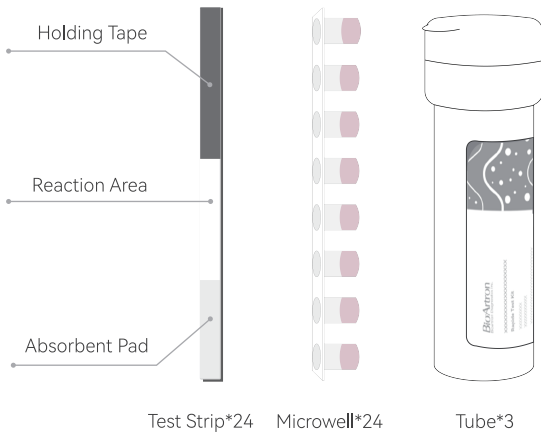


Aflatoxin M1 (AFT M1) Rapid Test Kit

Instructions For Use

Test Kit Manufacturer	Artron Laboratories Inc.
Test Kit Name	Aflatoxin M1 (AFT M1) Rapid Test Kit
Catalog Number	BDR-F32-413T24
Limit of Detection	30-50 ppt (ng/kg)
Test Specimens	Fresh raw milk
Type of Service	Qualitative
Test Format	Lateral flow strip
Kit Contents	<ul style="list-style-type: none"> 1 AFT M1 test strip x 24 2 Antibody-gold conjugate microwell x 24 3 Instructions for use x 1 4 Desiccants
Storage and Shelf Life	<ul style="list-style-type: none"> • Unopened test kit can be stored at 2-8°C for up to 12 months from date of manufacture indicated on the package. • Do not freeze the test kit. • Avoid direct sunlight, moisture or heat.



PREPARATION AND TEST PROCEDURE

Preparation

- 1 Please read through the test instructions carefully before the test.
- 2 Wait until all test device and milk sample have reached room temperature (15 ~30°C).
- 3 Shake the milk vigorously to ensure sample homogeneity.

Remove as many test strips and microwells as needed from the sealed container. Seal the rest of the test strips and microwells back and store at 2-8°C.

CAUTION: Please handle the test strip with the holding end only. Do not touch the sample end or the membrane zone.

Test Procedure

<p>1 Start the incubator and wait until the temperature reaches 40°C.</p>							
<p>2 Place the microwell(s) into the wells of the incubator (at 40°C).</p>							
<p>3 Immediately transfer the required amount of fresh raw milk sample to each of the microwells with a pipette.</p> <table border="1" style="margin: 10px auto;"> <thead> <tr> <th>Limit of Detection (ppt) (ng/kg)</th> <th>50</th> <th>30</th> </tr> </thead> <tbody> <tr> <th>Sample volume (µL)</th> <td>200</td> <td>300</td> </tr> </tbody> </table> <p>Completely dissolve the coating conjugate in the microwell by gently pipetting the mix up and down 5 to 6 times. When reagent in the microwells comes into contact with the milk sample, the reaction commences.</p>	Limit of Detection (ppt) (ng/kg)	50	30	Sample volume (µL)	200	300	<div style="text-align: center;"> <p>LoD: 50 ppt 200 µL Milk</p> <p>OR</p> <p>LoD: 30 ppt 300 µL Milk</p> <p>up and down 5 to 6 times</p> </div>
Limit of Detection (ppt) (ng/kg)	50	30					
Sample volume (µL)	200	300					
<p>4 Incubate the sample for 3 mins at 40°C.</p>							
<p>5 Dip the test strip into the microwell and let the strip develop colour for 7 mins at 40°C.</p>							
<p>6 After the 7-min colour development, take the test strip out of the microwell and immediately remove the sample end of the test strip and read the result within 1 min.</p>	<div style="text-align: center;"> <p>Read result within 1 Min</p> </div>						

RESULT INTERPRETATION

Result interpretation shall be conducted within the timeframe indicated above.

NEGATIVE



The test result is **NEGATIVE** if any of the following is observed:

- A lighter control band (C) and a darker test band (T), or
- Two bands in equal colour intensity appear.

This indicates the absence of AFT M1 in the milk sample or the concentration of the AFT M1 in the milk sample is below the selected limit of detection.

POSITIVE



The test result is **POSITIVE** if any of the following is observed:

- A darker control band (C) and a lighter test band (T), or
- T band is invisible, only C band appears.

This indicates that the concentration of the AFT M1 in the sample solution is at or above the selected limit of detection.

INVALID



No visible band in the control zone (C).

Repeat with a new test device. If the test still fails, please contact the manufacturer/distributor with the lot number.

- one in the control zone (C Band)
T Band intensity is higher than or equals to C Band intensity.

A **POSITIVE** specimen produces only one colour band in the control zone (C Band), or, in some cases, T Band also appears but its intensity is weaker than C Band intensity.

To serve as an internal process control, a control band was designed to indicate that the test was performed properly. By utilizing the different antigen/antibody reactions, this control band is always supposed to be seen after the test completes. Absence of

MATERIALS REQUIRED BUT NOT PROVIDED

- 20–200 µL pipette
- Incubator
- Clock or timer

WARNINGS AND PRECAUTIONS

- The test strips and the microwells must remain inside the stay-dry container before use.
- Do not reuse.
- Do not use kit components beyond expiration date.
- Do not use kit components if the container seal or the packaging is compromised.
- Do not mix or interchange different specimens or components from test kits with different lot numbers.
- Protective apparel such as laboratory coats, disposable gloves and eye protection should be worn at all times during tests.
- Wash hands thoroughly after the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Tap water, distilled water, deionized water or sample extraction solution cannot be used for negative control.
- Clean up spills thoroughly with appropriate disinfectants.

INTENDED USE / USER

Proudly presented by Bioartron Diagnostics Inc., the Aflatoxin M1 (AFT M1) Rapid Test Kit is an immunochromatographic assay adopting lateral flow technology and is designed for the onsite rapid qualitative detection of aflatoxin M1 molecules in fresh raw milk samples at or above the cutoff level of 30–50 ppt (ng/L).

This assay provides only a preliminary result. To obtain a confirmed analytical result, a more specific alternate chemical method is advised. This test kit is designed for use by food safety and food quality control personnel and people who are familiar with food safety inspection.

SUMMARY / ASSAY PRINCIPLES

Aflatoxin M1 is a chemical compound of the aflatoxin class, a group of mycotoxins produced by three species of *Aspergillus*: *Aspergillus flavus*, *Aspergillus parasiticus*, and the rare *Aspergillus nomius* which contaminate plant and plant products. Aflatoxin M1 can be found in milk or milk products obtained from livestock that have ingested contaminated feed. Aflatoxin M1 is now considered a carcinogen which might induce cancers. The USA as well as a number of European and Asian countries accept a maximum level of 0.5 ppb aflatoxin M1 in milk.

Bioartron Aflatoxin M1 (AFT M1) Rapid Test kit contains mouse monoclonal anti-aflatoxin M1 antibody-colloidal gold conjugate pre-dried in conjugate microwell. AFT M1-BSA conjugate antigen (on test zone) and goat anti mouse IgG (on control zone) are coated and immobilized on a reaction membrane.

The principal of Bioartron Aflatoxin M1 (AFT M1) Rapid Test is a solid phase, competitive inhibition immuno-chromatographic assay, in which AFT M1-BSA competes with AFT M1 molecules that may be present in samples, for limited antibody binding sites. When the absorbent pad (sample end) is soaked with the liquid sample, the liquid sample will migrate via capillary action toward the test window where the test reaction occurs.

A **NEGATIVE** specimen always produces two distinct colour bands:

- one in the test zone (T Band)

WARRANTY

Bioartron Diagnostics Inc. makes no warranty of any kind, either expressed or implied, except that the materials from which its products are made are of standard quality. If any materials are defective, Bioartron will provide a replacement of the product. Buyer assumes all risk and liability resulting from the use of this product. There is no warranty of merchantability of this product or of the fitness of the product for any purpose. Bioartron shall not be liable for any damages, including special or consequential damage, or expense arising directly or indirectly from the use of this product.

NOTE

Please contact Bioartron with a corresponding lot number if any expired, damaged, defective, contaminated, or invalid products are found.

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 this test kit demonstrates high accuracy in detecting aflatoxin M1 in the samples, a low incidence of false results can occur. Therefore, other reference tests are recommended (such as GC-MS) in case of questionable results. As with all detection tests, a definitive detection should not be based on the results of a single test but should only be made by the technicians/professional personnel after all laboratory findings have been evaluated.

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