

**U.S. DEPARTMENT OF AGRICULTURE
Grain Inspection, Packers and Stockyards Administration
Federal Grain Inspection Service**

CERTIFICATE NO.: FGIS 2017-094

CERTIFICATE OF CONFORMANCE

Quantitative test kit for deoxynivalenol (DON) in corn (field/dent corn, corn meal, corn flour, cracked corn, corn grits/polenta, corn screenings), wheat (whole grain wheat flour, wheat middlings, wheat red dog, wheat flour 2nd clear, wheat screenings), distillers dried grains with solubles (DDGS), and wheat bran.

For: EnviroLogix Inc.
Method: Lateral Flow Strip

Submitted by: EnviroLogix Inc.
500 Riverside Industrial Pkwy
Portland, ME 04103
Telephone: (207) 797-0300
Contact: Dr. Anna Rice

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

Test kits must be operated according to the GIPSA-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," March 2016 version. Evaluation tests that passed are summarized in Attachment I.

For further information, contact:

USDA, Grain Inspection, Packers and Stockyards Administration
Technology and Science Division
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Mary Coffey-Alonzo, Director
Technology and Science Division

Date: 10/24/2016

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 2017-094

ATTACHMENT I

Manufacturer: EnviroLogix Inc.
500 Riverside Industrial Pkwy
Portland, ME 04103
Telephone: (207) 797-0300
Contact: Dr. Anna Rice

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) and wheat bran.

TEST 4: AVOIDANCE OF TOXIC OR HAZARDOUS SUBSTANCES.

The Material Safety Data Sheets (MSDS) 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 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: GIPSA PERFORMANCE VERIFICATION.

The data generated by GIPSA 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.



United States Department of Agriculture

**Attachment I - Summary of Verification Data for Test Kit (2016122QN)
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	0.51	1	2.7	1	29
1	0.45	1	2.3	1	32
1	0.47	1	2.5	1	30
1	0.52	1	2.4	1	28
1	0.44	1	2.3	1	31
1	0.52	1	2.4	1	29
1	0.44	1	2.3	1	28
2	0.51	2	2.2	2	30
2	0.57	2	2.5	2	28
2	0.54	2	2.4	2	32
2	0.54	2	2.3	2	31
2	0.53	2	2.5	2	27
2	0.46	2	2.6	2	29
2	0.49	2	2.5	2	29
3	0.52	3	2.3	3	27
3	0.47	3	2.2	3	27
3	0.50	3	2.5	3	26
3	0.46	3	2.3	3	28
3	0.53	3	2.3	3	28
3	0.52	3	2.1	3	26
3	0.48	3	2.0	3	27
Total Out-of-Range	0		0		0
Acceptable Ranges	$CRV \pm 2*0.20*CRV$		$CRV \pm 2*0.12*CRV$		$CRV \pm 2*0.10*CRV$

CRV – Certified Reference Value



United States Department of Agriculture

**Attachment I - Summary of Verification Data for Test Kit (2016122QN)
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	33
1	0.49	1	2.4	1	33
1	0.46	1	2.4	1	31
1	0.51	1	2.2	1	33
1	0.53	1	2.1	1	33
1	0.39	1	2.2	1	34
1	0.46	1	2.1	1	35
2	0.50	2	2.2	2	34
2	0.52	2	2.0	2	31
2	0.50	2	2.2	2	34
2	0.44	2	2.3	2	34
2	0.46	2	2.3	2	31
2	0.49	2	2.2	2	34
2	0.48	2	2.3	2	34
3	0.50	3	2.0	3	32
3	0.54	3	2.4	3	32
3	0.48	3	2.3	3	31
3	0.49	3	2.1	3	31
3	0.47	3	2.1	3	32
3	0.45	3	2.3	3	31
3	0.51	3	2.3	3	34
Total Out-of-Range			0		0
Acceptable Ranges		$CRV \pm 2*0.20*CRV$	$CRV \pm 2*0.12*CRV$	$CRV \pm 2*0.10*CRV$	

CRV – Certified Reference Value