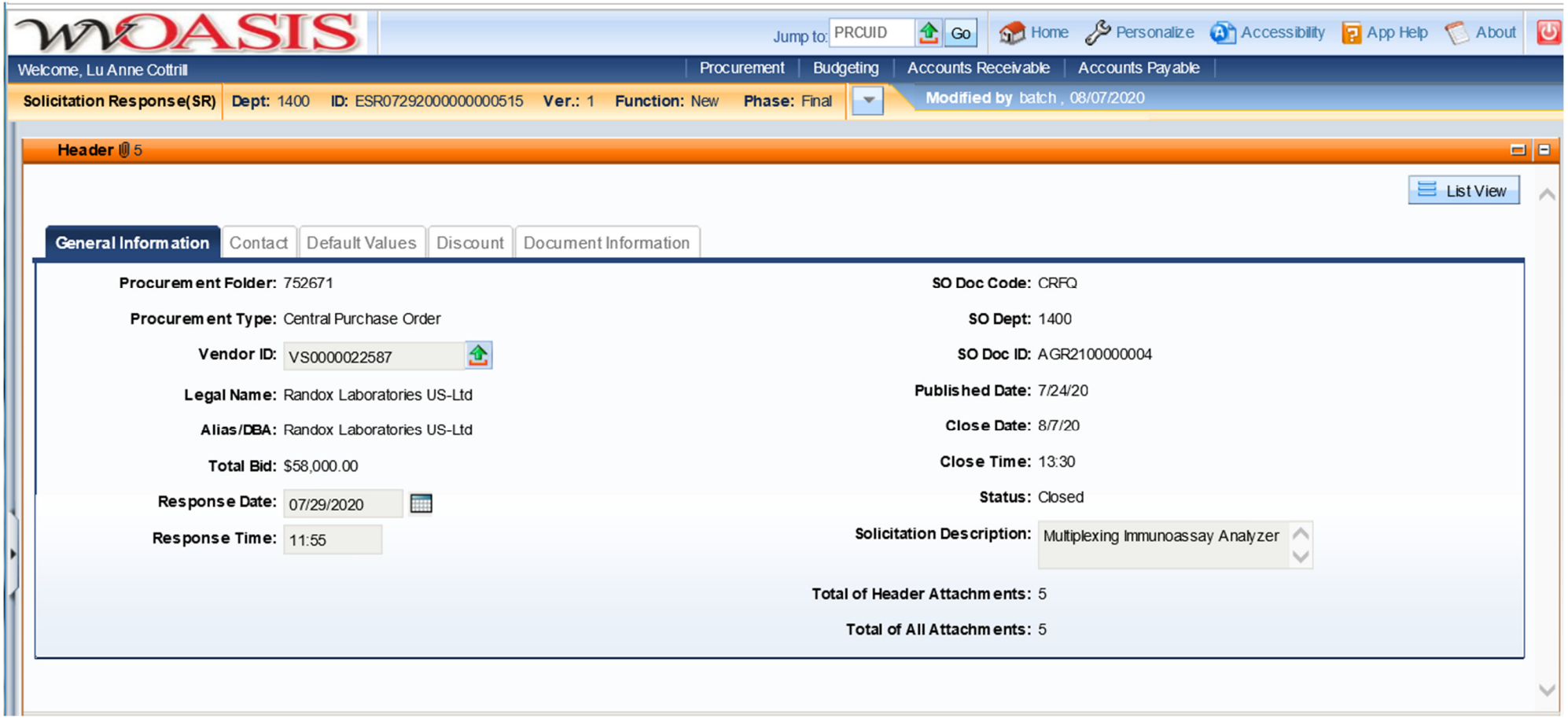
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.


wvOASIS
Jump to: PRCUID Go
Home
Personalize
Accessibility
App Help
About
Welcome, Lu Anne Cottrill
Procurement
Budgeting
Accounts Receivable
Accounts Payable
Solicitation Response(SR) Dept: 1400 ID: ESR07292000000000515 Ver.: 1 Function: New Phase: Final
Modified by batch , 08/07/2020
Header 5
List View
General Information
Contact
Default Values
Discount
Document Information
Procurement Folder: 752671
Procurement Type: Central Purchase Order
Vendor ID: VS0000022587
Legal Name: Randox Laboratories US-Ltd
Alias/DBA: Randox Laboratories US-Ltd
Total Bid: $58,000.00
Response Date: 07/29/2020
Response Time: 11:55
SO Doc Code: CRFQ
SO Dept: 1400
SO Doc ID: AGR2100000004
Published Date: 7/24/20
Close Date: 8/7/20
Close Time: 13:30
Status: Closed
Solicitation Description: Multiplexing Immunoassay Analyzer
Total of Header Attachments: 5
Total of All Attachments: 5

Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Solicitation Response

Proc Folder : 752671
Solicitation Description : Multiplexing Immunoassay Analyzer
Proc Type : Central Purchase Order

Date issued	Solicitation Closes	Solicitation Response	Version
	2020-08-07 13:30:00	SR 1400 ESR07292000000000515	1

VENDOR

VS0000022587

Randox Laboratories US-Ltd

Randox Laboratories US-Ltd

Solicitation Number: CRFQ 1400 AGR2100000004

Total Bid : $58,000.00 **Response Date:** 2020-07-29 **Response Time:** 11:55:16

Comments:

FOR INFORMATION CONTACT THE BUYER

Jessica S Chambers

(304) 558-0246
jessica.s.chambers@wv.gov

Signature on File **FEIN #** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Multiplexing Immunoassay Analyzer	1.00000	EA	$58,000.000000	$58,000.00

Comm Code	Manufacturer	Specification	Model #
41115864			

Extended Description : Multiplexing Immunoassay Analyzer

3.1.1 Multiplexing Immunoassay Analyzer

3.1.1.1 The multiplexing Immunoassay Analyzer must utilize Biochip Array Technology to analyze samples.

Randox can confirm that the Evidence Investigator utilizes Randox's patented Biochip Array Technology (BAT) to provide multiple results from a single sample. Please see Appendix 2 for a copy of the Evidence Investigator brochure.

3.1.1.1.1 Each Biochip must serve as a reaction well for a single sample

Each individual 9x9mm Biochip on the Evidence Investigator acts as the reaction well for a single sample, replacing multiple ELISA tests.

3.1.1.1.2 Each Biochip well must have a minimum of 44 discrete test regions

Multiple results can be obtained simultaneously from as little as 25µl of sample. Up to 45 samples and nine calibrators can be analyzed per run. Each Biochip well provides the user with up to 44 individual results from a single sample.

3.1.1.2 The Multiplexing Immunoassay Analyzer must be capable of analyzing 54 samples in under 3 hours

The Evidence Investigator is capable of testing up to 54 samples in a single run. The assay time for the Myco 7 array is 2 hours.

3.1.1.3 The Multiplexing Immunoassay Analyzer must be capable of quantitating the following mycotoxins in parts per billion (ppb); Aflatoxin B1/B2, Aflatoxin G1/G2, Ochratoxin A, Fumonisins, Deoxynivalenol, T2 toxin and Zearalenone.

The Evidence Investigator can cover all of the above mycotoxins listed with the Myco 9 Array. The analyzer reports the results in parts per billion (ppb).

3.1.1.4 The Multiplexing Immunoassay Analyzer must be capable of providing quantitative results in concentrations as low as parts per billion (ppb)

The Evidence Investigator provides the quantitative results for each assay in parts per billion (ppb).

3.1.1.5 The Multiplexing Immunoassay Analyzer must be capable of providing simultaneous detection of analytes for a single sample.

The Evidence Investigator uses our patented Biochip Array Technology (BAT) to provide multiple results from a single sample. Our comprehensive test menus allow for the screening of multiple sample types, providing quantitative results. These versatile arrays give customers the ability to accurately detect toxins and residues using a single platform.

3.1.1.6 The Multiplexing Immunoassay Analyzer must be validated for use in tissue, feed, cereals, honey, aquaculture and milk matrices

The Evidence Investigator is validated for use in the following matrices:

Tissue, feeds, cereals, honey, aquaculture, milk, serum, plasma, whole blood, urine, egg, cell culture supernatant, stool, saliva, bronchoalveolar lavage fluid and forensic matrices

3.1.1.7 The Multiplexing Immunoassay Analyzer must utilize image processing software to translate relative light units from chemiluminescent reactions into an analyte concentration.

Once the Biochip carrier is loaded into the Evidence Investigator the signal reagent is added to each Biochip before imaging. The light signal generated from each of the discrete test regions on the biochip is simultaneously detected. The analyzer uses unique image processing software to translate the light signal generated from the chemiluminescent reactions into an analyte concentration. No manual processing of data is required.

3.1.1.8 Any additional equipment necessary to operate the Multiplexing Immunoassay Analyzer must be included in quotation

All additional equipment necessary to operate the Evidence Investigator is included in our quotation, please see attached pricing schedule for full details.

The following supplementary equipment is included in the Evidence Investigator package:

- PC & imaging software
- Barcode scanner
- Thermoshaker
- Biochip carrier handling tray

3.1.1.9 All components of the instrument are new and not rebuilds, demos or returns

Randox can confirm that the Evidence Investigator which we are supplying as part of this bid is a new analyzer.

3.1.1.10 The vendor must provide documentation for recommended environmental conditions, electrical requirements and any other factor that would affect instrument performance.

Please see Appendix 3 for an extract of the Evidence Investigator Operator Manual. This manual is provided to the customer upon installation of the analyzer and lists the factors which would affect instrument performance.

3.1.1.11 The vendor will provide copies of all system manuals.

Randox can confirm that all system manuals will be supplied to the customer upon installation of the analyzer. These manuals are in English and can be provided in hard and/or soft copy.

3.1.1.12 A yearly price for the Maintenance Program or Protection Plan must be submitted with the quotation.

An annual price for Preventative Maintenance has been submitted, please see the Pricing Schedule for full details.

3.1.2 Workstation and Software

3.1.2.1 Computer must be equipped with Microsoft Windows 7 or newer

The Evidence Investigator comes with a computer which is equipped with a Windows 7 Operating system.

3.1.2.2 Program software must calculate all results and does not require any further manipulation of data by the analyst

On-board data analysis means that no manipulation of data is required. This reduced the scope for operator error and improves workflow due to rapid results.

3.1.2.3 Computer workstation must include a mouse, color monitor, keyboard, DVD-RW drive, at least 2 USB ports, printer and a barcode scanner

The Evidence Investigator comes with a printer, barcode scanner, carrier handling tray, thermoshaker and a computer with the following specifications:

- Processor: Intel Core i30-6100 Processor
- Memory: 4GB (1x4GB) 1600MHz DDR3L
- Hard Drive: 1TB 3.5in (7200 Rpm)
- Optical Drive: DVD ±RW
- USB: 6 USB Ports
- Display: Dell E-Series 17-inch color Monitor
- Mouse: Dell Optical MS116 Black Mouse
- Keyboard: UK (QWERTY) Dell KB216 Keyboard Black
- Operating system: Windows 7 professional (32 BIT) English

3.1.3 Shipping

3.1.3.1 Equipment must be delivered within 90 days after receipt of order

Randox can confirm that the Evidence Investigator will be delivered within 90 days after receipt of order.

3.1.3.2 The bidder must explain the details of its proposed packaging sizes for the deliverable(s). All equipment must be packaged and capable of fitting through access doors.

The Evidence Investigator has the following physical dimensions:

- Height - 29.5 in
- Depth -18.9 in
- Width -16.5 in
- Weight - 52.9lbs

The analyzer and all peripheral equipment will come packaged and are capable of fitting through access doors.

3.1.4 Installation

3.1.4.1 Vendor must be on-site for delivery and perform the installation (labor and supplies included) of the Multiplexing Immunoassay Analyzer.

Randox can confirm that one of our fully trained engineers will be on-site for delivery and will perform the installation of the Evidence Investigator.

3.1.4.2 The vendor must provide a written validation of the instrument's performance after installation

The Myco 7 array has been validated on the Evidence Investigator. Please see Appendix 4 for a copy of the Validation Report.

3.1.4.3 Installation shall be performed by the vendor

Randox can confirm that one of our fully trained engineers will be on-site for delivery and will perform the installation of the Evidence Investigator.

3.1.5 Validation

3.1.5 The vendor must provide a written validation of the instrument's performance after installation

The Myco 7 array has been validated on the Evidence Investigator. Please see Appendix 4 for a copy of the Validation Report.

3.1.6 Warranty

3.1.6.1 The vendor must provide a full one-year parts and labor warranty on all items, including preventative maintenances that are recommended by the vendor's preventative maintenance service plans

The Evidence Investigator comes with a comprehensive 12-month parts and service warranty. This includes:

- Telephone and email support during normal working hours
- Annual Service visit
- Comprehensive parts coverage
- Free software updates
- Travel and labor costs covered for site visits
- Remote Diagnostics

3.1.7 Training

3.1.7.1 Vendor will provide on-site training (labor and non-consumable supplies included) for all instruments and software.

Randox will send a fully trained engineer to provide on-site technical training for up to 3 trainees. Please see Appendix 5 for a breakdown of what is covered in training.

3.1.8 Preventative Maintenance

3.1.8.1 Preventative maintenance services shall be performed by the vendor who shall agree to have an adequate number of trained staff and replacement parts available in order to comply with the requirements in 3.1.8.2 and 3.1.8.3

Randox have a team of experienced Engineers and Technical Support Specialists that are trained on the Evidence Investigator to perform all preventative maintenance visits. Our U.S. Headquarters is based in West Virginia and we have a number of product specialists in the area. We also have a minimum stock level of Evidence Investigator spare parts kept in the Randox Warehouse in West Virginia. Therefore, all replacement parts will always be readily available.

3.1.8.2 Vendor must respond to service calls within 24 hours

Randox have a customer support network that is more than capable of responding to issues and troubleshooting remotely within 24 hours.

3.1.8.3 Vendor must be capable of performing all requests for repairs and/or service within three business days of request.

Randox have a customer service team that can ensure an onsite visit within three business days of notification of breakdown.

3.1.8.4 After any preventative maintenance or repairs have been completed on a particular instrument, the vendor shall guarantee the accuracy and precision of the instrument at the location where the instrument will be used.

As part of our service protocol, precision tests are performed to guarantee analyzer functionality after every breakdown repair or PM.

3.1.8.5 Reports of service will be signed by State of QV authorized laboratory personnel to ensure work has been completed.

As per our service protocol, a Site Visit Form (Service Report) is written up for every breakdown repair and PM performed, detailing the work and the status of the analyzer. The signatures of both the State of QV authorized laboratory personnel and Randox specialist are required.

Pricing Page

Item No.	Description	Additional Information	Model #/Brand Name	Quanity	Unit Price	Extended Amount
1	Multiplexing Immunoassay Analyzer, computer, printer, and software		EV3602	1	$58,000	$58,000
2	Shipping			1	$50.00	$50.00
3	Installation	Three days are required for installation. Installation is free of charge. We have validated matrices for each kit. Internal validation must be performed by the customer site.		1	$0.00	$0.00
4	Training/Warranty	Training is provided free of charge. Randox provides a 12 month warranty which is also free of charge.		1	$0.00	$0.00
5	Preventative Maintenance	PM visits are covered under the first years warranty. First years warranty is free of charge. After the first year, PM visits are covered under the Service Level Contracts which are charged at $7,500 per year.		1	$7,500	$7,500
	Failure to use this form may result in disqualification				GRAND TOTAL	$65,550
	Bidder / Vendor Information					
Name:	Randox Food Diagnostics					
Address:	515 Industrial Boulevard, Kearneysville, WV 25430					
Phone:	(304) 707-6926					
Email Address:	connor.sokal@randox.com					
Authorized Signature:	Connor Sokal					

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

CONSTRUCTION CONTRACTS: Under W. Va. Code § 5-22-1(i), the contracting public entity shall not award a construction contract to any bidder that is known to be in default on any monetary obligation owed to the state or a political subdivision of the state, including, but not limited to, obligations related to payroll taxes, property taxes, sales and use taxes, fire service fees, or other fines or fees.

ALL CONTRACTS: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that: (1) for construction contracts, the vendor is not in default on any monetary obligation owed to the state or a political subdivision of the state, and (2) for all other contracts, that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Randox Laboratories US - Ltd.

Authorized Signature: Tamara Kesecker Date: 28 - July - 2020

State of WV

County of Jefferson, to-wit:

Taken, subscribed, and sworn to before me this 28 day of July, 2020

My Commission expires Jun 18, 2023

AFFIX SEAL HERE

NOTARY PUBLIC OFFICIAL SEAL
URVIBEN P PATEL
State of West Virginia
My Comm. Exp. Jan 18, 2023
BCT
111 E Washington St Charles Town, WV 25414

NOTARY PUBLIC Urvi Patel.

DESIGNATED CONTACT: Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

Connor Sokal, Sales executive
(Name, Title)
CONNOR SOKAL, SALES EXECUTIVE
(Printed Name and Title)
515 INDUSTRIAL BLVD, KEARNEYSVILLE, WV 25430
(Address)
(304) 728-2890
(Phone Number) / (Fax Number)
connor.sokal@randox.com
(email address)

CERTIFICATION AND SIGNATURE: By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

RANDOX LABORATORIES US - LTD
(Company)
L Dalmeny
(Authorized Signature) (Representative Name, Title)

LIANNA DALMENY, TENDER COORDINATOR
(Printed Name and Title of Authorized Representative)

27 - JUL - 2020
(Date)

+44 (0) 28 9442 2413 ~~9445 29~~
(Phone Number) (Fax Number)

CERTIFICATE OF LIABILITY INSURANCE

12/10/2020 | DATE (MM/DD/YYYY) 12/18/2019

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies 444 W. 47th Street, Suite 900 Kansas City MO 64112-1906 (816) 960-9000	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1458381 Randox Laboratories - US Ltd. 515 Industrial Blvd. Kearneysville WV 25430-2778	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Federal Insurance Company — 20281 INSURER B : Hartford Casualty Insurance Company — 29424 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 13809777 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	Y	Y	99507191	12/10/2019	12/10/2020	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
	X Contractual Liab						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY			NOT APPLICABLE			COMBINED SINGLE LIMIT (Ea accident)	$ XXXXXXX
	ANY AUTO						BODILY INJURY (Per person)	$ XXXXXXX
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$ XXXXXXX
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$ XXXXXXX
								$ XXXXXXX
	UMBRELLA LIAB OCCUR			NOT APPLICABLE			EACH OCCURRENCE	$ XXXXXXX
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ XXXXXXX
	DED RETENTION $							$ XXXXXXX
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N	N/A	Y	37WBCAE6F9T	12/10/2019	12/10/2020	X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Randox Laboratories Ltd. is an additional insured with respect to the general liability coverage, only as required by written contract, subject to the terms and conditions of the policy. Subrogation is waived, only as required by written contract and where allowed by law, but subject to the terms and conditions of the policy.

CERTIFICATE HOLDER

13809777
Randox Laboratories Ltd.
Maeve Loane
55 Diamond Road
Crumlin
Co.Antrim UKBT29 4QY

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Joseph M Agnello

Evidence Investigator

Multiplexing... Proven, Perfected, Evolved

The first biochip analyser for protein and molecular arrays

Evidence Investigator

Versatile, efficient and comprehensive testing

The Evidence Investigator offers complete patient profiling with the most comprehensive test menu on the market. Consolidates immunoassay and molecular diagnostics on a single platform with protein and DNA biochips.

Utilising revolutionary Biochip Array Technology, the Evidence Investigator allows simultaneous detection of multiple analytes from a single sample for efficient and cost effective testing.

The Evidence Investigator is a compact, semi-automated benchtop platform applicable in a wide range of settings including:

- Pharma and drug development: pre-clinical and clinical studies
- Private/Public sector research applications
- Environmental laboratories
- Drug residue testing
- Veterinary laboratories
- Forensic/Drugs of abuse testing
- Clinical laboratories

Ready-to-use, nine biochip carrier

Randox biochips can support up to 22 assays per biochip.

Addition of assay reagents and sample to the biochips

Full reagent package provided. (QC) Controls to be ordered separately.

Multiple results can be obtained simultaneously from as little as 25µl of sample. Up to 45 samples and nine calibrators can be analysed per run.

54 biochips placed in thermoshaker

The thermoshaker provides the optimum heating environment for samples. The heated lid provides faster heat-up times, bi-directional heating, increased temperature range and standardisation of assay incubation conditions.

The Evidence Investigator package

Biochip imaging module

PC & imaging software

Barcode scanner

Thermoshaker

Biochip carrier handling tray

3

Washing of biochips

The washing procedure is quick and easy and is performed using a wash bottle.

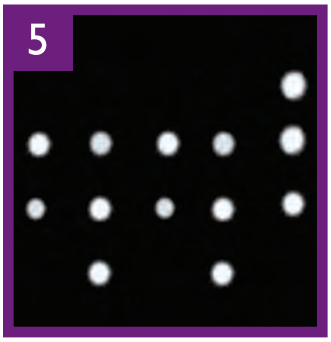
4

Biochip carrier loaded into Evidence Investigator

Signal reagent is added to each biochip before imaging.

It only takes 2 minutes for the Charged Coupled Device (CCD) camera to image each biochip carrier.

5



Discrete test sites on each biochip for individual analytes

The light signal generated from each of the discrete test regions on the biochip is simultaneously detected.

6

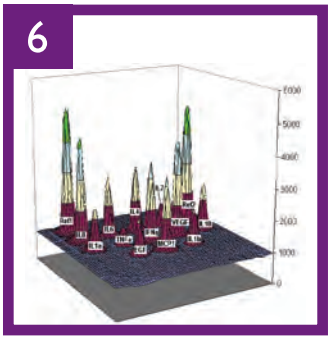


Image processing

The analyser uses unique image processing software to translate the light signal generated from the chemiluminescent reactions into an analyte concentration.

No manual processing of data required.

Why Evidence Investigator?

Industry leading technology for high quality results

Save time - save costs

- Multiplex testing allows multiple tests to be carried out from a single patient sample reducing the amount of time and labour spent on individual tests

Consolidation on one system

- The world's first platform allowing consolidation of immunoassay and molecular diagnostics with protein and DNA based biochips
- Delivering cost savings and improving laboratory efficiency

World's most diverse test menu

- More tests available than any other sole supplier
- Routine and novel markers available

Result traceability

- Chain of custody features
- Barcoded calibrators

Complete patient profiling

- Multiplex testing with Biochip Array Technology allows clinicians and investigators to consider the complete picture allowing for well informed decisions and accurate diagnosis

Optimum laboratory efficiency

- Multi-analyte controls and calibrators available for accurate and reliable laboratory testing
- Compact benchtop system saves valuable laboratory space

Reduced sample volume

- Analyse a complete profile of biomarkers from as little as 25µl of sample
- Ideal for paediatric testing
- Saves patient distress

High throughput

- The Evidence Investigator has the ability to process 702 tests in 70 minutes using the protein arrays
- It can also detect up to 40 mutations, SNPs or pathogens in as many as 54 samples at once, in as little as three hours for molecular applications

Quality results

- Inter and intra-assay CV's typically less than 10%
- Extensive QC capabilities with multi-analyte controls available
- User defined reference ranges
- Quantitative and qualitative results available

Multiple matrices available

- Immunoassay arrays: serum, plasma, whole blood, urine, tissue, egg, feed, honey, milk, cell culture supernatant, stool, saliva, bronchoalveolar lavage fluid and forensic matrices

No hidden costs

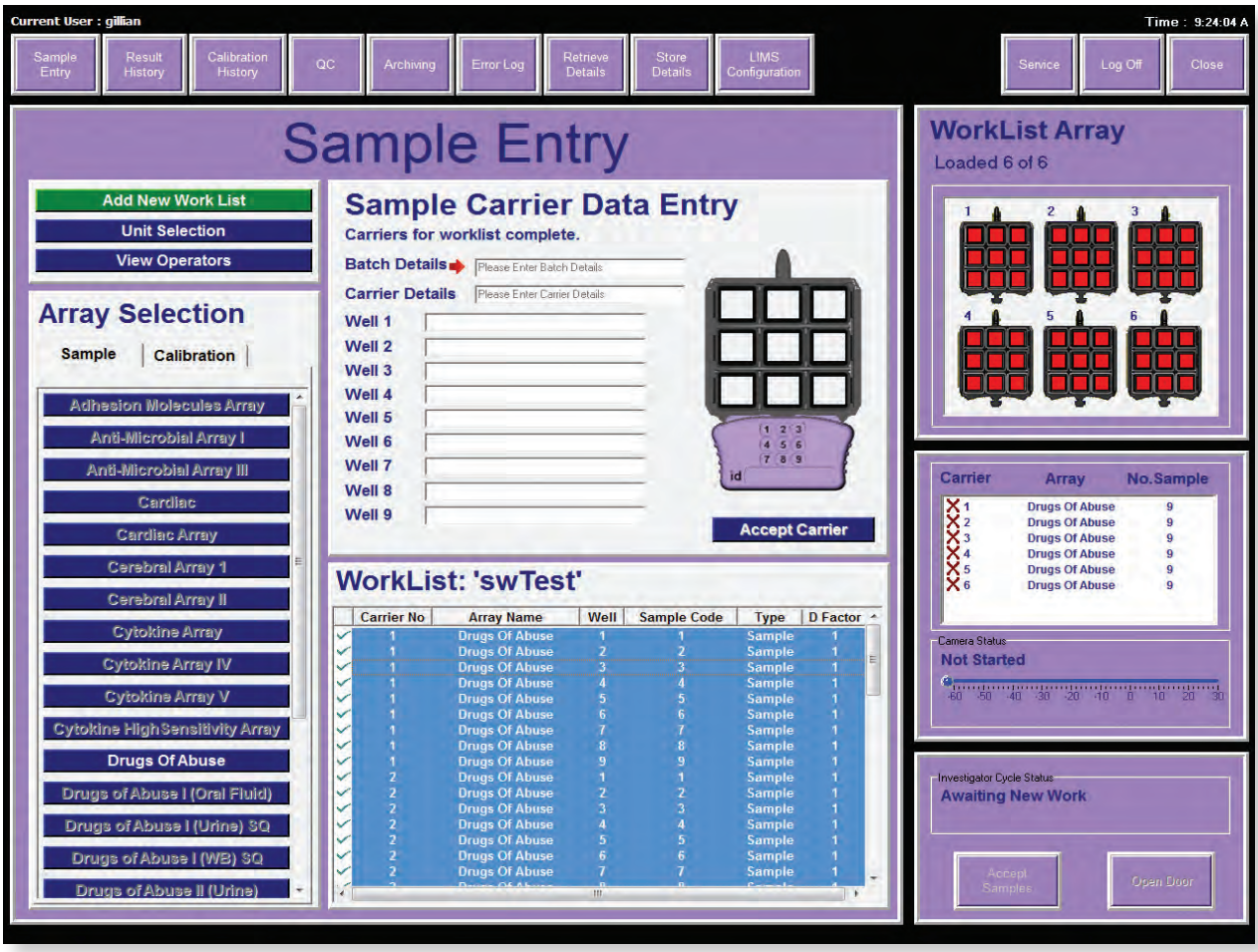
- Full analyser package includes biochip imaging module, PC and imaging software, thermoshaker, biochip carrier handling tray and barcode scanner
- Protein arrays: all inclusive kits including reagents, biochips, wash buffer and multi-analyte calibrators

Ease of operation

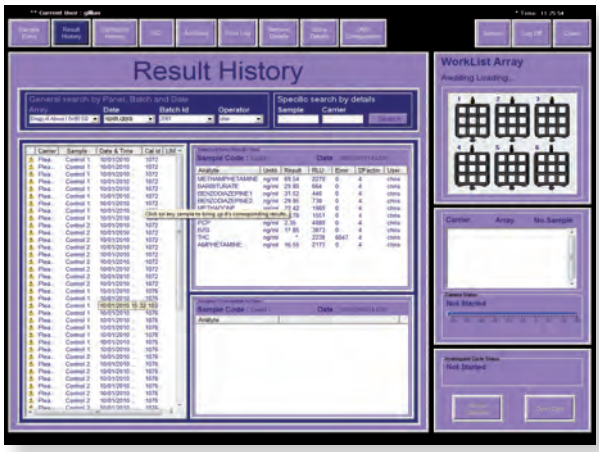
- Straightforward testing procedure, reducing operator error
- Ready to use biochips
- Minimal sample handling

Software

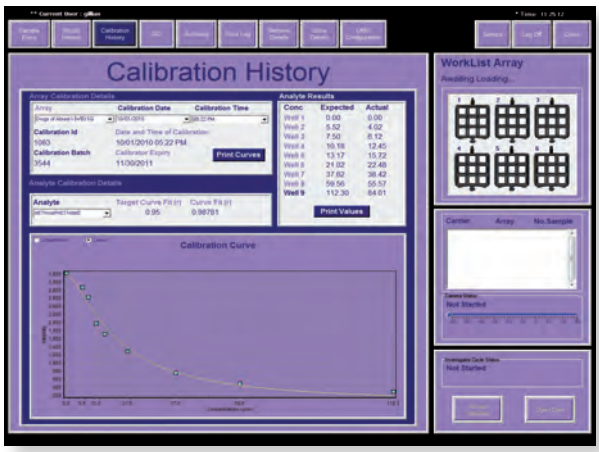
State of the art technology



Sample Entry screen



Results History screen



Calibration screen

On-board data analysis
- *No manipulation of results required*
- *Reduces the scope for operator error*
- *Rapid results improves workflow*

Extensive QC capabilities
- *Internal QC software included with Levey-Jennings charts multi-point QC rules and auto flagging of outliers*

Connectivity
- *LIMS integrated for convenient reporting*

Retrospective testing
- *Allows the user to retrieve previously unreported tests*
- *Reduces reagent wastage*
- *Saves time and labour costs*

Highly secure
- *Password protected for various user levels*
- *Full traceability of data*

Simplicity
- *Minimal training required*
- *Highly intuitive operating system*
- *Colour-coded sample addition*

Flexibility
- *Multi-format option for results review e.g. by array, by users, by date or sample code*
- *Fully printable reports*

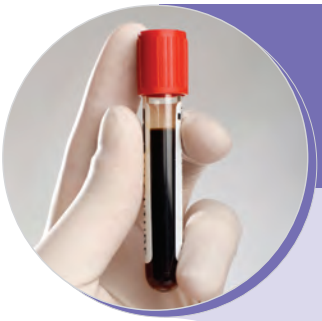
Storage facilities
- *Store up to 20,000 sample results*
- *Store up to 500,000 sample test results*

Service
- *Easy troubleshooting process*
- *Regular system checks to continually assure the operator of optimum system performance*

Molecular Arrays

Randox Molecular Diagnostics (MDx) offers a range of molecular arrays and assay formats, providing diagnostic, prognostic and predictive solutions for a range of conditions including sexually transmitted infection, respiratory infection, coronary heart disease (CHD), familial hypercholesterolemia and colorectal cancer with many more applications currently in development. The versatility of the Randox multiplex PCR and proprietary Biochip Array Technology is exemplified by the broad range of array formats available.

Molecular Array Protocol Outline



Step 1
Extraction
DNA/RNA extracted

Step 2
Amplificaton
Multiplex PCR reaction

Step 3
Hybridisation
Amplicon hybridisation/ conjugation to biochip array

Step 4
Detection
Imaging and result processing by Evidence Investigator analyser

Applications for a wide range of matrices

Benefits of the Respiratory Pathogen Array

- Simultaneously detect 22 bacterial and viral pathogens
- Comprehensive profile of pathogens identifies primary infection and secondary or multiple infections, which may otherwise remain untreated
- Rapid turnaround time of five hours
- May prevent the spread of infection through early and more appropriate intervention
- May reduce antibiotic misuse
- Reduced sample requirement

Benefits of the STI Array

- Simultaneously detect up to 10 STIs from a single patient sample
- Save time and cost associated with single infection detection
- Detection of asymptomatic co-infections
- Clear and easy results interpretation
- 54 patient samples can be processed simultaneously, with multiple runs possible in one working day

Benefits of the *KRAS, BRAF, PIK3CA* Array

- Compatible with a broad range of genomic DNA input and type:
  - Formalin fixed paraffin embedded (FFPE) tissue
  - Fresh/frozen tissue
- Detection of 1% mutant in a background of wildtype genomic DNA
- Single reaction multiplex PCR coupled to a biochip provides greater mutation coverage of the three most important genes *(KRAS, BRAF and PIK3CA*)* implicated in metastatic colorectal cancer therapy response
- Turnaround time of three hours

*PIK3CA for research use only

Benefits of the Familial Hypercholesterolemia Array

- Simultaneous detection of 40 FH-causing mutations across LDLR, ApoB and PCSK9 genes
- Samples can be assessed in small batches (as low as three samples)
- Turnaround time of three hours
- System can be used to detect single base changes, insertions and deletions, within the same multiplex PCR
- Only 20ng of genomic DNA required

Benefits of the Cardiac Risk Prediction Array

- Randox Cardiac Risk Prediction Array is a rapid simple method for reliable genetic risk assessment of CHD
- Combined with common risk factors, the array allows more accurate classification and preventative actions to be taken
- Identifies patients genetically predisposed to statin-induced myopathy
- Simple and rapid protocol allows a patient sample to be genotyped in one day
- All 19 SNPs can be genotyped simultaneously

Immunoassay Arrays

Highly accurate testing

- BAT has a proven high standard of accurate test results with typical CV's <10%
- Multiplex analysis minimises analytical variation between tests

Better patient diagnosis

- Testing for multiple markers simultaneously increases the amount of patient information rapidly available to the clinician, allowing for more informed patient diagnosis

Optimum efficiency

- Multi-analyte reagents and quality control material, provides highly efficient testing while eliminating any wastage

Assay formats

Protein / Antibody assay formats

Competitive immunoassay

In a competitive immunoassay, the more analyte present in a sample, the less labelled conjugate that will bind to the immunoreaction site. Therefore the signal produced will be low. If there is little analyte in the sample, more labelled conjugate will bind to the capture antibody resulting in a higher signal.

Sandwich immunoassay

In a sandwich immunoassay, the more analyte present in a sample, the more conjugate will bind to the capture antibody. As a result, the signal will be high. Conversely, lower signal is produced when the concentration of analyte in the sample is low.

Antibody Capture

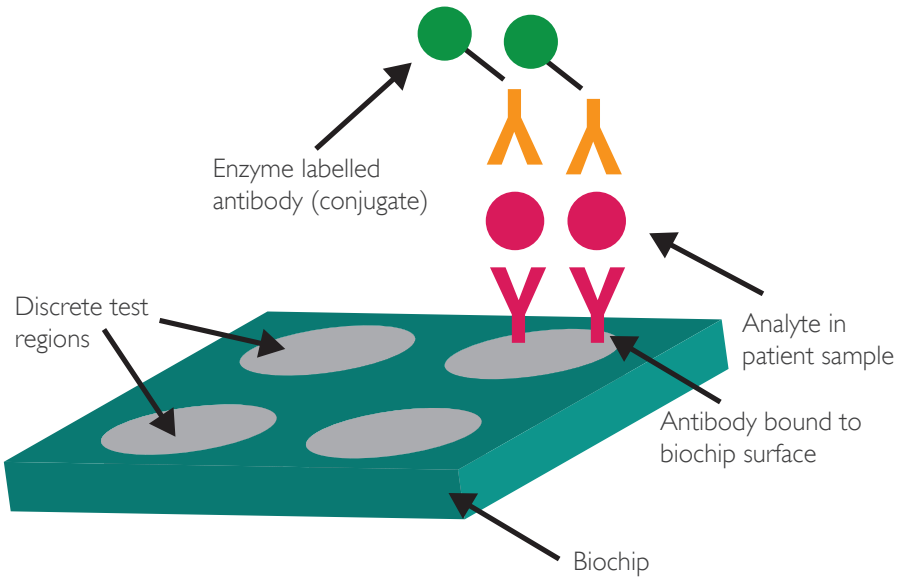
In this methodology antigens are immobilised onto the surface of the biochip and antibodies in the sample are then bound.

Small sample volume

- Reduced sample volume requirements puts the patient at ease
- Patient profiling saves precious sample if further analysis is required

Cost consolidation

- Multiplex testing reduces the amount of time spent on individual tests and associated laboratory costs



Sandwich immunoassay

Multiple sample types

- Multiple sample types can be used on one analyser including serum, plasma, whole blood, urine, oral fluid and alternative matrices
- This allows the clinician to offer flexible patient testing

Result traceability

- Barcoded controls and patient samples ensure complete traceability of results

Retrospective reporting

- Retrieve previously unreported results without additional testing, saving time

Wide and varied test menu

- Randox's vast biochip test menu allows clinicians to detect routine and novel markers for advanced diagnostic analysis

Extensive Quality Control features

- Internal quality control markers on every biochip ensure optimum assay performance
- Comprehensive Quality Control data is automatically created and displayed on Levey-Jennings charts

Biochip test menu

The world's largest and most diverse test menu

Applications available for serum and/or plasma

Clinical Arrays

Cardiac Array
Creatine Kinase Muscle Brain (CK-MB)
Heart Type Fatty Acid Binding Protein (H-FABP)
Myoglobin(Myo)
Troponin I (cTnI)

Thyroid Total Array
Thyroid Stimulating Hormone (TSH)
Total Thyroxine (TT4)
Total Tri-iodothyronine (TT3)

Fertility Hormone Array
Estradiol (EST)
Follicle Stimulating Hormone (FSH)
Luteinising Hormone (LH)
Progesterone (PROG)
Prolactin (PRL)
Testosterone (TEST)

Vitamin D Array (on evidence investigator only)
Vitamin D (VITD)

Thyroid Free Array
Free Thyroxine (FT4)
Free Tri-iodothyronine (FT3)
Thyroid Stimulating Hormone (TSH)

Tumour PSA Array
Carcinoembryonic Antigen (CEA)
Free Prostate Specific Antigen (fPSA)
Total Prostate Specific Antigen (tPSA)

Additional Assays*

Anti-Tg
Anti-TPO
Beta Crosslaps
Beta-hCG
CA 125
CA 15-3
CA 19-9
Carbamazepine
Digitoxin
Digoxin
Folate
Gentamicin
Growth hormone
Intact PTH
Methotrexate
Osteocalcin
Phenobarbital
Phenytoin
Sex Hormone-Binding Globulin (SHBG)
Thyroglobulin (Tg)
Theophylline
Tobramycin
Valproic Acid
Vancomycin
Vitamin B12
CAIII
GPBB

** In development*

Research Arrays

Adhesion Molecules Array
E-Selectin
L-Selectin
P-Selectin
Intercellular Adhesion Molecule-1 (ICAM-1)
Vascular Cell Adhesion Molecule-1 (VCAM-1)

Cerebral Array I
Brain-Derived Neurotrophic Factor (BDNF)
Glial Fibrillary Acidic Protein (GFAP)
Heart Type Fatty Acid Binding Protein (H-FABP)
Interleukin-6 (IL-6)

Cerebral Array II
C-Reactive Protein (CRP)
D-dimer
Neuron Specific Enolase (NSE)
Neutrophil Gelatinase-Associated Lipocalin (NGAL)
Soluble Tumour Necrosis Factor Receptor I (sTNFRI)

Cytokine Array I
Epidermal Growth Factor (EGF)
Interferon-γ (IFN-γ)
Interleukin-1α (IL-1α)
Interleukin-1β (IL-1β)
Interleukin-2 (IL-2)
Interleukin-4 (IL-4)
Interleukin-6 (IL-6)
Interleukin-8 (IL-8)
Interleukin-10 (IL-10)
Monocyte Chemotactic Protein-1 (MCP-1)
Tumour Necrosis Factor-α (TNF-α)
Vascular Endothelial Growth Factor (VEGF)
(High Sensitivity Array on Evidence Investigator only)

Cytokine Array II
Eotaxin
Insulin like Growth Factor 1, Free (IGF-1(free)
Interleukin-1 Receptor Antagonist (IL-1Ra)
Interleukin-12/ Interleukin 23p40 (IL-12/IL-23p40)
Interferon-γ -Inducible Protein 10 (IP-10)
Platelet Derived Growth Factor BB (PDGF-BB)
Regulated on Activation, Normal T Expressed and Secreted (RANTES)

Cytokine Array III
Granulocyte Macrophage Colony Stimulating Factor (GM-CSF)
Interleukin-5 (IL-5)
Interleukin-15 (IL-15)
Macrophage Inflammatory Protein - 1α (MIP-1α)

Cytokine Array IV
Matrix Metalloproteinase-9 (MMP-9)
Soluble IL-2 Receptor α (sIL-2Rα)
Soluble IL-6 Receptor (sIL-6R)
Soluble Tumour Necrosis Factor Receptor I (sTNFRI)
Soluble Tumour Necrosis Factor Receptor II (sTNFRII)

Cytokine Array V (On Evidence Investigator only)
Interleukin-3 (IL-3)
Interleukin-7 (IL-7)
Interleukin-13 (IL-13)
Interleukin-12p70 (IL-12p70)
Interleukin-23 (IL-23)

Endocrine Array
Cortisol
Dehydroepiandrosterone Sulphate (DHEAs)
Leptin
17α Hydroxyprogesterone

Metabolic Syndrome Array I
Ferritin
Insulin
Interleukin-6 (IL-6)
Leptin
Plasminogen Activator Inhibitor-1 (PAI-1)
Resistin
Tumour Necrosis Factor-α (TNFα)

Metabolic Syndrome Array II
Adiponectin
C-Reactive Protein (CRP)
Cystatin C

Applications available for serum and/or plasma

Molecular Arrays available on Evidence Investigator only

Respiratory Multiplex Array
Influenza A
Influenza B
Human adenovirus A/B/C/D/E
Human bocavirus 1/2/3
Human coronavirus 229E/NL63
Human coronavirus OC43/HKU1
Human enterovirus A/B/C
Human metapneumovirus
Human parainfluenza virus 1
Human parainfluenza virus 2
Human parainfluenza virus 3
Human parainfluenza virus 4
Human respiratory syncytial virus A
Human respiratory syncytial virus B
Human rhinovirus A/B
Chlamydophila pneumoniae
Haemophilus influenza
Legionella pneumophila
Moraxella catarrhalis
Mycoplasma pneumoniae
Staphylococcus aureus
Streptococcus pneumoniae

STI Multiplex Array
Chlamydia trachomatis
Neisseria gonorrhoea
Herpes simplex I
Herpes simplex II
Treponema pallidum (Syphilis)
Trichomonas vaginalis
Mycoplasma hominis
Mycoplasma genitalium
Ureaplasma urealyticum
Haemophilus ducreyi

K-RAS/BRAF/PIK3CA Array
K-RAS
BRAF
P1K3CA

Cardiac Risk Prediction Array

Familial Hypercholesterolemia Array

Toxicology Arrays

Drugs of Abuse Array I Plus
Amphetamine
Barbiturates
Benzodiazepine 1
Benzodiazepine 2
Buprenorphine
Cannabinoids
Cocaine metabolite (Benzoylecgonine)
MDMA
Methadone
Methamphetamine
Opiates
Phencyclidine
Tricyclic Antidepressants (TCAs Generic)

Drugs of Abuse Array II
Buprenorphine
Fentanyl
Generic Opioids
Ketamine
LSD
Methaqualone
MDMA
Oxycodone 1
Oxycodone 2
Propoxyphene

Drugs of Abuse Array III
Chloral Hydrate Metabolite
Ethyl Glucuronide
Fentanyl
Flunitrazepam
Ketamine Metabolite
Meperidine
Meprobamate
Zaleplon
Zolpidem
Zopiclone

Drugs of Abuse Array IV
Acetaminophen
Dextromethorphan
Escitalopram
Ethyl Glucuronide
Fluoxetine
Haloperidol
Ibuprofen
Methylphenidate
Salicylate
Sertraline
Tramadol
Trazodone
Tricyclic Antidepressants (TCAs Generic)

Drugs of Abuse Array V
Bath Salts I (Methcathinone + Mephedrone)
Bath Salts II (MDPV)
Benzylpiperazines
Mescaline
Phenylpiperazines I
Phenylpiperazines II
Salvinorin
Synthetic Cannabinoids I
Synthetic Cannabinoids II
Synthetic Cannabinoids III
Synthetic Cannabinoids IV

Drugs of Abuse Array VI
Meprobamate
Zaleplon
Zolpidem
Zopiclone

Applications available for urine, whole blood, oral fluid and a wide range of forensic matrices. (for urine applications creatinine is included as a dilution marker)

Additional Assays*
DOx Series
Mitragynine
NBOMe
UR144/XLR11
2Cx series*
Gabapentin*
Pregabalin*

** In development*

Food Diagnostics Arrays

Anthelmintics Array
Amino-benzimidazoles
Avermectins
Benzimidazoles
Levamisole
Moxidectin
Thiabendazole
Triclabendazole

Anti-Microbial Array I Plus
Sulphachlorpyridazine
Sulphadiazine
Sulphadimethoxine
Sulphadoxine
Sulphamerazine
Sulphamethazine
Sulphamethizole
Sulphamethoxazole
Sulphamethoxypyridazine
Sulphamonomethoxine
Sulphapyridine
Sulphaquinoxaline
Sulphathiazole
Sulphisoxazole
Trimethoprim

Anti-Microbial Array II
Ceftiofur
Quinolones
Thiamphenicol
Streptomycin
Tetracyclines
Tylosin

Anti-Microbial Array III
AHD
AMOZ
AOZ
Chloramphenicol
SEM
Chloramphenicol Glucuronide

Anti-Microbial Array III (Chloramphenicol only)
Chloramphenicol
Chloramphenicol Glucuronide

Anti-Microbial Array IV
Amikacin/Kanamycin
Apramycin
Bacitracin
Erythromycin
Lincosamides
Neomycin/Paromomycin
Spectinomycin
Spiramycin/Josamycin
Streptomycin/Dihydrostreptomycin
Tobramycin
Tylosin/Tilmicosin
Virginiamycin

Anti-Microbial Array V
Chloramphenicol
Nitroimidazoles

Coccidostats Array
Clopidol
Decoquinate
Diclazuril
Halofuginone
Imidocarb
Lasalocid
Maduramicin
Monensin
Nicarbazin
Robenidine
Salinomycin/Narasin
Toltrazuril

Growth Promoter Multiple Matrix Screen Array
β-agonists
Boldenone
Corticosteroids
Nandrolone
Ractopamine
Stanozolol
Stilbenes
Trenbolone
Zeranol

Growth Promoter Rapid Urine Screen Array
β-agonists
Boldenone
Corticosteroids
Ractopamine
Stanozolol
Trenbolone
Zeranol

Growth Promoter Multiple Matrix Screen Ractopamine Only Array
Ractopamine

Synthetic Steroids Array
Ethinylestradiol
Gestagens
Methlytestosterone
17β - Clostebol

Beta Lactam Antibiotics Array Plus
Beta-Lactams (generic)
Cephalexin
Cefuroxine

Beta-Agonists Array Zilpaterol Only
Zilpaterol

Applications available for feed, honey, milk, urine, tissue, egg, seafood

Unrivalled customer service

Our global network, ensuring local support

Local support

At Randox, we realise the importance of local support. Our global team of expert technical and applications staff ensure unbeatable customer service wherever you are in the world.

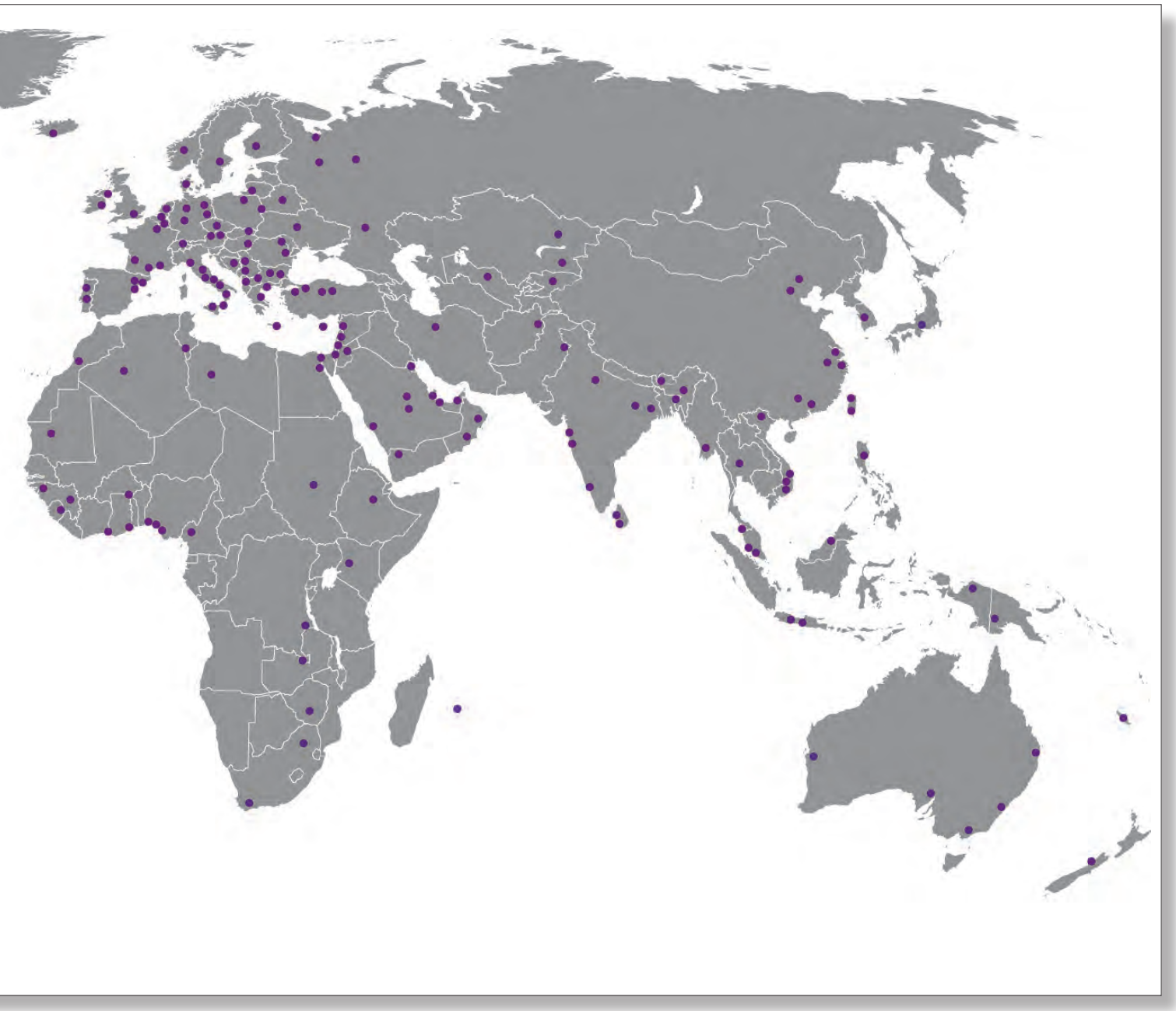
Time is critical in any laboratory, therefore you are our top priority. Dedicated specialists answer all your queries in a quick and thorough manner. With our field engineers on hand at any time, you can be sure of a fast response anywhere in the world.

Remote Access diagnostics

Our ground-breaking 'Remote Access' diagnostics allows immediate support of your system wherever, whenever, reducing downtime and ensuring you are operational as soon as possible.

Randox is committed to the smooth running of your laboratory, from the provision of quality products to unequalled customer support. We can access, diagnose and resolve many queries without the time and costs associated with call outs.

email: technical.services@randox.com



Evolution of Evidence

A proven technology has evolved

The Evidence Investigator, one system for multiple applications in research, clinical, forensic, drug residue and veterinary testing.

Biochip Array Technology, itself a revolution in immunoassay technology, has evolved continuously over the years, giving the world accurate, high quality results faster and more efficiently than any previous method. It enables clinicians and investigators to see the full picture with complete test profiles, whilst reducing labour, time and costs. Together,

Evidence Investigator

The Evidence Investigator brought Biochip Array Technology within reach of the smaller laboratory and extended the test menu to include molecular arrays.

Evidence

The original high throughput Evidence analyser still brings unrivalled benefits for batch analysis in the larger laboratory.

the technology and the analysers have evolved to allow application in fields as varied as clinical diagnostics, forensic toxicology, veterinary, drug residues, research and many more. Randox is committed to constant research and development, ensuring that you remain at the cutting edge of laboratory medicine.

Evidence Evolution

The Evidence Evolution is the world's first Random Access biochip testing platform, with advanced STAT testing capabilities.

Specifications

Physical Dimensions

Height	750mm, 29.5 in
Depth	480mm, 18.9 in
Width	420mm, 16.5 in
Weight	24Kg, 52.9lbs

Performance Characteristics

Accreditation	Internally accredited to full CE and UL certification
Analyser description	Semi-automated Biochip Array Analyser
Biochip capacity	Nine biochips on Evidence Investigator, 54 biochips on Thermoshaker
Biochip format	Biochip Carrier holds nine individual biochips
Calibration method	Nine point calibration
Connectivity	LIMS integration
Data back-up methods	Via writable DVD, CD, USB Mass-storage or Network folder
Environment	Operating temperature 16 to 25°C
	Relative Humidity < 80%
	Altitude < 2000m
	Pollution degree 2 (IEC 664)
Fuses	Mains Inlet Fuse (F1) T 2 A H 250V (20mm x 5mm)
	Motor Control Board (F1) T 1 A L 250V (20mm x 5mm)
Incubation time	Array-specific, 30-60 minutes
Installation requirements	Evidence Investigator must be connected to a single-phase power supply
Measurement principal	Competitive and Sandwich techniques with Chemiluminescent reaction
Network services	Highly Secure Remote Diagnostics, automated software and array updates
Peripherals	Printer, barcode scanner, carrier handling tray and thermoshaker
Quality control	Levey-Jennings, user definable multipoint rules
Reagent volume	Array specific, supplied in kits
Sample loading	Single carrier loading bay
Sample throughput	Array specific
Sample type	Array specific including serum, plasma, whole blood, urine, tissue, feed, honey, milk, egg, cell culture supernatant, stool, oral fluid, bronchoalveolar lavage fluid, forensic matrices
Sample volume	Array specific; 25-150µl

Start up / shut down time	Fully automated procedure; 420 seconds to cool down to operating temperature and 150 seconds warm up
Time to first result	Array specific

Power Requirements

Input voltage	Supply Voltage 100-120Vac, 60Hz, 22VA 200-240Vac, 50Hz, 30VA Installation category II Camera Power Supply 100-240Vac, 47-63Hz, 1.35A
UPS	Recommended

Water Requirements

Water quality	CLSI Type II or better

Catalogue No. / Ordering details

Evidence Investigator analyser	EV3602

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LT107 MAY15

Operation stations	**(a) Imaging Station** • High performance, scientific grade CCD camera cooled thermoelectrically to an operating temperature ≈ –50°C (ambient 25°C). • Back-illuminated sensor, Low noise system. • 16 bit. • Quantum Efficiency >65%. • Hermetically sealed evacuated head aids cooling. • Single Exposure dynamic range 0 – 40,000.
	(b) Analyser Power Unit Source • 100 – 120 V ac, 60 Hz, 22 V A. • 200 – 240 V ac, 50 Hz, 30 V A. • Installation Category II. • Camera Power Supply 100 – 240 V ac, 47 – 63 Hz, 1.35 A.
	(c) Carrier loading unit Robotic horizontal transport system.
12. Other functions	Array specific settings and functions.
13. Environment (under operation)	
Operating temperature	16 – 25°C.
Relative humidity	15 – 80% (non-condensing).
Altitude	< 2000 m.
Pollution degree	2 (IEC 664).
14. Dimensions (analyser only)	• Height 750 mm. • Width 420 mm. • Depth 480 mm. • Weight 24 kg (approx).
15. Power Supply	
Robotics supply voltage	• 100 – 120 V ac, 60 Hz, 22 V A. • 200 – 240 V ac, 50 Hz, 30 V A. • Installation category II.
Camera power supply	• 100 – 240 V ac, 47 – 63 Hz, 1.35 A.
16. Power requirements	Evidence Investigator must be connected to a single-phase power supply.
17. Connectors on imaging station	
Electrical connectors	• Appliance inlet. • 9 pin 'D' sub connector. • Main Analyser and Operational PC.
Fuses	Mains Inlet Fuses 2 x (F1)T 2 A H 250 V (20 mm x 5 mm).

IMPORTANT

FUSES MUST ONLY BE REPLACED WITH THE SAME TYPE AND RATING AS SPECIFIED ABOVE

MYCO 7 Array Validation Report
EV4065

RANDOX

Index

1. INTRODUCTION

This report gives details of the validation of the RANDOX Laboratories Ltd Evidence Investigator™ Myco 7 kit EV4065. Testing conducted using RANDOX Laboratories Ltd Evidence Investigator™ analyser EV3602. This validation was performed by a single laboratory. This validation was performed based on:

- Randox Standard Operating Procedures RRD-1961, RRD-2714, RRD-2087 and RRD-2742
- Commission Regulation (EU) No 519/2014.

Additionally, a reproducibility study was performed across various 9 laboratories using reference materials for Myco 7 kit EV4065.

2. AIM

To validate Myco 7 kit EV4065 for use with:

- Cereals and cereals milling products: wheat, corn, oats, barley, rye, soya, sugar beet, rapeseed.
- Cereal based, compound feed.

3. INTENDED USE

The Evidence Investigator™ Myco 7 kit is to be used for the simultaneous semi-quantitative detection of:

Ochratoxin A
Aflatoxin G1
Deoxynivalenol
Aflatoxin B1
Zearalenone
Fumonisins
T2-toxin

The array is intended for screening of samples only and positive results should be confirmed by another method.

4. PERFORMANCE

4.1 Calibration ranges and standardisation

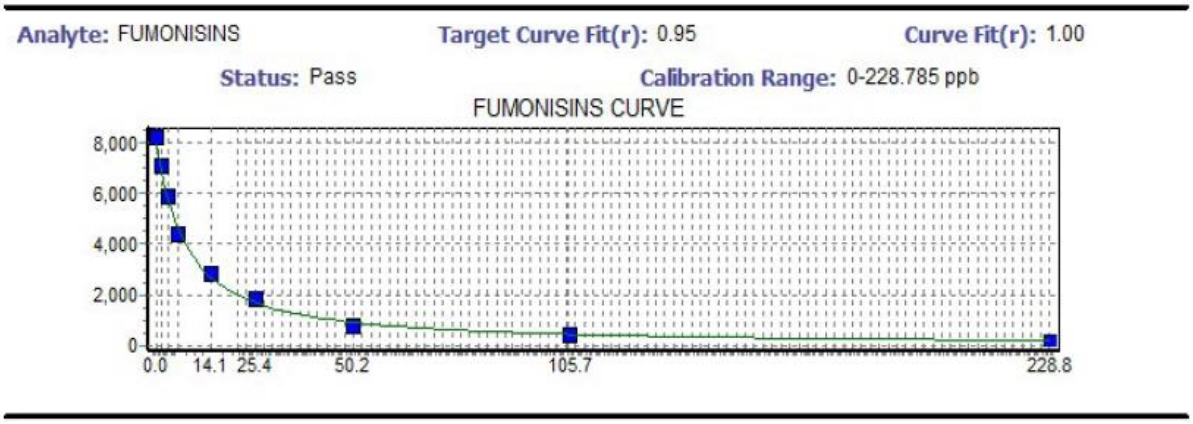
The calibration ranges for the individual analytes are indicated in Table 1. Typical calibration curves are shown in Figure 1.

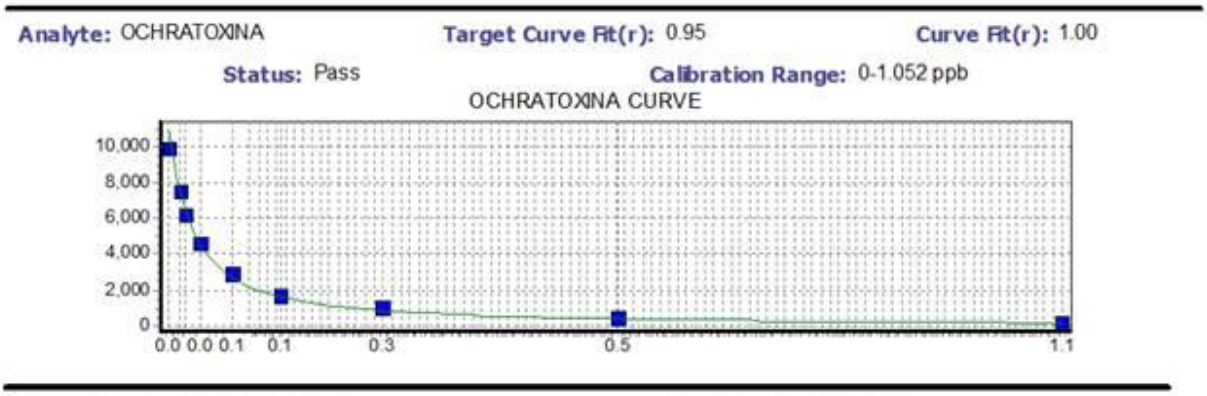
Table 1. Calibration Range and Standardisation

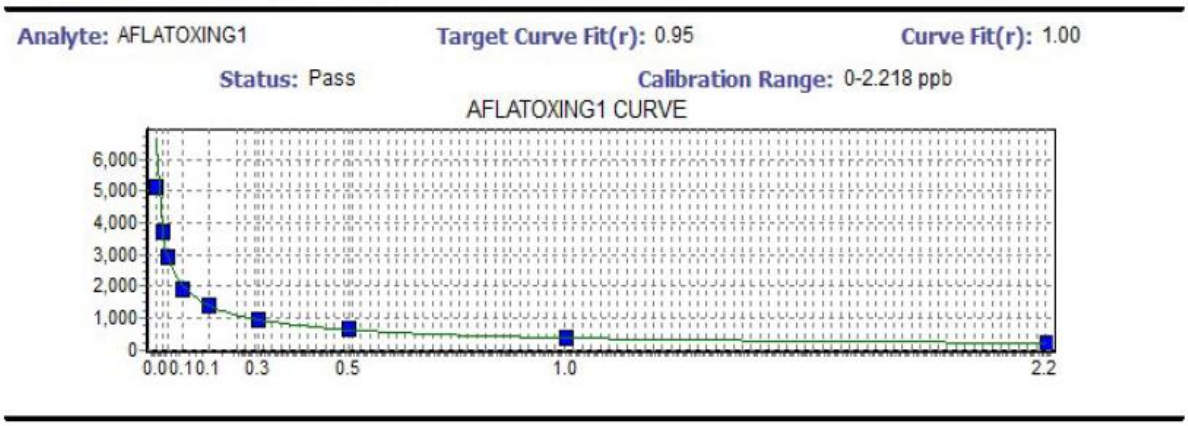
Analyte	Standardised to	Typical Calibration Range (ppb)
Ochratoxin A	Ochratoxin A	0 – 1
Aflatoxin G1	Aflatoxin G1	0 – 1.5
Deoxynivalenol	Deoxynivalenol	0 – 130
Aflatoxin B1	Aflatoxin B1	0 – 0.225
Zearalenone	Zearalenone	0 – 2
Fumonisins	Fumonisin B1	0 – 250
T2-toxin	T2-toxin	0 – 4

RANDOX

Figure 1. Typical Calibration Curves





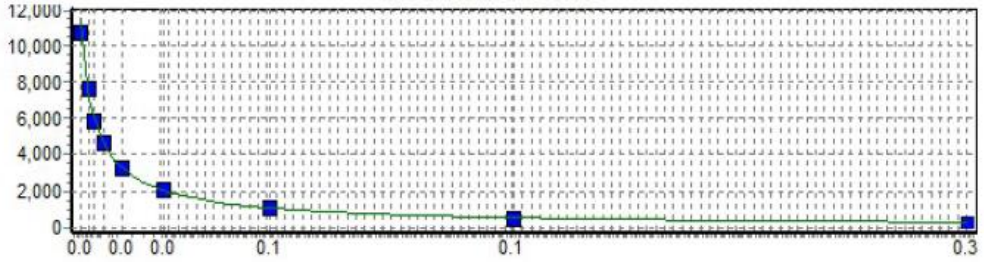


RANDOX

Analyte: AFLATOXINB1 **Target Curve Fit(r):** 0.95 **Curve Fit(r):** 1.00

Status: Pass **Calibration Range:** 0-0.276 ppb

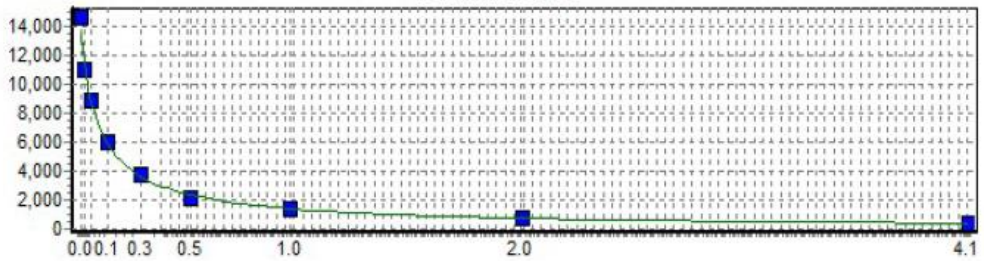
AFLATOXINB1 CURVE



Analyte: T2TOXIN **Target Curve Fit(r):** 0.95 **Curve Fit(r):** 1.00

Status: Pass **Calibration Range:** 0-4.062 ppb

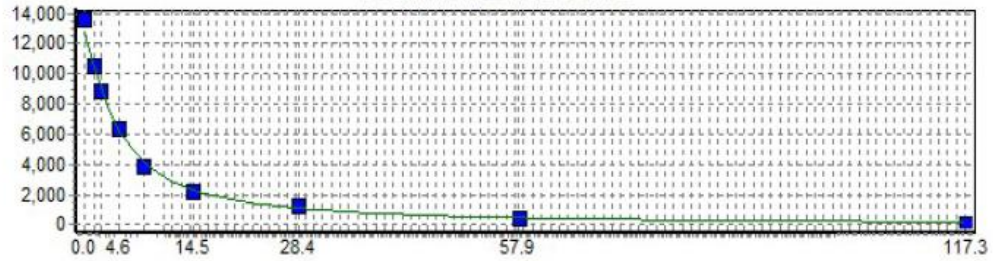
T2TOXIN CURVE



Analyte: DEOXYNIVALENOL **Target Curve Fit(r):** 0.95 **Curve Fit(r):** 1.00

Status: Pass **Calibration Range:** 0-117.282 ppb

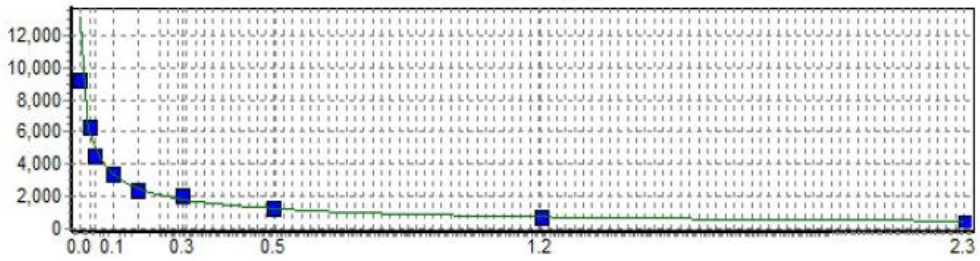
DEOXYNIVALENOL CURVE



Analyte: ZEARALENONE **Target Curve Fit(r):** 0.95 **Curve Fit(r):** 0.99

Status: Pass **Calibration Range:** 0-2.258 ppb

ZEARALENONE CURVE



4.2 Specificity

Cross-reactants were spiked into calibrator buffer at a concentration up to 10 times higher than the level 9 calibrator concentration for each analyte. A double dilution series of this was then prepared using calibrator buffer to give 7 further levels. Calibrator buffer was used as the level 1 calibrator for the cross-reactant curve. A standard curve was assayed along with the cross-reactant curve and IC50 value calculated for both standard curve (AIC50) and cross-reactant curve (SIC50). The % cross-reactivity was then calculated as (AIC50/SIC50) x100. The resulting % cross-reactivities are summarised in Tables 2-8.

Table 2. **Ochratoxin A % cross-reactivity**

Analyte	% Cross-Reactivity
Ochratoxin A	100%
Ochratoxin B	<1%
Deoxynivalenol	<1%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Fumonisin B1	<1%
Zearalenone	<1%
Aflatoxin B1	<1%
Aflatoxin G1	<1%
T2 toxin	<1%

Table 3. Aflatoxin G1 % cross-reactivity

Analyte	% Cross-Reactivity
Aflatoxin G1	100%
Aflatoxin G2	71%
Aflatoxin B1	8%
Aflatoxin B2	5%
Ochratoxin A	<1%
Deoxynivalenol	<1%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Zearalenone	<1%
Fumonisin B1	<1%
T2 toxin	<1%

Table 4. Deoxynivalenol % cross-reactivity

Analyte	% Cross-Reactivity
Deoxynivalenol	100%
3-Acetyldeoxynivalenol	723%
15-Acetyldeoxynivalenol	3%
Deoxynivalenol-3-glucoside	91%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Fumonisin B1	<1%
Ochratoxin A	<1%
Zearalenone	<1%
Aflatoxin B1	<1%
Aflatoxin G1	<1%
T2 toxin	<1%

Table 5. Aflatoxin B1 % cross-reactivity

Analyte	% Cross-Reactivity
Aflatoxin B1	100%
Aflatoxin B2	18%
Aflatoxin G1	15%
Aflatoxin G2	3%
Deoxynivalenol	<1%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Ochratoxin A	<1%
Zearalenone	<1%
Fumonisin B1	<1%
T2 toxin	<1%

Table 6. Fumonisins % cross-reactivity

Analyte	% Cross-Reactivity
Fumonisin B1	100%
Fumonisin B2	91%
Fumonisin B3	100%
Zearalenone	<1%
Deoxynivalenol	<1%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Ochratoxin A	<1%
Aflatoxin B1	<1%
Aflatoxin G1	<1%
T2 toxin	<1%

Table 7. Zearalenone % cross-reactivity

Analyte	% Cross-Reactivity
Zearalenone	100%
α-Zearalenol	114%
β-Zearalenol	69%
Zearalanone	65%
α-Zearalanol (Zeranol)	51%
β-Zearalanol (Taleranol)	52%
Deoxynivalenol	<1%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Ochratoxin A	<1%
Fumonisin B1	<1%
Aflatoxin B1	<1%
Aflatoxin G1	<1%
T2 toxin	<1%

Table 8. T2-toxin % cross-reactivity

Analyte	% Cross-Reactivity
T2-toxin	100%
HT2-toxin	27%
T2-triol	<1%
T2-tetraol	<1%
Fumonisin B1	<1%
Zearalenone	<1%
Deoxynivalenol	<1%
3-Acetyldeoxynivalenol	<1%
15-Acetydeoxynivalenol	<1%
Neosolaniol	<1%
Diacetoxyscirpenol	<1%
Paxilline	<1%
Ochratoxin A	<1%
Aflatoxin B1	<1%
Aflatoxin G1	<1%

4.3 Precision

Precision material (assay buffer) was spiked at 2 different concentration levels within the assay range. Each level of precision material was then directly (no extraction, dilution step applied) assayed 20 times within the same run and intra-assay precision was determined from the coefficient of variation (CV) of the 20 replicates of each precision material. The intra-assay precision data is summarised in Table 9.

Table 9. Intra-assay precision (assay buffer)

Analyte	Spiked concentration (ppb)	Concentration % CV
Ochratoxin A	0.125	4
	0.250	8
Aflatoxin G1	0.188	8
	0.375	9
Deoxynivalenol	12.500	2
	25.000	8
Aflatoxin B1	0.028	6
	0.056	10
Zearalenone	0.250	7
	0.500	11
Fumonisin	12.500	11
	25.000	10
T2 toxin	0.500	8
	1.000	12

4.4 Limit of detection – Screening Target Concentration - Cereals and cereal based feed samples.

Limit of Detection (LOD) is equal to **Screening Target Concentration (STC)**, the lowest concentration of interest for the detection of the mycotoxins in the sample and was validated by single laboratory validation according to Commission Regulation (EU) No 519/2014.

Samples. Stage 1a – Authentic cereals and cereals-based feeds (Table 10.) were analysed and confirmed negative externally by an accredited laboratory using HPLC (<LOD). These samples were analysed on Myco 7, EV4065A with a sample dilution factor 20 (sensitive detection level) and a preliminary LOD for each analyte was established (LOD = mean concentration +3SDs).
Stage 1b – Additional authentic cereals and cereal based feeds (Table 12.) were analysed on Myco 7, EV4065A with a sample dilution factor 20 (sensitive detection level) and samples reading below the preliminary LOD were selected to be used for at stage 2 – Myco 7, EV4065 Limit of Detection evaluation.
Stage 2 – All available samples evaluated under stage 1a and stage 1b were used for screening target concentration validation for the following cereals and their milling products including feed: corn, barley, rye, wheat, oats, soya, sugar beet, rapeseed. Confirmatory method LOD for Fumonisin B1 was higher than Myco 7 expected sensitivity level and Fumonisin B1 assay was validated at the lowest STC with a conclusion that the method is *fit-for-purpose* and consequently passing (EU) No 519/2014.

Screening Target Concentration. Blank samples used for STC validation were analysed both unspiked and spiked at STC concentrations, individual for each analyte as presented in Figures 2-8 and summarised in Table 11. A minimum of 33 and maximum of 81 cereals (corn, barley, rye, wheat, oats, soya, sugar beet, rapeseed) and their milling products including feed were analysed at repeatability conditions across 5 days. Combined results for all sample types were used for *cut-off value* determination and *fit-for-purpose* assessment, because all the samples belong to the same commodity group. (Table A, 'Commodity groups for the validation of screening methods', (EU) No 519/2014).

Cut-off value. The concentration above which the sample is classified as 'suspect/positive' was determined following the formula and summarised in Table 11:

$$Cut\text{-}off = R_{STC} - t\text{-}value_{0.05} * SD_{STC}$$

R_{STC} = mean response of the positive control samples (at STC)
t-value: one tailed t-value for a rate of false negative results of 5% (Table B, (EU) No 519/2014)
SD_{STC} = standard deviation of the positive control samples (at STC)

Fitness for purpose assessment. Rate of false suspect results was estimated from the blank control samples results. The t-value was calculated corresponding to the event that a result of a negative control sample was above the cut off value and incorrectly classified as suspect, t-value was determined following a formula:

$$t\text{-}value = (cut\ off - mean_{blank})/SD_{blank}$$

Fitness for purpose was assessed based on the rate of false suspect results, which were determined in two different ways and summarised in Table 11. Based on the obtained t-value the probability of false suspect results was determined by spread sheet function 'TDIST' for a one tailed distribution based on the degrees of freedom calculated from the number of experiments. The rate of false suspect results was also specified by one tailed t-distribution taken from a table for t-distribution based on obtained t-value.

Conclusion.
The rate of false suspect results passed the criterion (≤5%) specified under guideline document (Community Reference Laboratories Residues (CRLs) 20/1/2010) supplementing Commission Decision 2002/657/EC regarding validation of screening methods and proves that the Myco 7 kit is fit for purpose as a semi-quantitative screening method.

Table 10. Cereals and cereal based feed samples types evaluated under Stage 1a and 1b.

Matrix Type	Matrix Name
Animal Feed (complete)	Cattle Feed
	Cereal-based Animal Feed
	Horse Feed
	Pet Food
	TMR
	Turkey feed
Barley	Barley
	Crushed Barley
Beet	Beet Pulp
	Sugar Beet
Buckwheat	Buckwheat
Cassava Root	Tapioca
Copra	Copra Meal
Corn / Maize	Corn Flour
	Corn Germ Meal
	Corn Gluten Feed
	Corn Gluten Meal
	Extruded Corn
	Hominy
	Maize Crunch
	Maize Flakes / Flake Maize
	Maize Meal
	Wet Crushed Corn
	Whole Maize
	Yellow Maize
Cottonseed	Cottonseed Whole
	Cottonseed Hulls
	Cottonseed Meal
Distillers Grain	DDGS
	Corn DDGS

Matrix Type	Matrix Name
Hay	Lucerne (Alfalfa) Haylage
	Haylage
Millet	Millet
Mustard Seed	Mustard Seed
Oat	Oats
	Oatfeed
Palm Kernal	Palm Kernals
	Palm Kernel Meal
Rapeseed	Rapeseed
	Canola Meal
Rice	Rice Flour
	Rice Bran
	Rice Bran Hi Fat
Rye	Rye
Silage	Silage
	Corn Silage
Sorghum	Sorghum
Soya	Soya
	Soybean Meal
	Soy Hull
	Extruded Soybeans
Sunflower	Sunflower Meal
Triticale (rye-wheat)	Triticale
Wheat	Wheat
	Pollard
	Wheat Bran
	Wheat Flour

Table 11. Limit of detection = Screening Target Concentration for cereals and cereal based feed

Assay	Number of samples used for sensitivity validation	LOD = STC [ppb]	Cut-off value [ppb]	Mean +3*SD`s [ppb]	Rate of false suspect rate	
					TDIST [%]	t-distribution table [%]
Fumonisin B1	66	175.00	86.23	81.11	0.11	<0.1
Ochratoxin A	43	0.40	0.22	0.25	0.84	<1
Aflatoxin G1	69	0.50	0.33	0.29	0.04	<0.05
Deoxynivalenol	54	80.00	66.68	66.46	0.21	<1
T2-toxin	60	7.00	2.65	3.50	2.13	2 to 5
AflatoxinB1	79	0.25	0.16	0.11	0.0008	<0.1
Zearalenone	33	5.00	2.73	2.21	0.01	<0.1

Figure 2. Screening Target Concentration. Fumonisin B1, Myco 7.

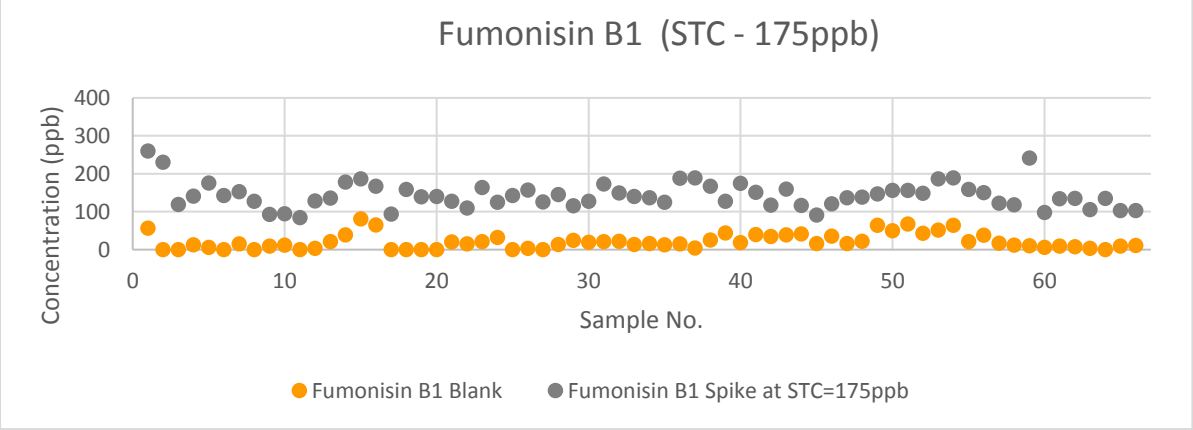


Figure 3. Screening Target Concentration. Ochratoxin A, Myco 7.

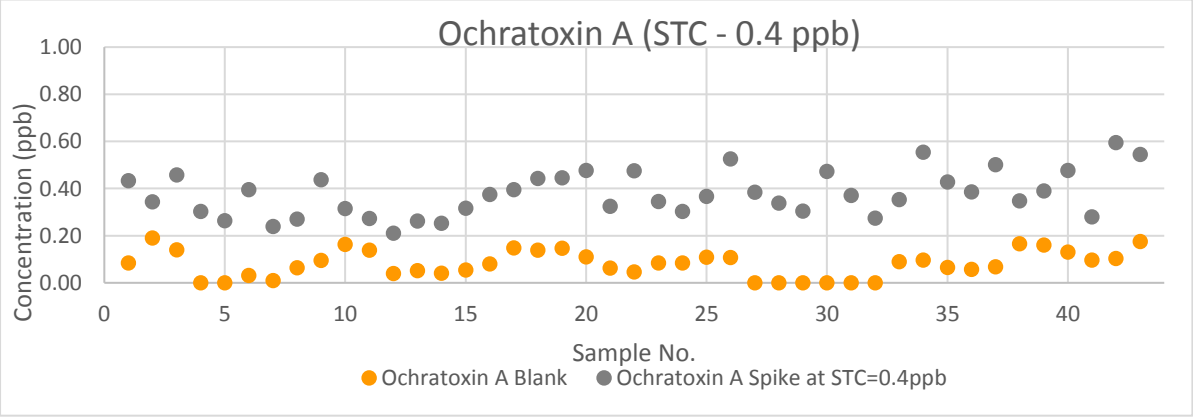


Figure 4. Screening Target Concentration. Aflatoxin G1, Myco 7.

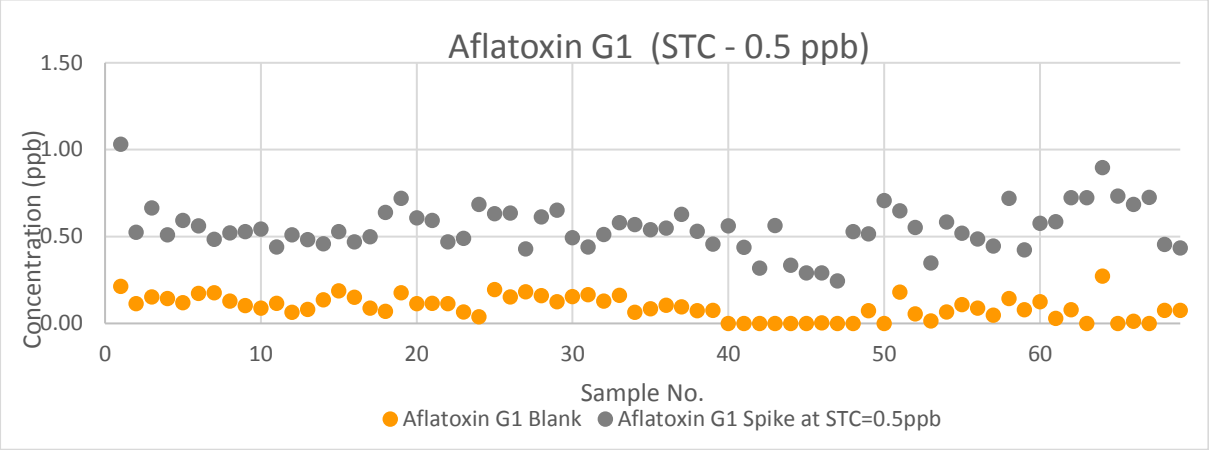


Figure 5. Screening Target Concentration. Deoxynivalenol, Myco 7.

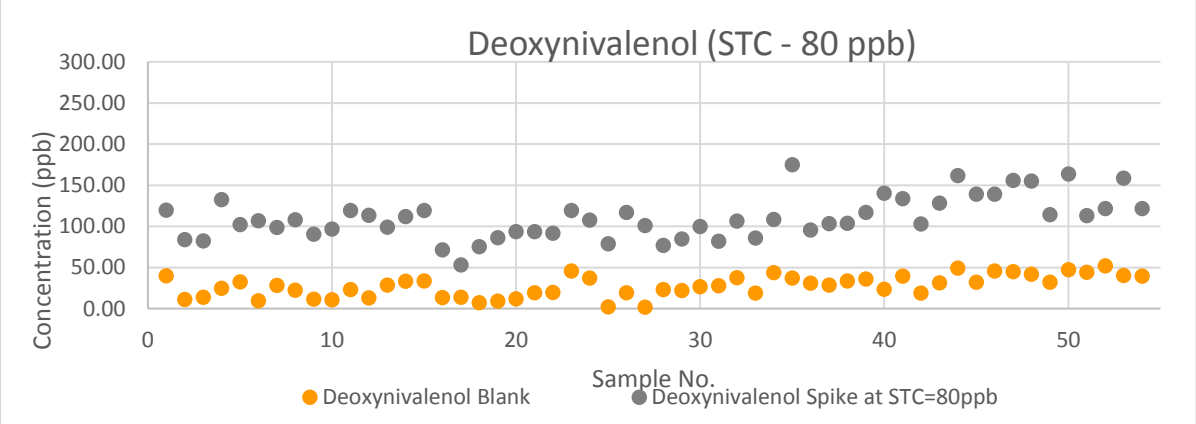


Figure 6. Screening Target Concentration. T2-toxin, Myco 7.

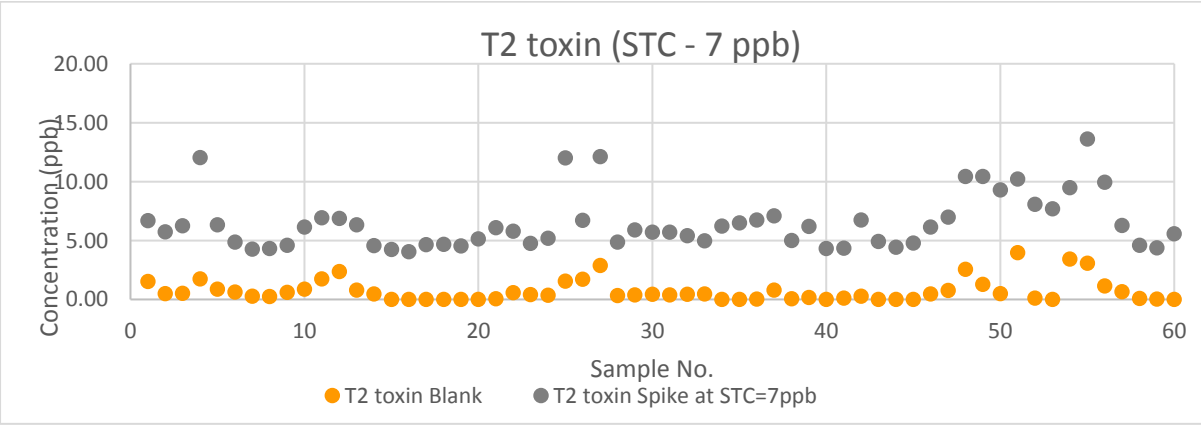


Figure 7. Screening Target Concentration. Aflatoxin B1, Myco 7.

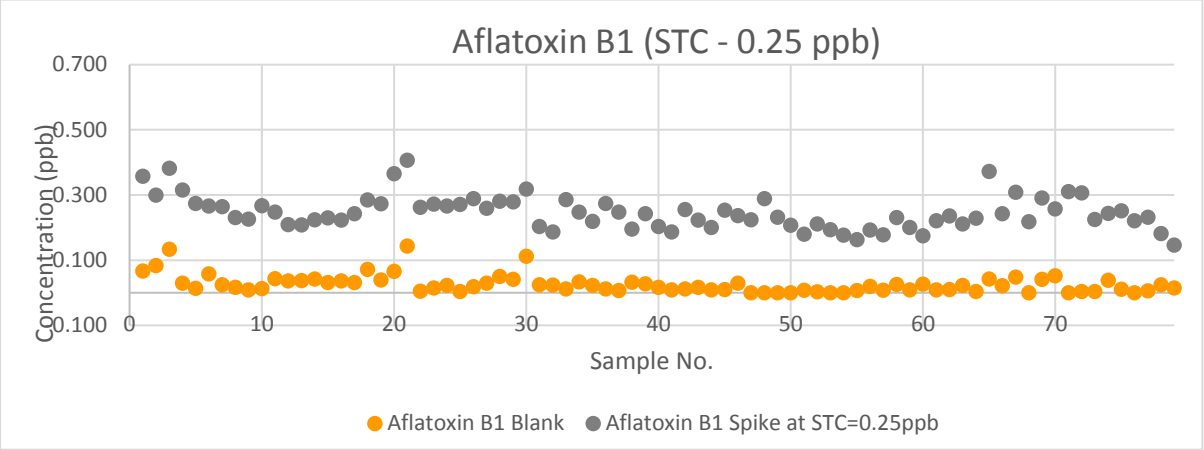
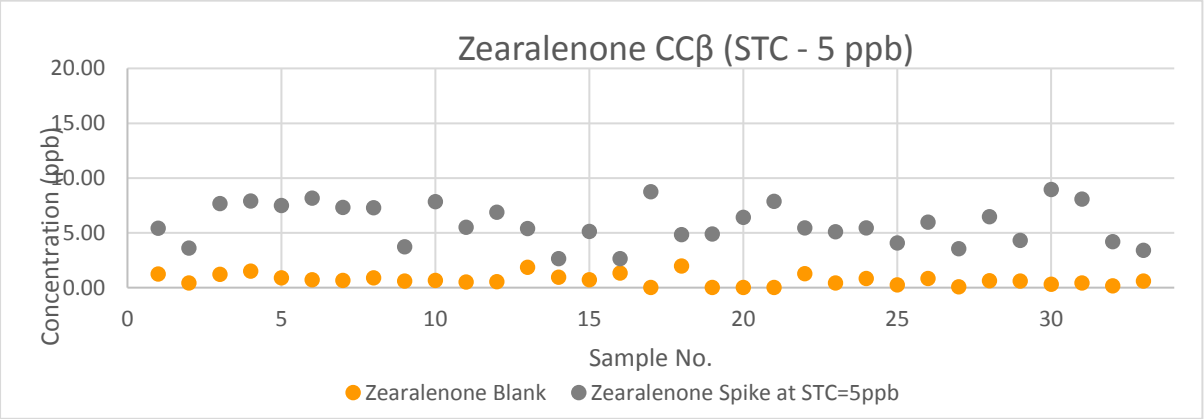


Figure 8. Screening Target Concentration. Zearalenone, Myco 7.



4.5. Sample dilution factor and corresponding assays measuring ranges.

Myco 7 was validated as described under section 4.4 and summarised in Table 11 for the lowest sample dilution factor (equal to 20), called the sensitive detection level. However, kit performance was verified at dilution factors up to 250 therefore samples can be screened at any dilution factor between 20 and 250. Dilution factor equal to 250 is called the monitory detection level. Limits of detection when using sample dilution factor 250 were determined based on the LOD's from dilution factor 20 and accounting for the higher sample dilution. The summary of assays LOD's and measuring ranges are presented in the Table 12.

Table 12. Myco 7 Limits of Detection (LOD) and measuring ranges for both sensitive and monitory detection levels.

Assay	Sensitive detection level (sample dilution factor 20)		Monitory detection level (sample dilution factor 250)	
	LOD = STC [ppb]	Measuring range [ppb]	LOD [ppb]	Measuring range [ppb]
Fumonisin B1	175.00	0 – 5,000	2187.5	0 – 62,500
Ochratoxin A	0.40	0 – 20	5	0 – 250
Aflatoxin G1	0.50	0 – 30	6.25	0 – 375
Deoxynivalenol	80.00	0 – 2,600	1000	0 – 32,500
T2-toxin	7.00	0 – 80	87.5	0 – 1,000
AflatoxinB1	0.25	0 – 4.5	3.125	0 – 56.25
Zearalenone	5.00	0 – 40	62.5	0 – 500

4.6 Recovery - Cereals and cereal based feed samples.

In addition to the validation requirements for semi-quantitative methods as stipulated in Commission Regulation (EU) No 519/2014 recovery was evaluated by testing fortified cereals and cereal based feed samples. Commodities evaluated include: corn, barley, rye, wheat, oats, soya, sugar beet, rapeseed, cereal based feed. These were investigated at three spiking concentrations: low, medium and high. Fortification levels were set for sensitive detection level and were above the STC and within each assay measuring range. The summary of recovery profile for each assay was established as average recovery of combined results for all commodities included in the study. Determined recoveries were all within recommended recovery range specified in 4.3.1.1 section (Annex II, 'Performance criteria, Specific requirement for confirmatory methods', (EU) No 519/2014).
Note: Commission Regulation (EU) No 519/2014 does not stipulate specific recovery requirements for semi-quantitative screening methods.
Fortification level, average concentration, average recovery and coefficient of variation were determined and presented together with criteria for precision assessment under repeatability conditions and maximum measurement uncertainty (Uf) used for 'Fitness-for-purposed' approach (Table 13).
Maximum permitted precision under repeatability conditions was assessed according to Commission Regulation (EU) No 519/2014 based on the fortification level. RSD_R values were taken either directly from the 4.3.1.1 section (Annex II, 'Performance criteria, Specific requirement for confirmatory methods', (EU) No 519/2014) or for missing analytes determined following one of two referenced Horwitz equations, original Horwitz equation or the modified Horwitz equation (RSD_R):

Original Horwitz equation for values $1.2 \times 10^{-7} \leq X_{AVE} \leq 0.138$:

$$RSD_R = 2^{(1-0.5 \log X_{AVE})}$$

Modified Horwitz equation for values $< 1.2 \times 10^{-7}$:

$$RSD_R = 22\ \%$$

Recommended precision values were determined applying 0.66 factor (for repeatability conditions) to values derived from Horwitz equation, whereas maximum permitted precision values were determined multiplying recommended precision values by factor 2 as stated under specific requirements for confirmatory analysis in Commission Regulation (EU) No 519/2014. Coefficients of variation describe precision and are presented in Table 15. Precision for all the assays within recovery study under repeatability conditions was within maximum permitted levels.

Additionally, 'Fitness for -purpose' approach was assessed for all the analytes under recovery conditions (4.3.1.2, Annex II, 'Performance criteria, Specific requirement for confirmatory methods', (EU) No 519/2014). Determination of maximum standard measurement uncertainty using the formula below was performed for this assessment:

$$Uf = \sqrt{(LOD/2)^2 + (\alpha \times C)^2}$$

Uf – is the maximum measurement uncertainty (µg/kg)

LOD – is the Limit of detection of the method (µg/kg)

α – is a constant, numeric factor to be used depending on the value of C. The values to be used are set out in Table (4.3.1.2 section, Annex II, 'Fitness for -purpose', Specific requirement for confirmatory methods', (EU) No 519/2014)

C – is the concentration of interest (µg/kg)

Uf value was further recalculated as a percentage value using fortification level and presented in the Table 15. All the results generated for recovery study were within determined maximum measurement uncertainty [%].

Table 13. Recovery study summary.

Assay	Fortification level [ppb]	Mean concentration ± SD [ppb]	Mean Recovery ± SD [%]	Concentration and recovery CV [%]	Maximum permitted precision under repeatability conditions according to Commission Regulation (EU) No 519/2014 RSDr [%]	Uf according to Commission Regulation (EU) No 519/2014 [± %]
Fumonisin B1	200.0	176.0 ± 45.2	88.0 ± 22.6	25.7	30.0	47.3
	500.0	475.7 ± 96.2	95.1 ± 19.2	20.2	30.0	25.1
	1000.0	930.3 ± 21.8	93.0 ± 2.2	2.3	20.0	17.4
Ochratoxin A	1.0	1.1 ± 0.2	102.0 ± 20.8	20.3	29.0	28.3
	4.0	3.8 ± 0.5	93.8 ± 12.3	13.1	29.0	20.6
	10.0	10.6 ± 1.1	99.9 ± 10.9	10.9	29.0	20.1
Aflatoxin G1	0.5	0.5 ± 0.05	99.0 ± 9.4	9.5	29.0	53.9
	4.0	3.9 ± 0.2	97.1 ± 4.0	4.1	29.0	21.0
	10.0	10.2 ± 0.8	102.1 ± 7.6	7.5	29.0	20.2
Deoxynivalenol	162.5	152.1 ± 13.4	93.6 ± 8.2	8.8	20.0	30.5
	520.0	444.0 ± 24.3	85.4 ± 4.7	5.5	20.0	19.6
	1300.0	1177.0 ± 70.0	90.5 ± 5.4	5.9	20.0	25.0
T2 toxin	10.0	8.7 ± 1.4	87.2 ± 13.8	15.8	>30	40.3
	20.0	18.8 ± 3.4	93.9 ± 16.9	18.0	30.0	26.6
	40.0	38.4 ± 4.1	96.0 ± 10.3	10.8	30.0	21.8
Aflatoxin B1	2.0	2.1 ± 0.1	104.4 ± 3.2	3.1	29.0	23.6
	4.0	4.2 ± 0.2	105.4 ± 4.1	3.8	29.0	21.0
	10.0	9.4 ± 0.4	94.2 ± 4.2	4.5	29.0	20.2
Zearalenone	10.0	8.7 ± 1.4	87.2 ± 13.8	15.8	>30	40.3
	20.0	18.8 ± 3.4	93.9 ± 16.9	18.0	30.0	26.6
	40.0	38.4 ± 4.1	96.0 ± 10.3	10.8	30.0	21.8

4.7 Reproducibility Study

External Study 1.

Reproducibility was performed under a third-party evaluation study consisting of 9 different laboratories and 9 different operators (unfamiliar with the technology) using 15 finished animal, cereal based feed samples, 1 corn reference material from FAPAS and 1 control supplied with the kit. All 17 samples used for the study were above LOD for the following analytes Ochratoxin A, Aflatoxin B1, T2-toxin, Deoxynivalenol, Zearalenone. 15 out of the 17 samples were above LOD for the Fumonisins assay. 11 out of the 17 samples were above LOD for the Aflatoxin G1 assay.

The reproducibility data was established by determination of Z-score and precision following IUPAC Guide (2010) and applying criteria specified under Commission Regulation (EU) No 519/2014.

Z-Score

Z-Score was determined following the formula:

$$Z\text{-}Score_a = (X_a - X_{ave}) / \sigma_{targ}$$

$Z\text{-}score_A$ – Z-score value for individual measuring point (individual laboratory, single sample)
X_A – individual measuring point concentration (individual laboratory, single sample, individual assay)
X_{AVE} – mean concentration across all laboratories (all laboratories, single sample, individual assay)
σ_{targ} – externally determined target standard deviation, compliant with fit-for-purpose approach, following formula:

$$\sigma_{targ} = \%RSD / 100 * X_{AVE}$$

%RSD – maximum permitted standard deviation values specified in Commission Regulation (EU) No 519/2014 for confirmatory methods. Percentage standard deviation under reproducibility condition taken directly from 4.3.1.1 section (Annex II, 'Performance criteria, Specific requirement for confirmatory methods', (EU) No 519/2014) or for analytes missing determined following either original Horwitz equation or the modified Horwitz equation (RSD_R):

Original Horwitz equation for values $1.2 \times 10^{-7} \leq X_{AVE} \leq 0.138$:

$$RSD_R = 2^{(1-0.5 \log X_{AVE})}$$

Modified Horwitz equation for values $< 1.2 \times 10^{-7}$:

$$RSD_R = 22\%$$

The acceptance criteria as specified on IUPAC Guide (2010) considers Z-score within ±2, while Z-score values outside ±3 are unacceptable, and questionable with intermediate values. Based on the probability versus values normal distribution, 95% of Z-score fall within ±2 and 99.9% of Z-score fall within ±3. Up to 152 measuring points were provided for each assay and ≥ 99.3% samples were within acceptable range ±2 and are summarised in Table 14.

Table 14. Z-Score summary

	Z-Score results within acceptable range ±2	n
	σ_{targ}	(Number of samples x number of labs)
Fumonisins	100%	133
Ochratoxin A	99.3%	151
Aflatoxin G1	100%	91
Deoxynivalenol	99.3%	151
T-2 Toxin	99.3%	150
Aflatoxin B1	99.3%	152
Zearalenone	99.3%	150

Precision

Precision was assessed for all the samples for all the assays by comparing the relative standard deviation generated within the study and the maximum permitted precision values assessed under reproducibility conditions according to Commission Regulation (EU) No 519/2014 for confirmatory methods. Maximum precision values (relative standard deviation) were either taken directly from 4.3.1.1 section (Annex II, 'Performance criteria, Specific requirement for confirmatory methods', (EU) No 519/2014) or for analytes missing determined following either original Horwitz equation or the modified Horwitz equation (RSD_R):

Original Horwitz equation for values $1.2 \times 10^{-7} \leq X_{AVE} \leq 0.138$:

$$RSD_R = 2^{(1-0.5 \log X_{AVE})}$$

Modified Horwitz equation for values $< 1.2 \times 10^{-7}$:

$$RSD_R = 22\%$$

Recommended precision values were taken directly from Horwitz equation, for the analytes the additional calculations were performed, whereas maximum permitted precision values were determined multiplying recommended precision values by factor 2 as stated under specific requirements for confirmatory analysis in Commission Regulation (EU) No 519/2014.

Precision for all the samples across all the assays within this external study under reproducibility conditions was within maximum permitted levels specified in Commission Regulation (EU) No 519/2014 for confirmatory methods and is presented in Table 15.

Table 15. Precision under reproducibility conditions. Study 1.

Sample No	Assay	Mean Concentration [ppb]	Standard Deviation [ppb]	RSD [%]	Maximum permitted precision under reproducibility conditions according to Commission Regulation (EU) No 519/2014 RSDR [%]
Feed Sample 1	Fumonisin	3273	576	17.6	30.0
	Ochratoxin A	110.4	10.6	9.6	30.0
	Deoxynivalenol	767.4	101.7	13.3	40.0
	T2 toxin	90.4	18.2	20.1	50.0
	Zearalenone	250.0	31.2	12.5	40.0
	Aflatoxin B1	33.6	5.0	14.9	44.0
	Aflatoxin G1	3.98	0.63	15.8	44.0
Feed Sample 2	Ochratoxin A	11.5	2.4	20.9	30.0
	Deoxynivalenol	1026.7	327.3	31.9	40.0
	T2 toxin	238.8	39.5	16.5	50.0
	Zearalenone	444.2	158.1	35.6	40.0
	Aflatoxin B1	29.2	9.9	34.1	44.0
	Aflatoxin G1	3.87	0.64	16.5	44.0
Feed Sample 3	Fumonisin	2663	538	20.2	30.0
	Ochratoxin A	248.0	49.6	20.0	30.0
	Deoxynivalenol	1415.5	145.4	10.3	40.0
	T2 toxin	1346.0	306.0	22.7	40.0
	Zearalenone	394.0	25.4	6.5	40.0
	Aflatoxin B1	17.0	3.5	20.3	44.0
	Aflatoxin G1	2.12	0.34	16.2	44.0
Feed Sample 4	Fumonisin	1498	225	15.0	30.0
	Ochratoxin A	195.7	33.6	17.2	30.0
	Deoxynivalenol	1154.5	190.6	16.5	40.0
	T2 toxin	488.4	84.5	17.3	40.0
	Zearalenone	205.2	24.0	11.7	40.0
	Aflatoxin B1	18.1	3.4	19.0	44.0
	Aflatoxin G1	2.03	0.35	17.5	44.0
Feed Sample 5	Fumonisin	5766	1065	18.5	30.0
	Ochratoxin A	137.0	12.1	8.8	30.0
	Deoxynivalenol	832.2	176.0	21.2	40.0
	T2 toxin	95.4	29.8	31.2	50.0
	Zearalenone	197.3	52.2	26.4	40.0
	Aflatoxin B1	24.2	4.0	16.7	44.0

RANDOX

Sample No	Assay	Mean Concentration [ppb]	Standard Deviation [ppb]	RSD [%]	Maximum permitted precision under reproducibility conditions according to Commission Regulation (EU) No 519/2014 RSDR [%]
Feed Sample 6	Fumonisin	8896	1051	11.8	30.0
	Ochratoxin A	137.1	21.2	15.5	30.0
	Deoxynivalenol	972.6	138.4	14.2	40.0
	T2 toxin	100.9	23.5	23.3	50.0
	Zearalenone	188.8	33.3	17.6	40.0
	Aflatoxin B1	3.6	1.5	41.6	44.0
Feed Sample 7	Fumonisin	1505	278	18.5	30.0
	Ochratoxin A	307.5	53.6	17.4	30.0
	Deoxynivalenol	801.3	115.9	14.5	40.0
	T2 toxin	120.9	24.3	20.1	50.0
	Zearalenone	601.4	107.8	17.9	40.0
	Aflatoxin B1	12.0	1.4	11.8	44.0
Feed Sample 8	Fumonisin	2704	625	23.1	30.0
	Ochratoxin A	235.7	52.5	22.3	30.0
	Deoxynivalenol	902.6	138.9	15.4	40.0
	T2 toxin	433.0	83.5	19.3	40.0
	Zearalenone	295.5	33.3	11.3	40.0
	Aflatoxin B1	11.7	1.7	14.4	44.0
Feed Sample 9	Fumonisin	2453	347	14.2	30.0
	Ochratoxin A	239.5	47.6	19.9	30.0
	Deoxynivalenol	1171.3	131.8	11.3	40.0
	T2 toxin	1070.5	197.4	18.4	40.0
	Zearalenone	409.0	73.5	18.0	40.0
	Aflatoxin B1	13.7	2.1	15.0	44.0
Feed Sample 10	Ochratoxin A	12.1	2.5	20.5	30.0
	Deoxynivalenol	865.0	170.3	19.7	40.0
	T2 toxin	204.9	47.4	23.1	50.0
	Zearalenone	712.3	151.2	21.2	40.0
	Aflatoxin B1	42.4	6.5	15.2	44.0
	Aflatoxin G1	3.97	0.83	20.8	44.0
Feed Sample 11	Fumonisin	7715	1929	25.0	30.0
	Ochratoxin A	18.0	2.9	15.9	30.0
	Deoxynivalenol	11442.7	1673.3	14.6	40.0
	T2 toxin	407.4	75.0	18.4	40.0
	Zearalenone	2691.9	357.8	13.3	40.0
	Aflatoxin B1	123.4	29.8	24.2	43.8
	Aflatoxin G1	11.30	2.84	25.1	44.0

Sample No	Assay	Mean Concentration [ppb]	Standard Deviation [ppb]	RSD [%]	Maximum permitted precision under reproducibility conditions according to Commission Regulation (EU) No 519/2014 RSDR [%]
Feed Sample 12	Fumonisin	2464	565	22.9	30.0
	Ochratoxin A	260.4	40.3	15.5	30.0
	Deoxynivalenol	927.1	131.4	14.2	40.0
	T2 toxin	472.2	88.6	18.8	40.0
	Zearalenone	301.2	46.0	15.3	40.0
	Aflatoxin B1	12.7	1.9	15.2	44.0
Feed Sample 13	Fumonisin	1518	267	17.6	30.0
	Ochratoxin A	323.0	47.4	14.7	30.0
	Deoxynivalenol	871.9	158.5	18.2	40.0
	T2 toxin	134.6	20.0	14.9	50.0
	Zearalenone	683.1	149.6	21.9	40.0
	Aflatoxin B1	12.0	1.9	16.1	44.0
	Aflatoxin G1	1.62	0.29	17.8	44.0
Feed Sample 14	Fumonisin	6352	1108	17.4	30.0
	Ochratoxin A	152.8	29.7	19.5	30.0
	Deoxynivalenol	967.9	162.4	16.8	40.0
	T2 toxin	99.7	17.2	17.2	50.0
	Zearalenone	199.2	33.5	16.8	40.0
	Aflatoxin B1	27.9	4.4	15.8	44.0
	Aflatoxin G1	2.81	0.39	13.9	44.0
Feed Sample 15	Fumonisin	9472	1149	12.1	30.0
	Ochratoxin A	159.7	44.3	27.7	30.0
	Deoxynivalenol	1029.2	165.5	16.1	40.0
	T2 toxin	97.3	8.4	8.7	50.0
	Zearalenone	188.3	25.1	13.3	40.0
	Aflatoxin B1	3.2	0.7	22.9	44.0
Myco 7 control	Fumonisin	13.4	1.7	12.8	60.0
	Ochratoxin A	0.0746	0.0073	9.8	60.0
	Deoxynivalenol	6.08	0.63	10.4	40.0
	T2 toxin	0.242	0.041	16.7	50.0
	Zearalenone	0.134	0.019	14.3	50.0
	Aflatoxin B1	0.0132	0.0015	11.7	44.0
	Aflatoxin G1	0.104	0.007	6.5	44.0
FAPAS, corn 4335	Fumonisin	401	53	13.1	30.0
	Ochratoxin A	3.53	0.47	13.3	30.0
	Deoxynivalenol	718.7	118.8	16.5	40.0
	T2 toxin	81.7	16.9	20.7	50.0
	Zearalenone	127.4	30.4	23.8	40.0
	Aflatoxin B1	5.40	1.20	22.2	44.0

External Study 2.

Reproducibility was performed under a third-party evaluation study within 10 various laboratories in 3 different countries using the same, corn FAPAS Quality Control Material, T04342QC (Figure 9). Reference material was aliquoted in 5g portions and sen7 together with a kit to various laboratories. Corn sample was contaminated with 8 mycotoxins, which were detected by 6 different assays on Myco 7 array. Fumonisin B1 and B2 were both detected by Fumonisins assay and showed as a total concentration of both toxins. Similarly, for T2-toxin and HT2-toxin, which were both detected by T2-toxin assay and showed as a total concentration of both toxins.

Figure 9. Fapas Quality Control material data sheet.

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FAPAS QC MATERIAL DATA SHEET	T04342QC
Matrix	Maize
Weight / Volume of Contents	200g

Analyte	Assigned Value, X_a	Range for |z| ≤2	Units	No. of data points producing X_a
Aflatoxin B1	4.86	2.72 - 7.00	µg/kg	62
Deoxynivalenol (DON)	743	494 - 991	µg/kg	61
Zearalenone (ZON)	131	74 - 188	µg/kg	60
Ochratoxin A	3.46	1.94 - 4.98	µg/kg	57
FB1	275	168 - 382	µg/kg	51
FB2	223	133 - 312	µg/kg	49
Total Fumonisins (sum FB1 & FB2)	485	312 - 658	µg/kg	45
T-2	57.9	32.4 - 83.3	µg/kg	45
HT-2	81.8	45.8 - 117.7	µg/kg	38
Sum T2 & HT-2	132	75 - 190	µg/kg	36

This data sheet is applicable until	08 Jun 2022

Precision

Precision was assessed for all the assays by comparing the relative standard deviation generated within the study and the maximum permitted precision values assessed under reproducibility conditions according to Commission Regulation (EU) No 519/2014 for confirmatory methods. Maximum precision values (relative standard deviation) were either taken directly from 4.3.1.1 section (Annex II, 'Performance criteria, Specific requirement for confirmatory methods', (EU) No 519/2014) or for analyte missing determined following either original Horwitz equation or the modified Horwitz equation (RSD_R):

Original Horwitz equation for values $1.2 \times 10^{-7} \leq X_{AVE} \leq 0.138$:

$$RSD_R = 2^{(1-0.5 \log X_{AVE})}$$

Modified Horwitz equation for values $< 1.2 \times 10^{-7}$:

$$RSD_R = 22\%$$

Recommended precision values were taken directly from Horwitz equation, for the analyte the additional calculations were performed, whereas maximum permitted precision values were determined multiplying recommended precision values by factor 2 as stated under specific requirements for confirmatory analysis in Commission Regulation (EU) No 519/2014.

All the assays precision evaluated within external study 2 under reproducibility conditions was within maximum permitted levels specified in Commission Regulation (EU) No 519/2014 for confirmatory methods and is presented in Table 16.

Table 16. Precision under reproducibility conditions. Study 2.

Assay	Mean Concentration [ppb]	Standard Deviation [ppb]	RSD [%]	Maximum permitted precision under reproducibility conditions according to Commission Regulation (EU) No 519/2014 RSDR [%]
Fumonisins	399.9	43.9	11.0	60
Ochratoxin A	3.5	0.5	13.8	30
Deoxynivalenol	728.6	99.0	13.6	40
T2 toxin	80.4	15.4	19.1	50
Aflatoxin B1	5.3	1.1	20.7	44
Zearalenone	121.8	24.4	20.0	40

Accuracy

The accuracy of Myco 7 array was evaluated by comparison of data generated within a study and assigned concentration together with acceptable concentration ranges for Z-score being within ±2 by FAPAS PT scheme. To enable direct comparison of FAPAS assigned concentration and data generated within a study assigned concentrations for Fumonisns and T2-toxin assays were recalculated following cross-reactivity profile of those assays and the toxins present in the sample. The accuracy of Myco 7 array was acceptable for all the assays under consideration. All the data generated within the study fell within the minimum and maximum concentrations of FAPAS assigned Z-score range for all the assays investigated on Myco 7 array and are summarised in the Table 17.

Table 17. Comparison of FAPAS Quality control material assigned concentration within FAPAS PT Scheme and generated within Study 2.

Myco 7 Assays	FAPAS assigned concentration [ppb]	Laboratories										FAPAS assigned Z-score range	
		USA								Spain	Mexico	Minimum concentration [ppb]	maximum concentration [ppb]
		1	2	3	4	5	6	7	8	9	10		
Fumonisins	477.9*	319.6	432.6	401.9	472.2	380.1	388.4	351.8	438.1	397.1	417.2	289.0*	665.9*
Ochratoxin A	3.46	3.48	3.85	2.82	3.66	3.69	3.26	4.35	3.15	2.81	3.73	1.94	4.98
Deoxynivalenol	743	608	764	657	884	727	704	875	794	634	640	494	991
T2 toxin	80.0*	70.7	71.0	53.2	95.5	84.9	88.7	108.3	81.3	70.0	80.6	44.8*	115.0*
Aflatoxin B1	4.9	4.6	3.8	4.2	6.6	6.3	6.2	6.9	4.8	4.5	5.2	2.7	7.0
Zearalenone	131.0	110.0	96.7	102.2	154.3	173.8	121.7	107.8	115.9	108.5	127.0	74.0	188.0

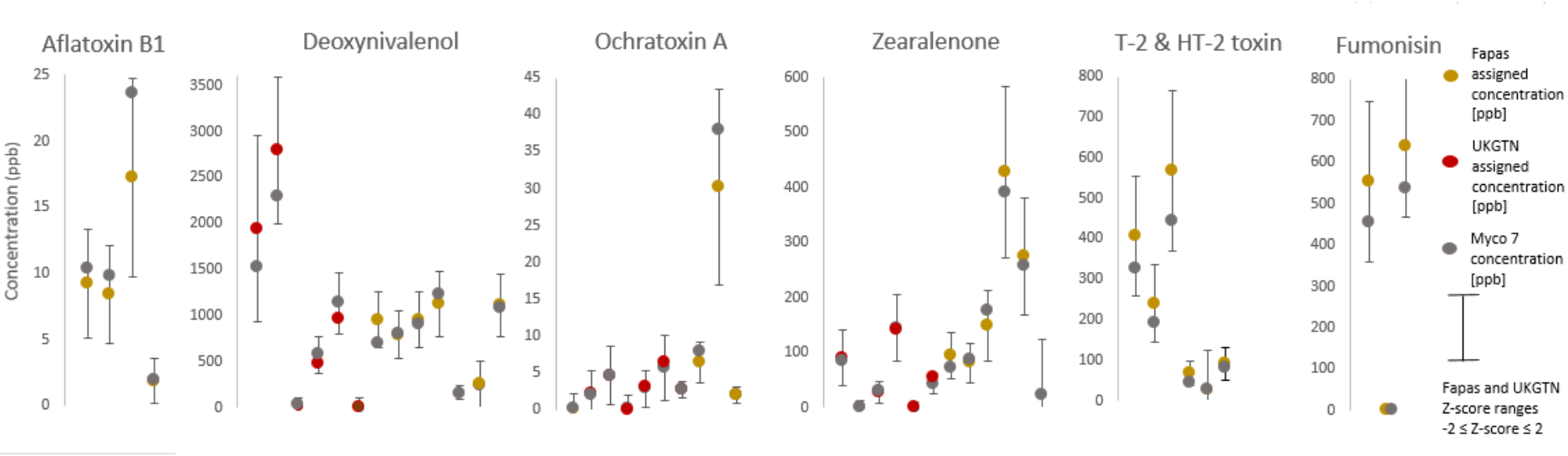
* FAPAS assigned concentration as well as minimum and maximum concentration ranges for Fumonisins and T2-toxin assays were recalculated following cross-reactivity profile for Fumonisin B2 and HT2-toxin present in the sample.

4.8 Certified Reference Materials (CRM) – FAPAS, UKGTN and Trilogy samples study

4.8.1. FAPAS and UKGTN - Proficiency Test Schemes

FAPAS is the largest and most comprehensive analytical chemistry proficiency testing scheme in the food sector. United Kingdom Grain Testing Network is another Proficiency Test Scheme provider in UK.
As a part of independent check of biochip technology and Myco 7array performance, both FAPAS and UKGTN Proficiency Test providers materials were analysed on Myco 7. Samples tested within FAPAS scheme included maize, maize flour, cereals-based animal feed, wheat flour and oat flour. UKGTN provided wheat and barley materials. Samples contained either one or multiple mycotoxins. All reported results for FAPAS and UKGTN Proficiency Test materials were within the Z-score ≤2 and presented in Figure 10. Myco 7 assigned concentrations were recalculated, where applicable, accounting for cross-reactivity based on proficiency test reports when received.

Figure 10. FAPAS and UKGTN Proficiency Test materials results assigned on Myco 7 biochip array.



4.8.2. Quality Certified Test Materials

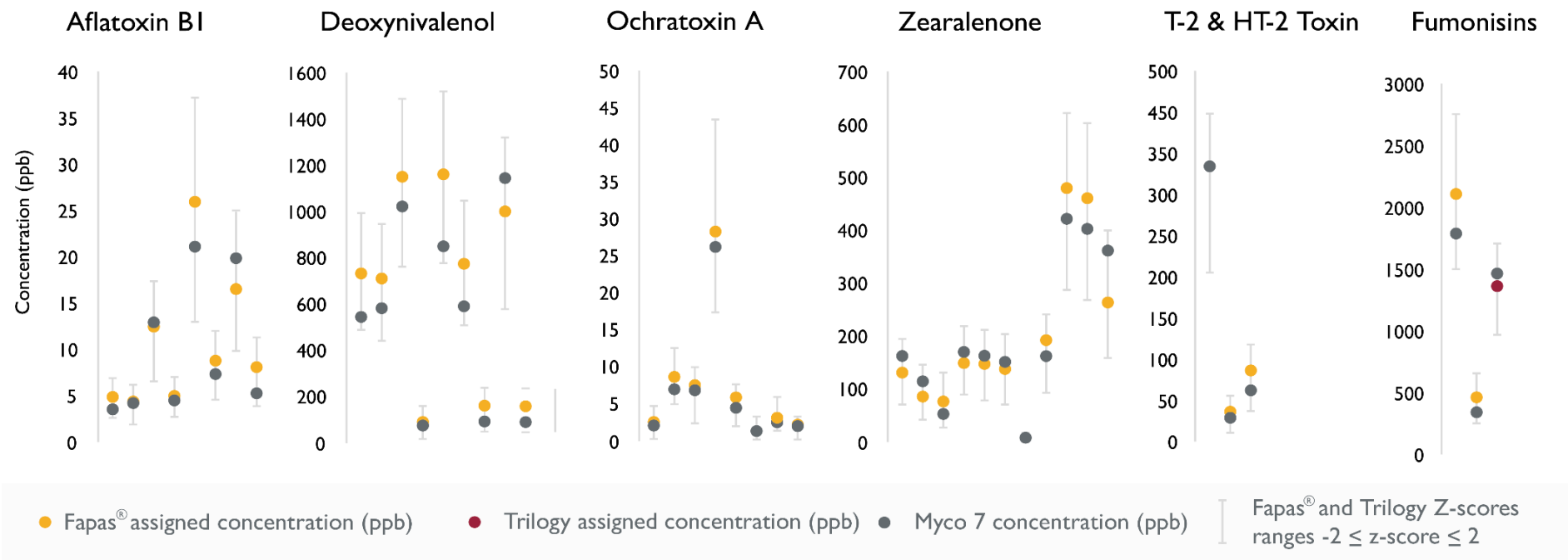
There are multiple certified test materials providers available on the market for mycotoxins, including FAPAS and Trilogy. FAPAS QC test materials are authentic food matrices that have been sufficiently well established from the results of laboratories participating in a proficiency test to be used by laboratories as quality control materials.

The values have been derived as a consensus of a number of laboratories using a variety of methods and the satisfactory range indicates the range between which results would have been awarded a satisfactory z-score in the proficiency test. The satisfactory range is set as a range that is considered fit for purpose and reflects the expected inter-laboratory reproducibility. Trilogy certified reference materials and naturally contaminated samples which were assessed according to ISO17034:2016 using single laboratory either LC-MS/MS or HPLC analysis.

As a part of external recovery study, FAPAS QC samples including maize, cereal-based animal feed, wheat flour and infant food cereal-based and Trilogy CR maize were analysed on Myco 7 and data presented in Figure 11. All the results for FAPAS QC materials were within the Z-score ≤2. The Trilogy samples were also showing perfect correlation, being within uncertainty range (measurement of uncertainty k=2).

Myco 7 assigned concentrations were recalculated where applicable accounting for cross-reactivity based on FAPAS QC certificates.

Figure 11. FAPAS QC and Trilogy QC samples results assigned on Myco 7 biochip array.



4.9 Stability

Stability assessment has been carried out with a combination of accelerated stability studies and real-time assessment (Table 18).

Table 18. Stability of Myco 7 kit and associated components

	Shelf-life	**18 Months**
Myco 7 Array kit (EV4065)	*Liquid ready-to-use Calibrators and Control*	18 months
	Liquid 20x concentrate Conjugate	18 months
	Assay diluent	24 months
	Conjugate diluent	24 months
	Biochips	24 months

5.0 Conclusion

Assay range, specificity and stability of all reagents including control material met design input and was determined to be suitable for use. Precision CV's were ≤12% for all 7 analytes across the concentrations assessed in buffer under repeatability conditions and therefore met design inputs.
Screening Target Concentration was validated following Commission Regulation (EU) No 519/2014 for semi-quantitative methods and rate for false suspect rate was set ≤ 2% for all assays for cereals and cereal based feed.
Recovery met design input for all analytes. Precision assessment and maximum measurement uncertainty (Uf) used for 'Fitness-for-purposed' approach for recovery study, both were within criteria established according to Commission Regulation (EU) No 519/2014.
Myco 7 reproducibility was performed under two external studies. Inter-assay precision assessed under External Study 1 showed perfect rate of passed criteria for either Z-score and precision. Z-Scores were between 99.3 and 100% and passed IUPAC Guide (2010) criterion of 95% Z-score pass at ±2. Precision assessed under reproducibility conditions for all the samples across all the assays within external study 1 was within maximum permitted levels specified in Commission Regulation (EU) No 519/2014 for confirmatory methods.
The external study 2 performed within 10 various laboratories showed perfect accuracy, were all data points generated for FAPAS certified material were within Z-score acceptance criteria ±2. Precision assessed under reproducibility conditions for all the assays within external study 2 was within maximum permitted levels specified in Commission Regulation (EU) No 519/2014 for confirmatory methods.
All results generated within single laboratory validation either within Proficiency Test Schemes or using certified reference materials for various cereals and cereal based feed matrices were all within acceptable Z-score ranges ±2 for all assays. Myco 7 Array EV4065 provides a robust screening tool for the detection of mycotoxins.

References:

- Kuselman I. and Fajgelj A., 2010, IUPAC/CITAC Guide. Selection and use of proficiency testing Schemes for a limited number of participants – Chemical Analytical Laboratories. (IUPAC Technical Report)
- Commission Regulation (EU) No 519/2014, Official Journal of the European Union, L147/29-43