hull, including malting barley), malted barley (with hull, 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, wheat (including whole grain wheat flour, wheat middlings, wheat red dog flour 2nd clear, and wheat screenings), white wheat flour, sorghum, soybean (including whole soybean and full-fat soy flour). The Certificate of Conformance, FGIS 2023-170, 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.

Sincerely,

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

Enclosure: COC FGIS 2023-170

Attachment: Attachment I – Summary of Verification Data for Test Kit 2022211 QN



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**Attachment I - Summary of Verification Data for Test Kit (2022211 QN)
Aflatoxins in Corn**

BYONOIY 96 Absorbance

<u>5 ppb Level</u>		<u>20 ppb Level</u>		<u>300 ppb Level</u>	
Analyst	Reading	Analyst	Reading	Analyst	Reading
1	5.03	1	18.20	1	297.8
1	3.31	1	17.13	1	379.1
1	4.42	1	18.26	1	251.7
1	3.31	1	19.32	1	332.2
1	4.22	1	14.28	1	307.6
1	4.34	1	13.74	1	231.2
1	4.21	1	15.59	1	249.4
2	5.04	2	15.79	2	232.2
2	4.73	2	13.68	2	213.9
2	4.82	2	17.73	2	223.6
2	5.78	2	15.75	2	233.4
2	6.34	2	17.06	2	261.6
2	6.13	2	16.73	2	220.1
2	4.70	2	16.82	2	215.3
3	4.99	3	15.83	3	247.8
3	5.34	3	15.60	3	244.3
3	5.39	3	16.94	3	256.6
3	6.23	3	14.71	3	207.9
3	4.28	3	12.70	3	196.8
3	3.12	3	9.45†	3	201.8
3	3.04	3	16.24	3	192.1†
Total Out-of-Range	0		1		1
Acceptable Ranges	CRV ± 2*0.25*CRV	Acceptable Ranges	CRV ± 2*0.20*CRV	Acceptable Ranges	CRV ± 2*0.16*CRV

CRV – Certified Reference Value

† Out-of-range