AgraStrip® Pro
Deoxynivalenol WATEX®

Part #: 10006320

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Intended Use

The AgraStrip® Pro Deoxynivalenol WATEX® test kit is an immunochromatographic assay designed for the quantitative analysis of the presence of deoxynivalenol in food and feed components.

Performance characteristics

Limit of detection (LOD): 0.1 ppm (corn, wheat)

Limit of quantification (LOQ): 0.2 ppm (corn, wheat)

Range of quantitation: 0 – 44 ppm

Assay time: 4 minutes

About Deoxynivalenol

Deoxynivalenol (DON) is a type-B trichothecene and is mainly produced by certain Fusarium species e.g. Fusarium graminearum. This mycotoxin occurs predominantly in grains such as wheat, barley, oats, rye, and maize. DON is highly toxic, levels above 1 ppm are considered potentially harmful to swine. Humans are thought to exhibit a similar vomiting syndrome when consuming DON-contaminated grain.
The US Food and Drug Association advisory levels for DON (Mycotoxin Legislation USA – 2010) are as follows: (1) 1 ppm for finished wheat products for human consumption; (2) 5 ppm for grain and grain by-products intended for swine and other animals; and not to exceed 1 ppm in the diets of swine and 2 ppm in the diets of other animals; (3) 10 ppm for grain and grain by-products for ruminating beef and feedlot cattle older than 4 months and for chickens; and not to exceed 5 ppm in the diet.
The European Commission sets maximum levels of DON in foodstuffs in EC regulation 1881/2006: (1) 1.25 ppm for unprocessed cereals other than durum wheat, oats and maize; (2) 1.75 ppm for unprocessed durum wheat and oats and unprocessed maize; (3) 0.75 ppm for cereals intended for direct human consumption, cereal flour, bran and germ as end-product marketed for direct human consumption, and pasta (dry); (4) 0.5 ppm for bread (including small bakery wares), pastries, biscuits, cereal snacks and breakfast cereal.

Product information

About the lateral flow device test kit

The AgraStrip® Pro Deoxynivalenol WATEX® test is a direct competitive immuno-chromatographic test that quantitatively determines the presence of deoxynivalenol. This product is intended for use in grains, cereals, and other commodities.

Storage information

Upon receipt, immediately transfer the AgraStrip® Pro Deoxynivalenol WATEX® Strips and Dilution Buffer to refrigerated storage and keep it at 2 – 8 °C (35 – 46 °F) when not in use.
Extraction Buffer Bags and consumables can be stored at room temperature (15 – 25 °C (59 – 77 °F)). Do not freeze. Do not use the kit beyond the expiration date indicated on the package.

Contents of the kit

The AgraStrip® Pro Deoxynivalenol WATEX® test kit contains following items:

- 1 tube containing 40 AgraStrip® Pro Deoxynivalenol WATEX® Strips
- 1 bag containing 40 AgraStrip® Pro Cartridges (10006165)
- 1 foil bag containing 40 AgraStrip® Pro WATEX® Extraction Buffer Bags
- 1 bottle of 50 ml AgraStrip® Pro Deoxynivalenol WATEX® Dilution Buffer
- 2 bags of 40 yellow or white pipette tips
- 1 bag of 40 blue pipette tips
- 2 bags of 20 microcentrifuge tubes (dilution tubes)
- 4 rolls each of 10 pieces each of Whirl-Pak® filter Bags
- 1 tube holder
- 1 QR card for the AgraVision™ Pro Reader

Materials required but not included

Extraction Procedure:

- Analytical balance (10002581 - 110V or 10002748 - 220V) with a weighing capacity up to 400 g
- Graduated cylinder (10002612) with a minimum capacity of 100 mL
- Distilled, de-ionized or bottled water for extraction
- Centrifuge

Assay Procedure:

- 10006324: AgraVision™ Pro Reader
- Single channel pipettes capable of pipetting up to 1000 µl or below fixed volume pipettes
  Fixed 100 µl pipette
  Fixed 1000 µl pipette

AgraStrip® Pro WATEX® test – Assay principle

The AgraStrip® Pro Deoxynivalenol WATEX® test is a one-step lateral flow immuno-chromatographic assay for the quantitative screening of deoxynivalenol (DON) present in samples. The test is based on a competition immunoassay format. The sample extract migrates through the conjugate pad containing DON specific monoclonal antibodies conjugated to colloidal gold nanoparticles. In the case of the AgraStrip® Pro Deoxynivalenol WATEX® test, if the sample is positive for DON mycotoxin, the mycotoxin will bind to the nanoparticle-antibody complex (conjugate) and migrate into the detection zone. In the competitive format, the test line consists of immobilized analyte molecules (in this case, DON mycotoxin) conjugated to a protein carrier. Any unbound DON antibody will be captured in the test zone forming a visible line. As the DON concentration in the sample increases, the DON mycotoxin will be captured by the antibody-gold particles and reduce the interaction of antibody-gold particle with the test zone analyte, resulting in a reduced signal at the test line. The color intensity of the line is therefore inversely proportional to the concentration of DON in the sample. The control line indicates proper flow through the strip and should always be visible in the control zone, irrespective of the presence/absence of DON mycotoxin. The DON test strips are measured using an AgraVision™ Pro Reader, which quantifies the concentration of DON in the sample.

Protocol at a glance

The following section gives only an overview of the AgraStrip® Pro test procedure when using the AgraVision™ Pro Reader. Before performing the assay, please read this package insert carefully.

Turn on the AgraVision™ Pro reader by plugging it in and follow the set up procedure according to the instructions.

Weigh in 10 g of adequately ground representative sample and add one extraction buffer bag into the side of the Whirl-Pak® filter bag, preferably on the same side as the sample.

Add 50 ml of distilled water to Whirl-Pak® filter bag.

Seal the bag and shake vigorously for 2 minutes.

Allow sample to settle for 1 minute.

Pipette 1000 µl assay dilution buffer into a dilution tube. Add 100 µl of sample extract. Take extract from the side opposite the side into which the sample was weighed.

Centrifuge the diluted sample extract for 30 seconds. Take the supernatant for further testing.

Insert the AgraStrip® Pro test strip into the AgraVision™ Pro cartridge. Transfer the cartridge containing the test strip into the port of the reader.

Enter sample ID and select matrix and quantitation range.

Add 100 µl sample to the AgraVision™ Pro cartridge.

AgraStrip® Pro WATEX® test procedure

Before starting

Procedural guidelines:

- Make sure you have everything you need ready before starting the test.
- All reagents and kit components must be allowed to reach room temperature, 18 –30 °C (64 – 86 °F), before use.
- Do not return unused reagents into their original bottles.

Precautions:

- Store AgraStrip® Pro WATEX® test strips and dilution buffer at 2 – 8 °C (35 – 46 °F) when not in use, and do not use beyond the expiration date.
- Test strips must be kept inside their original tubes.
- Adhere to the instructions of the test procedures.
- Do not re-use test strips.
- Do not re-use AgraVision™ Pro cartridges.
- Treat all materials, containers and devices that are exposed to the sample or standards as if they were contaminated with toxin.
- The components in this test kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- Dispose of all single-use materials, containers and devices appropriately after use.

Reagent and sample preparation

Sample preparation

Sample Extraction – One for All WATEX®

**The sample extraction is applicable to all AgraStrip® Pro WATEX® products*

1. Obtain a representative sample of the specimen you want to analyze and grind it so that 95% will pass through a 20-mesh (sieve opening 0.84 mm), then thoroughly mix the subsample portion.
2. Weigh out 10 ± 0.1 g of ground sample into one side of a Whirl-Pak® filter bag.
3. Remove one extraction buffer bag from the foil pouch and add it to the same side of the Whirl-Pak® filter bag. The extraction buffer bag will dissolve completely during the extraction process.
4. Add 50 ml of distilled, deionized or bottled water and close the Whirl-Pak® filter bag.
5. Vigorously shake for 2 minutes at room temperature.
6. Open the Whirl-Pak® filter bag and place the filter on the same side as the sample.
7. Allow sample to settle for 1 minute.
8. Meanwhile, you can prepare the assay dilution step.

AgraVision™ Pro Reader set up

Turn the AgraVision™ Pro reader on prior to the test run.
Choose the appropriate testing target (mycotoxins).
The instrument will automatically heat up to the temperature needed to run the specific test.

Note: Do not insert the AgraStrip® Pro test strip until the instrument prompts you to do so.

Prior to the test run, a QR card containing information regarding the test method specific to the lot of the test kit must be inserted into the reader (the slot is located in the center of the port system). The information from

the QR code will be saved. The QR code has to be scanned once per lot.

Note: We recommend screening and saving all QR cards for new test kit lots prior to running the test.

Note: For detailed instructions see the AgraVision™ Pro user manual.

Technical support

Not sure if the test works with your specific samples or matrices? Let our longstanding experience in mycotoxin testing work for you. Contact the technical sales representative in your region to know more.

Assay Protocol

Extract Dilution

1. Add 1000 µL dilution buffer using the blue pipette tip, and then add 100 µL sample extract using yellow or white pipette tip into the dilution buffer and mix well. This represents a 1:11 with dilution. Extract should be pipetted from the side of filter bag opposite the ground sample. If the sample has a large foam head, tilt the bag for easier access to the supernatant below.

   Note: Diluted samples must be used within one hour, otherwise they are no longer effective.

   Note: Make sure the pipette tip has been completely emptied.

2. The diluted sample must be centrifuged for 30 seconds at 2000 g using an appropriate device, such as a microcentrifuge. Then, carefully pipette up the supernatant. The sample supernatant is now ready for testing.

Quantitation range 1: 0 – 4.2 ppm

1. Insert an AgraStrip® Pro test strip into the AgraVision™ Pro cartridge.
2. Insert the AgraVision™ Pro cartridge containing the test strip into any empty port/slot within the AgraVision™ Pro reader.
3. The data matrix code on the test strip will be recognized by the reader. The reader automatically detects the type of test and the lot ID.
4. Enter the sample ID and choose the quantitation range and sample matrix then press enter (tick mark). Wait until a flashing drop prompts the user to add the sample. Add 100 µl of the diluted centrifuged extract into the back of the AgraVision™ Pro cartridge.

   The AgraVision™ Pro reader detects the fluid front in the cartridge and will automatically start the timer for the incubation. Additional samples can be tested using the other available 3 slots of the system in parallel.

5. The test results will be automatically displayed on the relevant slot of the AgraVision™ reader.

Quantitation range 2: 3.1 – 44 ppm

1. If the reader detects a concentration **greater than 4.2 ppm**, the previously diluted sample extract (diluted extract from quantitation range 1) can be further diluted at a ratio of 1:11 (i.e. use a blue pipette tip to add 1000 µL of dilution buffer to a dilution tube. Use a yellow pipette tip to add 100 µL of previously diluted extract to the dilution buffer). An additional measurement should be performed by repeating steps (1) – (5) of the test procedure.

Limit of detection (LOD): 0.1 ppm (corn, wheat)

Limit of quantitation (LOQ): 0.2 ppm (corn, wheat)

Range of quantitation 1: 0 – 4.2 ppm
Range of quantitation 2: 3.1 – 44 ppm

Note: AgraStrip® Pro Deoxynivalenol WATEX® tests give quantitative results in the above defined quantitation range. For example, if the quantitation range is 0 – 4.2 ppm and the test result 4.3 ppm it will be displayed as > 4.2 ppm. If the result is lower than the second quantitation range (e.g. 3.1 – 44 ppm) it will be reported as < 3.1 ppm.

Warranty and Liabilities

The user assumes all risk in using Romer Labs products and services. Romer Labs will warrant that its products and services meet all quality control standards set by Romer Labs and Romer Labs will, at its option, repair or replace any product, components, or repeat services which prove to be defective in workmanship or material within product specific warranty periods or expiration dates and which our examination shall disclose to our satisfaction to be defective as such. This warranty is expressly in lieu of all other warranties, expressed or implied, as to description, quality, merchantability, fitness for any particular purpose, productiveness, or any other matter. Romer Labs shall be in no way responsible for the proper use of its products. Romer Labs hereby disclaims all other remedies, warranties, guarantees or liabilities, expressed or implied, arising by law or otherwise, and it shall have no liability for any lost profits or damage, direct, indirect or otherwise, to person or property, in connection with the use of any of its products or services. This warranty shall not be extended, altered or varied except by a written instrument signed by an authorized representative of Romer Labs.

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