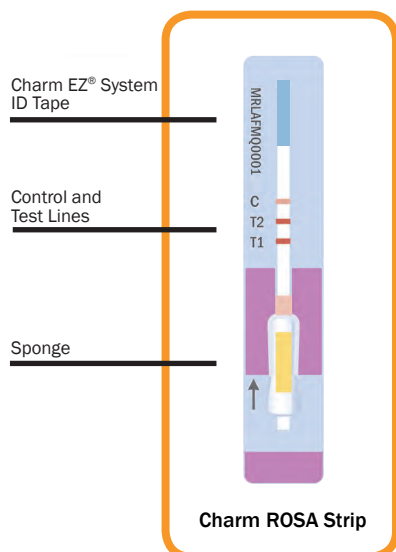


Charm MRL Aflatoxin M1 Quantitative Test for Milk



Product Overview



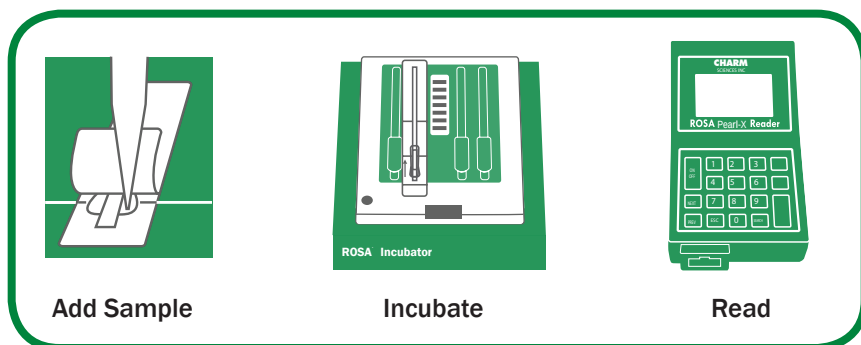
The **Charm® MRL Aflatoxin M1 Quantitative Test** delivers rapid and accurate results using ROSA® (Rapid One Step Assay) lateral flow technology. The MRLAFMQ is the only quantitative lateral flow test that detects aflatoxin M1 in milk at the EU MRL of 0.050 ppb (50 ppt).

Charm MRL Aflatoxin M1 Quantitative Test:

- ✓ Range: 0 to 100 ppt
- ✓ Results in 15 minutes
- ✓ Meets EU MRL

15
minutes

Simple Procedure



Or combine all 3 steps
using the Charm EZ system

Concentration - Response Curve for Aflatoxin M1 in Milk 0 to 7 °C	
Concentration ppt ^A	% Positive on ROSA Reader
0 ppt	0 %
25 ppt	0 %
50 ppt	100 %
75 ppt	100 %

^A ng/kg = parts per trillion

Ordering Info



Order Codes	Each Kit Includes
LF-MRLAFMQ-20K LF-MRLAFMQ-100K LF-MRLAFMQ-500K	Test Strips and Positive Control

See Operator's Manual for additional kits and order codes



Operator's Manual: Charm® MRL Aflatoxin M1 Quantitative Test for Raw Commingled Cow Milk

Kit Information

Introduction

The Charm MRL Aflatoxin M1 Quantitative Test is an immunoreceptor assay utilizing ROSA® (Rapid One Step Assay) lateral flow technology. Aflatoxin M1 interacts with colored beads in the lateral flow test strip, and the color intensity in the test and control zones is measured by the ROSA Reader or Charm EZ and displayed as ppt (parts per trillion). The Charm MRL Aflatoxin M1 Quantitative Test detects aflatoxin M1 at the EU MRL (maximum residue limit) of 0.050 µg/kg or 50 ppt. The test is designed for use by dairy, intake, laboratory, field, and regulatory personnel.

Kit Contents and Materials Needed

Supplied with Kits	Disposables	Equipment
- MRLAFMQ Test Strips 50 ppt Aflatoxin M1 Standard - Operator's Manual	- Pipet Tips or - ROSA-Pipets	- ROSA Incubator (40°C) and ROSA Reader or - Charm EZ (optional) - Printer (optional) 300 µl Pipet (optional)

Charm ROSA equipment available only from Charm Sciences Inc.
For details and ordering information see **Order Codes and Kit Contents**.

Sensitivity and Selectivity

Aflatoxin-free raw cow milk yields negative results at least 99% of the time.

Sensitivity and Range of Quantitation: 0 to 100 ppt Aflatoxin M1

Limit of Detection: Less than 15 ppt Aflatoxin M1

Precision and Accuracy at 50 ppt: 95% Confidence Interval: 54 ± 14 ppt Aflatoxin M1 (RSD = 13%)

Table 1. Sensitivity – Concentration-Response Curve for Aflatoxin M1 in Cow Milk at 0 to 7°C

Qualitative positive result is based on ROSA Reader or Charm EZ READING greater than or equal to 40 ppt. See **Interpretation**.

Concentration ppt*	% Positive† on ROSA Reader or Charm EZ
0	0
25	0
50†	100
75	100

* parts per trillion or ng/kg

† Positive at least 95% of the time.

Interferences

There are no known interferences from drugs at 100 ppb in the following animal drug families: aminoglycosides, amphenicols, beta-lactams/cephalosporins, fluoroquinolones, macrolides/lincosamides, nitrofurans, tetracyclines, sulfa drugs, or chlorothiazide, dexamethasone, dipyrone, flunixin, furosemide, ivermectin, novobiocin, oxytocin, PABA, phenylbutazone, trichlormethiazide, and thiabendazole. There are no interferences from somatic cells at 5×10^5 SCC/ml or bacteria at 3×10^5 CFU/ml.

Storage

Store MRLAFMQ test strips and Aflatoxin M1 Standard refrigerated (defined as 0 to 7°C or 0 to 4.4°C for US certified labs). See **Reagents and Storage** for details.

Charm Sciences, Inc.

659 Andover Street, Lawrence, Massachusetts, 01843-1032, USA

Tel: +1.978.687.9200 | Fax: +1.978.687.9216 | Email: info@charm.com | www.charm.com

© 2017 Charm Sciences Inc. Charm, Charm EZ and ROSA names and Running Cow image are registered trademarks, and test strip packaging is trade dress, of Charm Sciences Inc. See www.charm.com/en/us-patents for a list of U.S. issued patents and pending, published U.S. and PCT applications.



Daily Performance Check

- Daily and before retesting "initial positive" samples, check ROSA Reader or Charm EZ performance using the supplied Calibration Strips. With Rosa Reader, enter performance mode in ROSA Reader by sequentially pressing ESC, 5, ENTER.
 - For ROSA Reader Version 1.09.08 or lower, read Calibration Strips on any calibrated non-ALFA channel in 3-line mode (rapid blink) in performance mode (ESC, 5, ENTER).
 - For ROSA Pearl Reader, read Calibration Strips on specially calibrated SLAFMQ mode of the AFLA channel in performance mode (ESC, 5, ENTER).

With Charm EZ, go to menu and follow on-screen instructions. Calibration Strips must test within range.

- Test one Negative Control and one Positive Control prior to testing actual samples to verify performance of test strips and equipment.
 - For ROSA Reader Version 1.09.08 or lower, read Negative and Positive Control test strips on specially calibrated AFLA channel in 3-line mode (rapid blink).
 - For ROSA Pearl Reader, read Negative and Positive Control test strips on specially calibrated SLAFMQ mode of the AFLA channel in 3-line mode in performance mode.

Control test strips must test in specified ranges:

- **Negative Control: READING 0 ppt and RESULT NEGATIVE**
- **Positive Control: READING 40 to 68 ppt and RESULT POSITIVE**
- If Calibration Strips or Controls do not perform in specified ranges, discontinue use and contact Charm Sciences for assistance.

Precautions

- High fat samples (greater than 6.0%) may cause invalid results. Do not read invalid test strips in the ROSA Reader or Charm EZ.
- Debris on test strips may alter the ROSA Reader or Charm EZ optics. Keep equipment clean and wipe dust and milk off test strips before inserting in ROSA Reader or Charm EZ.
- ROSA Incubator or Charm EZ must be clean and level. ROSA Incubator or Charm EZ temperature must be $40^{\circ}\text{C} \pm 1^{\circ}\text{C}$. The temperature indicator should match ROSA Incubator temperature. A daily thermometer check is recommended. Keep ROSA Incubator lid lowered, but not latched, unless performing procedure.
- ROSA Incubators may take more than 10 minutes to reach proper temperature, depending on ambient temperature.
- The Charm EZ may take up to 3 minutes to reach proper temperature, depending on ambient temperature.
- Turning on the Charm EZ without the SD Card or the Slide Mechanism properly inserted will result in an error message.

**Charm
EZ**



**This strip is not
Charm EZ compatible.
Remove strip and
insert correct type.**

- The Charm EZ Reader is not compatible with all Charm test strips.
- Older, non-compatible test strips will result in an error message when inserted into the Charm EZ.
- For a complete list of Charm EZ compatible tests contact your local representative or Charm Sciences at +1.978.687.9200 or support@charm.com.

Retest of Initial Positive

1. Test "initial positive" samples in duplicate along with one Negative Control and one Positive Control.
2. **Negative Control must be RESULT NEGATIVE with READING 0 ppt on ROSA Reader or Charm EZ.**
3. **Positive Control must be RESULT POSITIVE with READING 40 to 68 ppt on ROSA Reader or Charm EZ.**
4. If either Control is not within range, repeat testing of "initial positive" with Controls. If either Control is still not within range after retest, discontinue testing and contact Charm Sciences.
5. If both Controls are within range and either or both of the retested samples are **RESULT POSITIVE**, the sample is an "Aflatoxin Positive Test".

Order Codes and Kit Contents

KITS	NOT SUPPLIED WITH KIT
LF-MRLAFMQ-40K: (1) container of 40 MRLAFMQ test strips (1) 50 ppt Aflatoxin M1 Standard (1) Operator's Manual	1-MLT-100 (box of 100 disposable pipet tips, 200-1000 µl)
LF-MRLAFMQ-100K: (1) container of 100 MRLAFMQ test strips (2) 50 ppt Aflatoxin M1 Standards (1) Operator's Manual	1-MLT-BG (bag of 1,000 disposable pipet tips, 200-1000 µl)
LF-MRLAFMQ-100ESK: (1) container of 100 MRLAFMQ test strips (6) 50 ppt Aflatoxin M1 Standards (1) Operator's Manual	1-MLT-X1 (2 boxes of 100 disposable pipet tips, 200-1000 µl)
LF-MRLAFMQ-500K: (5) LF-MRLAFMQ-100K	1-MLT-X4 (10 boxes of 100 disposable pipet tips, 200-1000 µl)
	LF-ROSA-PIPET-500 (500 disposable ROSA-pipets, 300 µl)
	LF-ROSA-PIPET-5000 (5000 disposable ROSA-pipets, 300 µl)
	PIP-300UL-1STOP-M (300 µl fixed volume pipet)
	PIP-100-1000UL-1STOP (100 to 1000 µl pipet)
	LF-INC4-15-40 (4 place ROSA Incubator with 15 minute timer, 40°C)
	LF-INC2-15-40 (2 place ROSA Incubator with 15 minute timer, 40°C)
	LF-ROSA-PEARL-X-NB (ROSA Pearl-X Reader)
	LF-ROSA-EZ (Charm EZ System)

Warranty Information

Charm Sciences, Inc. ("Charm") warrants each reagent product, including but not limited to test kits, to be free from defects in materials and workmanship and to be free from deviations from the specifications and descriptions of Charm's reagent products appearing in Charm's product literature, when stored under appropriate conditions and given normal, proper and intended usage, until the expiration of such reagent product's stated shelf life, or, if none is stated, for one year from the date of delivery of such reagent product to the end-user purchaser. **THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER STATUTORY, EXPRESS, IMPLIED (INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE).** The warranty provided herein may not be altered except by express written agreement signed by an officer of Charm. Representations, oral or written, which are inconsistent with this warranty are not authorized and if given, should not be relied upon. In the event of a breach of the foregoing warranty, Charm's sole obligation shall be to replace any reagent product or part thereof that proves defective in materials or workmanship within the warranty period, provided the customer notifies Charm promptly of any such defect prior to the expiration of said warranty period. The exclusive remedy provided herein shall not be deemed to have failed of its essential purpose so long as Charm is willing to replace any nonconforming reagent product or part. **Charm shall not be liable for consequential, incidental, special or any other indirect damages resulting from economic loss or property damages sustained by any customer from the use of its reagent products.** Except for Charm's obligation set forth above to replace any reagent product that proves defective within the warranty period, Charm shall not be liable for any damages of any kind arising out of or caused by any incorrect or erroneous test results obtained while using any such reagent product, whether or not caused by a defect in such reagent product.