



QUANTUM M1

Lateral Flow Test Kit

for the quantitative determination of Aflatoxin M1 in fresh raw milk

This Lateral Flow test kit is manufactured by ProGnosis Biotech S.A.

ProGnosis Biotech S.A. is ISO 9001:2015 certified by TÜV Hellas (TÜV NORD).

Use only the current version of Product Data Sheet enclosed with the kit.

Quantum M1, W3130/W3160, is a Lateral Flow Test kit for the quantitative determination of Aflatoxin M1 in fresh raw milk.

This kit contains all reagents required for 30 or 60 reactions.

Matrix:

Fresh raw cow's milk

- Test Time : 14min
- Range: 15 - 150 ppt
- Limit of detection (LOD): 9ppt
- Limit of quantification (LOQ): 15ppt
- Shelf life: 12 months

1. Description

Quantum M1 is a Lateral Flow device for the quantitative determination of Aflatoxin M1 in fresh raw cow's milk.

2. General Information

Aflatoxins are toxic metabolites of major concern to the dairy industry, generally produced by *Aspergillus flavus*, *A. parasiticus* and *A. nomius*. They can have immunosuppressive, mutagenic, teratogenic and carcinogenic effects. Aflatoxins ingested by animals through contaminated pellets and forage are bio-transformed at the hepatic level into Aflatoxin M1 (AFM1). This metabolite is then excreted in the milk used for human consumption and is also present in dairy products. AFM1 in milk and milk products poses certain hygienic risks for human health. Consequently, the EU has established a limit of 0.05 µg/kg (50 ppt) for AFM1.

3. Principle of the Method

The Quantum M1 lateral flow test is based on the principles of a competitive format immunoassay. The test line (T) is placed below two control lines, C1 and C2. The detection system consists of a specific antibody against AFM1, conjugated to colloidal gold. During testing, the milk sample flows through the membrane, carrying along the detection system. If the sample is free of AFM1, color development occurs at the test line, indicating the absence of AFM1 in the milk sample. Conversely, the presence of AFM1 in the sample will cause a reduced colored signal at the test line. The test line color intensity is inversely proportional to the concentration of AFM1 present in the sample. By utilizing S-Flow software, AFM1 is accurately quantified. A valid test should always have the two upper control lines red.

4. Reagents Provided

Quantum M1 kit contains sufficient reagents and materials for 30/60 measurements.

- 30/60 tests (cassette format) in foils
- 30/60 disposable fixed-volume plastic pipettes
- Instruction manual

5. Materials required but not provided

- Clock or timer
- S-Flow software along with matching scanner device provided by lateral logic ltd

6. Storage Instructions

Store kit components between 2 - 8°C. Do not freeze any components provided. Expiry of the kit and reagents is stated on their labels and no quality guarantee is accepted after the expiration date. The expiry of the kit components can only be guaranteed if the components are stored properly and the reagent is not contaminated due to prior handling.

7. Safety and Precautions for use

All reagents should be brought to room temperature (21 - 25°C) before use (at least half an hour). Do not re-use any of the kit components. Do not use thawed milk.

8. Method Procedure

1. Before opening the reagents, take the kit out of the refrigerator (for at least half an hour) and wait until the temperature of the reagents reaches the ambient temperature.
2. Open as many foils with cassettes as the number of milk samples to be tested.
3. Shake the milk samples vigorously by hand or vortex.
4. Use a disposable fixed-volume plastic pipette and add the sample in the circular window of the cassette. The ideal temperature of the milk is between 4 - 18°C. Do not re-use the plastic pipettes.
5. **Always** place the cassette **inside** the plastic holder and press SCAN using the S-Flow software. The cassette must be facing up. The 14 minute count down starts immediately.

9. Interpretation of results

The Quantum M1 lateral flow test is manufactured to work **only with a scanner device**, S-Flow or 3PR.

1st Quantum read: 7 minutes after the start of the analysis the device scans the cassette automatically,

- ⇒ If the sample is free of AFM1 or contains AFM1 at a concentration below the LOQ (AFM1<15ppt), the analysis stops.
- ⇒ If the sample is suspected positive for AFM1, the analysis continues until it completes 14 minutes.

Final Quantum read: After the end of analysis the S-Flow software will use a Lot specific curve to calculate the results in parts per trillion (ppt).

Note: Visual interpretation of the stick is NOT possible.

10. General Specifications

- **Cross-reactivity:** The anti-Aflatoxin M1 antibody has <5% cross reactivity with Aflatoxin M2 and no cross-reactions other mycotoxins (Ochratoxin A, Zearalenone, Deoxynivalenol and Fumonisin B1) and other unrelated compounds, such as antibiotics (Benzylpenicillin, Cefalonium, Oxytetracycline, Erythromycin, Neomycin, Enrofloxacin, Sulfadiazine, Trimethoprim and Dapsone).
- **Matrix:** Fresh raw cow's milk.
- **IC50** = 55 - 75ppt.
- **Limit of detection (LOD):** 9ppt.
- **Limit of quantification (LOQ):** 15ppt.

11. Interferences

There are no interferences from somatic cells at 10⁶ SCC/ml or bacteria at 3x10⁶ CFU/ml.

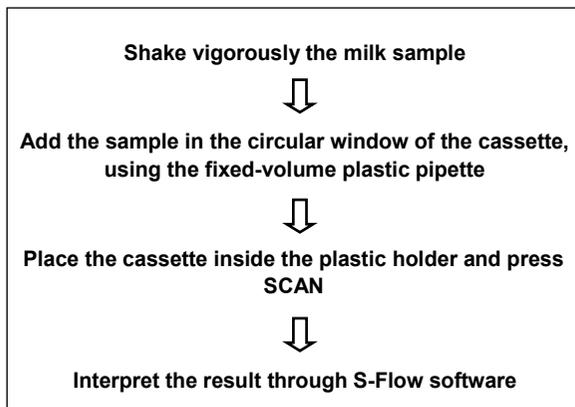
12. Performance Evaluation

Proficiency Tests

All products participate frequently in Proficiency Tests. For more information, visit the individual product page in our website: www.prognosis-biotech.com

13. Summary of method

Total method time: 14 minutes



All immune assays supplied by ProGnosis Biotech S.A., are warranted to meet or exceed our published specification when used under normal conditions in your laboratory. If the product fails during the stated period, a replacement product will be issued.

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LATERAL FLOW TEST KIT

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