

**U.S. DEPARTMENT OF AGRICULTURE
Federal Grain Inspection Service**

CERTIFICATE NO.: FGIS 2019-128

CERTIFICATE OF CONFORMANCE

Quantitative test kit for deoxynivalenol (DON) in corn (field/dent corn, corn meal, cracked corn, corn grits/polenta, corn screenings), wheat (including wheat screenings) and additional commodities listed under TEST 3.

For: EnviroLogix Inc.
Method: Lateral Flow Strip

Submitted by: EnviroLogix Inc.
500 Riverside Industrial Pkwy
Portland, ME 04103
Telephone: (207) 797-0300
Contact: Mr. Gow Brendan

Standard Features and Options

Model: QuickTox Kit for QuickScan DON FLEX, Product # AQ 304 BG
Sample Preparation: Grind sample so that $\geq 95\%$ passes through a 20 mesh sieve
Extraction Method: Shake 50-gram sample with 250 mL deionized water for 0.5 minute using mechanical shaker at 300 rpm
Temperature Range: 18 – 30 °C (64 – 86 °F)
DON Level: 0.50 – 30 ppm
Detection Technique: EnviroLogix QuickScan System and EnviroLogix QuickScan II Reader

Test kits must be operated according to the FGIS-issued instructions.

This test kit underwent an initial verification of performance under the authority of Section 7B (c) of the United States Grain Standards Act, as amended, and was found to meet all test performance criteria as defined in "Design Criteria and Test Performance Specifications for Quantitative Deoxynivalenol (DON) Test Kits," June 2018 version. Evaluation tests that passed are summarized in Attachment I.

For further information, contact:

USDA, Federal Grain Inspection Service
Technology and Science Division
Analytical Chemistry Branch
10383 N. Ambassador Drive
Kansas City, Missouri 64153-1394 Telephone: (816) 891-0449



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

Date: 10-2-2019

Certificate Expires Three Year from the Date Signed

Note: The mention of firm name or trade products does not imply that they are endorsed or recommended by the United States Department of Agriculture over other firms or similar products not mentioned.

Type Evaluation
Certificate No.: FGIS 2019-128

ATTACHMENT I

Manufacturer: EnviroLogix Inc.
500 Riverside Industrial Pkwy
Portland, ME 04103
Telephone: (207) 797-0300
Contact: Mr. Gow Brendan

TEST 1: TIME REQUIRED FOR COMPLETION OF AN ANALYSIS.

The data submitted by the manufacturer indicated that the analysis time required for one sample was less than the maximum limit of 30 minutes.

TEST 2: COMPARATIVE ACCURACY OF TEST KITS ON WHEAT AND CORN SAMPLES NATURALLY CONTAMINATED WITH DEOXYNIVALENOL.

The data submitted by the test kit manufacturer for four wheat samples and four corn samples, naturally contaminated at approximately 0.5, 2, 5, and 30 ppm DON, met the performance criteria.

TEST 3: SUGGESTED ADDITIONAL COMMODITIES.

The manufacturer submitted data supporting the performance of this kit with additional commodities: distillers dried grains with solubles (DDGS), malted barley (including malted barley flour), and sorghum.

TEST 4: AVOIDANCE OF TOXIC OR HAZARDOUS SUBSTANCES.

The Safety Data Sheets (SDS) provided by the manufacturer confirmed this test kit meets safety requirements.

TEST 5: SENSITIVITY TO ELECTROMAGNETIC FIELDS (EMF).

A statement of certification has been provided that indicated the EnviroLogix QuickScan System and EnviroLogix QuickScan II Reader met the EMF sensitivity requirements.

TEST 6: TEMPERATURE SENSITIVITY.

The data submitted by the test kit manufacturer supported performance of the kit at 18 °C, 24 °C, and 30 °C.

TEST 7: STABILITY.

The data submitted by the test kit manufacturer supported storage and stability claims.

TEST 8: FGIS PERFORMANCE VERIFICATION.

The data generated by FGIS staff showed the test kit is capable of quantifying DON in wheat and corn from 0.50 – 30 ppm. The evaluation was conducted using the EnviroLogix QuickScan System and EnviroLogix QuickScan II Reader.



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Technology and Science Division
10383 North Ambassador Drive
Kansas City, MO 64153

**Attachment I - Summary of Verification Data for Test Kit (2019164QN)
Deoxynivalenol in Wheat**

EnviroLogix QuickScan System

<u>0.5 ppm Level</u>		<u>2 ppm Level</u>		<u>30 ppm Level</u>	
Analyst	Reading	Analyst	Reading	Analyst	Reading
1	0.57	1	2.1	1	29
1	0.66	1	2.5	1	31
1	0.63	1	2.4	1	28
1	0.67	1	2.2	1	29
1	0.66	1	2.3	1	29
1	0.67	1	2.3	1	28
1	0.64	1	2.4	1	29
2	0.62	2	2.1	2	28
2	0.67	2	2.3	2	28
2	0.60	2	2.3	2	30
2	0.61	2	2.3	2	29
2	0.57	2	2.2	2	29
2	0.68	2	2.1	2	28
2	0.62	2	2.2	2	28
3	0.66	3	2.1	3	29
3	0.63	3	2.1	3	28
3	0.59	3	2.3	3	29
3	0.61	3	2.1	3	29
3	0.60	3	2.2	3	30
3	0.66	3	2.2	3	30
3	0.67	3	2.3	3	30
Total Out-of-Range	0	0	0	0	0
Acceptable Ranges	CRV ± 2*0.20*CRV	CRV ± 2*0.12*CRV	CRV ± 2*0.10*CRV	CRV ± 2*0.10*CRV	CRV ± 2*0.10*CRV

CRV – Certified Reference Value



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**Attachment I - Summary of Verification Data for Test Kit (2019164QN)
Deoxynivalenol in Corn**

EnviroLogix QuickScan System

<u>0.5 ppm Level</u>		<u>2 ppm Level</u>		<u>30 ppm Level</u>	
Analyst	Reading	Analyst	Reading	Analyst	Reading
1	0.51	1	2.2	1	29
1	0.45	1	2.3	1	31
1	0.36	1	2.2	1	30
1	0.43	1	1.8	1	30
1	0.36	1	2.4	1	31
1	0.33	1	2.2	1	30
1	0.44	1	2.3	1	28
2	0.41	2	2.1	2	30
2	0.45	2	2.1	2	29
2	0.46	2	2.1	2	30
2	0.44	2	2.1	2	27
2	0.38	2	2.1	2	28
2	0.43	2	2.0	2	27
2	0.39	2	2.1	2	28
3	0.37	3	2.1	3	32
3	0.39	3	2.1	3	32
3	0.35	3	2.0	3	30
3	0.41	3	2.1	3	28
3	0.42	3	2.0	3	32
3	0.39	3	2.1	3	32
3	0.39	3	2.1	3	29
Total Out-of-Range	0	Total Out-of-Range	0	Total Out-of-Range	0
Acceptable Ranges	CRV ± 2*0.20*CRV	Acceptable Ranges	CRV ± 2*0.12*CRV	Acceptable Ranges	CRV ± 2*0.10*CRV
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**Attachment I - Summary of Verification Data for Test Kit (2019164QN)
Deoxynivalenol in Wheat**

EnviroLogix QuickScan II Reader

<u>0.5 ppm Level</u>		<u>2 ppm Level</u>		<u>30 ppm Level</u>	
Analyst	Reading	Analyst	Reading	Analyst	Reading
1	0.55	1	2.1	1	30
1	0.67	1	2.4	1	29
1	0.64	1	2.4	1	29
1	0.69	1	2.2	1	29
1	0.66	1	2.4	1	31
1	0.68	1	2.3	1	30
1	0.65	1	2.3	1	29
2	0.66	2	2.1	2	29
2	0.69	2	2.3	2	27
2	0.62	2	2.3	2	30
2	0.63	2	2.2	2	28
2	0.62	2	2.2	2	28
2	0.68	2	2.1	2	27
2	0.67	2	2.3	2	28
3	0.69	3	2.1	3	29
3	0.66	3	2.1	3	29
3	0.61	3	2.2	3	28
3	0.58	3	2.1	3	29
3	0.59	3	2.2	3	31
3	0.65	3	2.3	3	29
3	0.68	3	2.3	3	29
Total Out-of-Range	0		0		0
Acceptable Ranges	CRV ± 2*0.20*CRV		CRV ± 2*0.12*CRV		CRV ± 2*0.10*CRV
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**Attachment I - Summary of Verification Data for Test Kit (2019164QN)
Deoxynivalenol in Corn**

EnviroLogix QuickScan II Reader

<u>0.5 ppm Level</u>		<u>2 ppm Level</u>		<u>30 ppm Level</u>	
Analyst	Reading	Analyst	Reading	Analyst	Reading
1	0.50	1	2.1	1	29
1	0.44	1	2.2	1	31
1	0.36	1	2.2	1	29
1	0.45	1	1.9	1	30
1	0.35	1	2.3	1	31
1	0.34	1	2.2	1	30
1	0.46	1	2.3	1	29
2	0.44	2	2.1	2	30
2	0.42	2	2.1	2	29
2	0.49	2	2.1	2	31
2	0.44	2	2.1	2	26
2	0.38	2	2.1	2	27
2	0.43	2	2.0	2	30
2	0.44	2	2.1	2	28
3	0.37	3	2.0	3	29
3	0.37	3	2.2	3	32
3	0.36	3	1.9	3	28
3	0.43	3	2.1	3	32
3	0.38	3	2.0	3	30
3	0.34	3	2.1	3	31
3	0.37	3	2.0	3	33†
Total Out-of-Range	0		0		1
Acceptable Ranges	CRV ± 2*0.20*CRV		CRV ± 2*0.12*CRV		CRV ± 2*0.10*CRV
CRV – Certified Reference Value					