

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

CERTIFICATE NO.: FGIS 2012-008

CERTIFICATE OF CONFORMANCE

Quantitative test kit for deoxynivalenol (DON) in wheat, corn, barley, distillers dried grains w/solubles, malted barley, milled rice, oats, rough rice, sorghum, wheat flour, and wheat middlings.

For: Charm Sciences, Inc.
Method: Lateral Flow Strip

Submitted by: Charm Sciences, Inc.
659 Andover Street
Lawrence, MA 01843
Telephone: (800) 343-2170
Contact: Dr. Mark Tess

Standard Features and Options

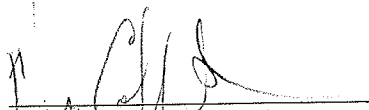
Model: Charm ROSA® FAST5 DON Quantitative, Product # LF-DONQ-FAST5.
Sample Preparation: Clean, ground sample so that 95% passes through a 20 mesh sieve.
Extraction Method: 50-gram sample with distilled or deionized water.
Temperature Range: 18-30 °C (64-86 °F).
DON Level: 0.5-5.0 ppm.
Detection Technique: Reader: Charm ROSA®-M Reader, Model # LF-ROSAREADER-M-NB.

Test kits must be operated according to the instructions in the GIPSA Deoxynivalenol (DON) Handbook.

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," September 2010 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
Biotechnology and Analytical Services Branch
10383 N. Ambassador Drive
Kansas City, Missouri 64153-1394 Telephone: (816) 891-0401


Mary Coffey Alonzo, Director
Technology and Science Division

Date: 12/23/2011

Certificate Expires Three Years 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 2012-008

ATTACHMENT I
Method: Lateral Flow Strip

Manufacturer: Charm Sciences, Inc.
659 Andover Street
Lawrence, MA 01843
Telephone: (800) 343-2170
Contact: Dr. Mark Tess

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 (DON).

The data submitted by the test kit manufacturer for four wheat samples and four corn samples, naturally contaminated with DON, containing approximately 0.5, 1.0, 2.0, and 5.0 ppm DON, met the performance criteria.

TEST 3: SUGGESTED ADDITIONAL COMMODITIES.

The manufacturer submitted data for the following additional commodities: barley, distillers dried grains w/solubles, malted barley, milled rice, oats, rough rice, sorghum, wheat flour, and wheat middlings.

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).

The Charm ROSA[®]-M Reader, Model # LF-ROSAREADER-M-NB, was previously approved by GIPSA for use in the official inspection system having met all EMF 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 in the range of 0.5–5.0 ppm DON. The evaluation was conducted using the Charm ROSA[®]-M Reader, Model # LF-ROSAREADER-M-NB.

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ADDENDUM CERTIFICATE NO.: FGIS 2012-008.1

ADDENDUM TO CERTIFICATE OF CONFORMANCE NO.: FGIS 2012-008 (December 23, 2011)

Quantitative test kit for deoxynivalenol (DON) in wheat bran.

For: Charm Sciences, Inc.
Method: Lateral flow strip

Submitted by: Charm Sciences, Inc.
659 Andover Street
Lawrence, MA 01843
Telephone: (800) 343-2170
Contact: Dr. Mark Tess

Standard Features and Options


Model: Charm ROSA[®] FAST5 DON Quantitative, Product # LF-DONQ-FAST5.
Sample Preparation: Clean, ground sample so that 95% passes through a 20 mesh sieve.
Extraction Method: 50-gram sample with distilled or deionized water.
Temperature Range: 18-30 °C (64-86 °F).
DON Level: 0.5-5.0 ppm.
Detection Technique: Reader: Charm ROSA[®]-M Reader, Model # LF-ROSAREADER-M-NB.

Test kits must be operated according to the instructions in the GIPSA Deoxynivalenol (DON) Handbook.

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 Kit" September 2010 version. The evaluation tests that were passed are summarized in Attachment I.

For further information, contact:

USDA, Grain Inspection, Packers and Stockyards Administration
Technology and Science Division
Biotechnology and Analytical Services Branch
10383 N. Ambassador Drive
Kansas City, Missouri 64153-1394 Telephone: (816) 891-0401


Mary Coffey Alonzo, Director
Technology and Science Division

Date: 12/29/2011

Addendum Certificate Expires Three Years from the Initial Certificate Signing Date Listed Above

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
Addendum Certificate No.: FGIS 2012-008.1

ATTACHMENT I

Manufacturer: Charm Sciences, Inc.
659 Andover Street
Lawrence, MA 01843
Telephone: (800) 343-2170
Contact: Dr. Mark Tess

TEST 3: SUGGESTED ADDITIONAL COMMODITIES.

The manufacturer submitted data for the following additional commodity: wheat bran.