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Royal Immunochromatographic One-Step Test

Aflatoxin B1 (AFT)

User Instruction

Catalog Number: A06-01-418

INTENDED USE

Royal One Step Aflatoxin B1 (AFT) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of Aflatoxin B1 in grains, nuts, oilseeds, cereals, spices and other commodities at or above the cutoff level of 10 ng/ml (10 ppb). It is intended for professional use.

This assay provides only a preliminary result. Professional judgment should be sought to further evaluate the result of the test, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is advised.

CONTENTS

- ☐ Pouch Contents: Test strip, Desiccant
- ☐ Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- ☐ Clean, dry collection container (plastic or glass)
- ☐ Clock or timer
- ☐ Sample grinder

WARNINGS AND PRECAUTIONS

- ☐ Do not reuse.
- ☐ Do not use if the pouch seal or its packaging is compromised.
- ☐ Do not use after the expiration date shown on the pouch.
- ☐ Do not mix and interchange different specimens.
- ☐ Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- ☐ Wash hands thoroughly after finishing the tests.
- ☐ Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- ☐ Clean up spills thoroughly with appropriate disinfectants.
- ☐ Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedure.
- ☐ Dispose OF all specimens and used devices in a properbio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- ☐ Keep out of children’s reach.

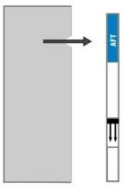
SPECIMEN PREPARATION

1. Grind 5 gram of test samples
2. Add 25 ml of 60% methanol and 1 g NaCl.
3. Mix the components by shaking the bottle or vortexing for 1 min.
4. Pour liquid into filter syringe and filter into collection tube.
5. Dilute the filtered liquid 3-4 fold with PBS +0.5% BSA.

➤ The final concentration of methanol needs to be less than or equal to 20% in the extracted liquid sample.

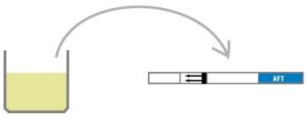
TEST PROCEDURES

1. Remove the testing device from the foil pouch by tearing at the notch. Hold the strip at the colored end.



2. Immerse the strip into the specimen with the arrow end pointing towards the specimen. Do not immerse past the MAX line.

3. Take the strip out after a minimum of 10 sec. Lay the strip (MAX side facing up) flat on a clean, dry, non-absorbent surface.



4. Read the result in 5-10 minutes. Ensure that the background of the test area is white before interpreting the result.

➤ DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

SUMMARY AND PRINCIPLE OF THE ASSAY

Aflatoxins are a group of mycotoxins produced by members of the Aspergillus genus (A. flavus, A. parasiticus and A. nomius.). Six major aflatoxins have been identified: aflatoxin B1, B2, G1, and G2 are produced by fungi; aflatoxins M1 and M2 are in vivo metabolites of aflatoxin B1 and B2 that are identified in milk, urine, and blood samples. The Aspergillus fungi are present throughout the world and their toxins are produced during growth and after harvest. All six aflatoxins have been assigned carcinogenic status by the U.S. Environmental Protection Agency (EPA) and are considered to be among the strongest, naturally occurring carcinogens in the world. The U.S. Food and Drug Administration (FDA) sets limit on 20 ppb in all food commodities for human and livestock.

Royal One-Step AFT Test device contains mouse monoclonal anti- AFT B1 antibody-colloidal gold conjugate deposited and pre-dried on a conjugate pad. AFT B1-BSA conjugate antigens (on the test region) and goat anti mouse IgG (on the control region) are coated and immobilized on a reaction membrane.

The principle behind Royal One-Step AFT Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which a chemically labeled drug (drug conjugate) competes with the drug that may be present in for a urine sample, leading to limited antibody binding sites. When the absorbent pad is soaked with urine, the urine will migrate via capillary action towards the test window where the test reaction occurs. A negative specimen produces two distinct pink bands, one in the test zone and one in the control zone; a positive specimen produces only one pink band in the control zone.

To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

RESULT INTERPRETATIONS

Negative

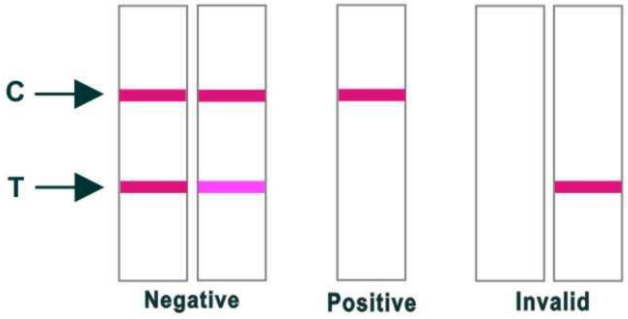
Two pink bands appear at the control and test regions, indicating absence of aflatoxin or the concentration of the Aflatoxin in the sample is below the cutoff value (10 ppb).

Positive

A pink band appears only at the control region, indicating the concentration of the aflatoxin in the sample is at or above the cutoff level (10ng/ml).

Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.



QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored line in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.

The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

Humidity and temperature can adversely affect results.

The instructions for the use of the test should be followed during testing procedures.

There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.

Although the test demonstrates superior accuracy in detecting AFT, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

For technical assistance or questions regarding the use of this test,

please call **Royal Biotech**

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