



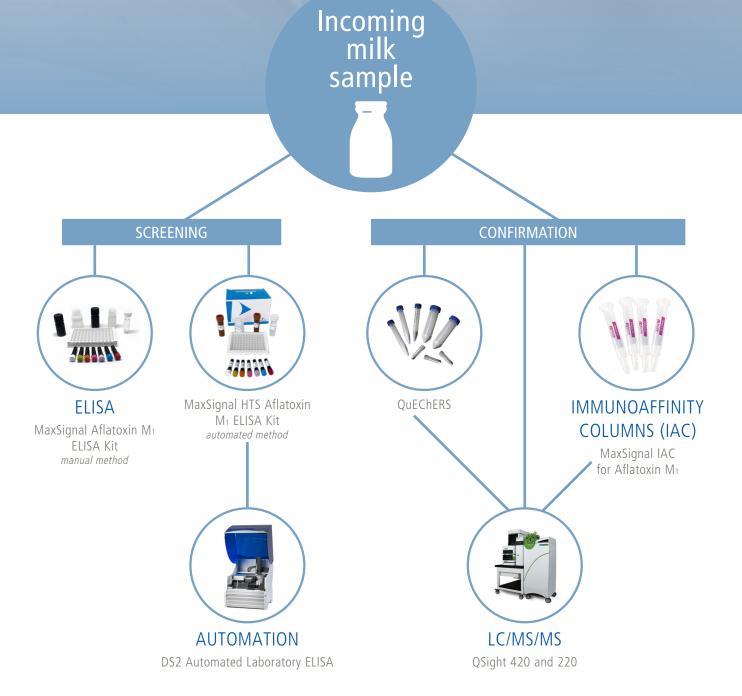
AFLATOXIN M1 PREVALENCE & REGULATIONS

- Humid atmospheric conditions are giving rise to mycotoxins in food and feed products.
- Mycotoxin contamination can occur pre-harvest when the crop is growing or post-harvest during processing, packaging, distribution, or storage of finished food products.
- Aflatoxin M_1 is a metabolite of aflatoxin B_1 commonly found in dairy products. Presence of aflatoxin M_1 occurs when dairy cattle ingest feed contaminated with aflatoxin B_1 .
- Aflatoxins are known to be carcinogenic and it is important to monitor the supply of dairy and dairy based products for contamination
- Since aflatoxins B₁ and M₁ are carcinogenic to humans, the action level of 0.5 parts per billion of aflatoxin M₁ in milk is strictly enforced by the United States Food and Drug Administration (FDA). EU imposed an action limit of 0.05 parts per billions of aflatoxin M₁ in milk and 0.025 ppb for infant formula.
- Sampling and monitoring procedures are strictly enforced for consumer safety.



AFLATOXIN M₁ SOLUTION

For third party food testing labs or producers who want to conduct aflatoxin M₁ analysis in dairy products, our automated aflatoxin M₁ ELISA assay and QSight LC/MS/MS aflatoxin M₁ analyzer provide sensitive, accurate, and fit for purpose screening and confirmative analysis solutions that you can use out of box.



MaxSignal Aflatoxin M₁ ELISAs

ELISA assays are widely used for the detection of aflatoxins M₁ in milk for regulatory conformance owing to the high sensitivity, selectivity, and ease of use of the method. The MaxSignal® Aflatoxin M₁ ELISA Kit is a competitive enzyme immunoassay for the quantitative analysis of aflatoxin M₁, the hydroxylated metabolite of aflatoxin B₁. The MaxSignal® HTS Aflatoxin M₁ ELISA Kit automated solution is an end-to-end workflow platform that includes simple, comprehensive multiplexed sample prep, ready-to-use reagents and standards, and a state-of-the-art automated, high-throughput detection platform. The assay is able to detect aflatoxin M₁ in full fat milk equally as well as in de-fatted milk allowing technicians to chose to skip the defatting step, saving valuable time. With less hands-on requirements, the simplified workflow saves time and enables faster, more informed decision making around dairy samples while reduceing cross-contamination. Additional features included in the system such as the integrated bar-code scanner can provide excellent sample traceability and can be easily linked to LIMS for seamless result recording and sharing.



Detection Limit (ng/g or ppb)			
Milk Powder*	0.08		
Milk	0.023		
Yogurt*	0.02		

^{*}Manual method only (#FOOD-1060-05)



SPECIFICITY

Analyte	Cross-Reactivity (%)
Aflatoxin M ₁	100
Aflatoxin B ₁	59
Aflatoxin B ₂	14
Aflatoxin G ₂	13
Aflatoxin G ₁	10





1 2 3 4 5 6 7 8 9 10 11 12





Milk samples

MaxSignal HTS ELISA kit

Transfer extract to each assay strip

192 samples capability

Process and read via automated ELISA platform

DS2 Automated Laboratory ELISA

Designed with full walkaway capability, the DS2 can quickly and easily process two 96-well microplates and up to 192 samples in less than 90 minutes. Additionally, it features the most intuitive control system available, including simple chain of custody and instrument diagnostics.

This system delivers no-fuss, sample-in/results-out automation of microplate assays, taking charge of the entire workflow:

- Sample dilution and distribution;
- · Incubation, washing, and reagent dispensing;
- Reading with automatic data reduction and quality control;
- Automatic barcode scanning.

The easy-to-use DS2 Automated Laboratory ELISA system is designed for efficiency and reliability, with few moving parts – one multifunction robot arm does everything from pipetting to operating the barcode reader. Plus, the system's vertical design and patent-pending multiplate carrier saves space, enabling maximum consumables storage in minimal benchtop footprint.

With the DS2 Automated Laboratory ELISA system, you get:

- 216 sample tips
- 96 dilution vessels in 8-way strips
- 20 reagent tips
- 8 large and 10 medium reagent bottles
- 24 standard/control bottles

Furthermore, you can set the instrument to prompt you if you need to take any immediate actions such as adding reagents or wash fluids. The DS2 Automated Laboratory ELISA system can deliver an audible alarm or send you an email outlining any problems. Integrated self-diagnostics make troubleshooting easy



– you can even send our technical support team a problem description from within the application, with system information attached automatically.

POWERFUL SOFTWARE THAT INTUITS YOUR NEEDS

DS-Matrix[™] software allows you to rapidly integrate automation in the lab with confidence. The simple graphical interface means that any lab technician can use the DS2 Automated Laboratory ELISA system with minimal training. With easy to use DS-Matrix software, you get:

Assay Writer

Drag-and-drop icons walk you through the programming process, prompting you step by step, making assay setup easy. And if you miss a critical step? The Assay Writer lets you know before you move on.

Process Simulator

No need to waste reagents or consumables: the system shows you a full animation of the assay steps you've outlined. If you want to adjust the assay parameters, the system shows you how it will work before you implement the change.

Process Timeline

Once you begin running your assay, you know exactly where you are and how much time is left.

ESI

Patent-pending technology that provides in-process verification of critical fluid and sample transfer.

Recording

The system enables recording and assurance of lot-specific data.

QSight

Ideal for analyzing food samples, our robust and reliable QSight® triple quad systems consistently deliver the throughput and productivity you need in your analytical testing lab. This powerful LC/MS/MS system is engineered to deliver exponentially better sensitivity that commercial testing labs, and global food manufacturers and exporters need. It's the perfect instrument for labs that need uncompromising performance.

- Highest sensitivity to meet the most demanding regulations
- Easy-to-use with ready to implement methods just set and forget
- Patented flow-based technology StayClean[™] Source enables up to 15% more productivity and has a self-cleaning design for maximum sensitivity and exceptional uptime
- Laminar Flow Ion Guide™ for highly efficient field-free transmission, with minimal maintenance requirements
- Dual Source technology gives you the capability to set ESI or APCI modes, with two independent probes for true multiplexing
- Simplicity™ 3Q software provides easy-to-use solution and streamlined workflow that make method development, data acquisition and processing, result reporting intuitive and straightforward
- Simplicity 3Q real time data processing feature minimizes time of processing



 Simplicity 3Q provides various feature such as Audit trial, user roles and tracking the files to meet GLP/GMP requirements

LC/MS/MS provides most accurate and reliable confirmative quantitation of trace level contaminants in food product. For Aflatoxin M₁ analysis, we have developed three different sample preparation methods to meet various regulation needs for milk and infant formula. Combining the sample preparation methods with validated QSight LC/MS/MS methods, we provide you with complete end-to-end, turn-key confirmative solutions for aflatoxin M₁ analysis in dairy products.

SAMPLE PREPARATION METHOD

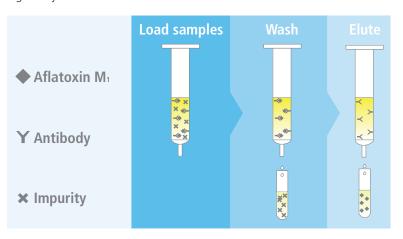
Liquid-liquid extraction		MAIN STEPS	ADVANTAGES
Liquid-liquid extraction with concentration & reconstitution	Add extraction solvent Centrifuge Filtrate	Simple, fast, and most cost effective to meet FDA requirements.	
		Add extraction solvent Add QuCHERS salt Centrifuge reconstitute	Simple, fast, and cost effective to meet both FDA and EU requirements.
Liquid-liquid extraction with IAC clean up		Add extraction solvent Centrifuge Dilute with IAC & column reconstitute	Cleaner sample for more accurate results, meet all regulatory MRLs.



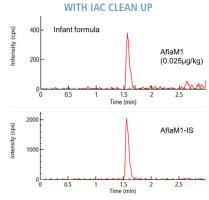
While similar levels of analytical performance can be achieved with or without IAC clean-up, the IAC clean-up does help to show cleaner chromatogram with less interference and background noise, therefore providing better and more reliable testing results. This is due to the exceptionally high selectivity of IAC.

The IAC uses the highly specific interactions between antigen and antibody to purify and enrich the target substance. The specific antibody present in the column selectively binds the target substance in the sample, and the unbound impurities flow out of the column. The target substance bound on the column is then eluted with eluent, so as to achieve the high-efficiency purification and concentration of the target substance.

Highly concentrated and purified samples enhance the accuracy of the results with minimal to none matrix effects. This is more pronounced in complex sample matrices and increases the sensitivity to meet all regulatory MRL's.



WITHOUT IAC CLEAN UP 1000 Infant formula AflaM1 (0.025μg/kg) 1000 0.5 1 1.5 2 2.5



Immunoaffinity column clean-up provides a cleaner chromatogram with lower background noise as seen in the graphs on the bottom.

	Liquid-liquid extraction	Liquid-liquid extraction with concentration & reconstitution	Liquid-liquid extraction with IAC clean up
Linearity			
Linear range (µg/kg)	0.1-100	0.005-5	0.005-5
Correlation coefficient (R ²)	>0.99	>0.99	>0.99
Precision			
LFM (spiked at 0.025 μ g/kg, n= 5), RSD (%)	< 15%	< 15%	< 15%
Recovery (Accuracy)			
Laboratory Reagent Blank (LRB) (ng/mL)	0	0	0
Sample Blank (μg/kg) (%)	0	0	0
Laboratory Fortified Matrix (three levels, %)	93.2-112	89.4-112	85.9-115
Limit of Quantification (LOQ)			
Method LOQ for milk (S/N =10) (μ g/kg)	0.15	0.005	0.005
Method LOQ infant formula (S/N =10) (μ g/kg)	0.15	0.005	0.01

PART #	PRODUCT	QTY
FOOD-1060-05	MaxSignal Aflatoxin M₁ ELISA Kit	96 tests
FOOD-4006-01	MaxSignal HTS Aflatoxin M₁ ELISA Kit	96 tests
DS2010	DS2 Automated Laboratory ELISA	_
BC003844	QSight 400 series	_
BC003382	QSight 200 series	_
FOOD-1506-01	MaxSignal IAC for Aflatoxin M ₁	25 X 3 mL

PerkinElmer, Inc. 940 Winter Street Waltham, MA 02451 USA P: (800) 762-4000 or (+1) 203-925-4602 www.perkinelmer.com

