



FOOD XPLOER (FOX) INSTRUCTION FOR USE

For Research Use only!

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I. LIABILITY STATEMENT

This IFU has been reviewed for accuracy. The instructions for FOX Food Xplorer were correct at the time of publication. Subsequent versions of this guide may be updated without prior notice.

The FOX Food Xplorer kit is a device intended for use by trained laboratory personnel only. The FOX Food Xplorer kit may only be used for its intended purpose in accordance with this IFU. The IFU must be observed without exception. If you are unfamiliar with the use of the FOX Food Xplorer kit, you are obliged to obtain information from MacroArray Diagnostics (MADx) before using it. MADx assumes no liability for improper use of the FOX Food Xplorer. MADx shall only be liable for any harm or damage to property directly or indirectly resulting from errors in this IFU in the event of gross negligence or intent, and for personal injury only within the scope of the mandatory statutory provisions.

If any term or provision in this IFU shall be held to be illegal or unenforceable, in whole or in part, under any enactment or rule of law, such term or provision or part shall to that extent be deemed not to form part of this IFU but the enforceability of the remainder of this IFU shall not be affected.

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II. DESCRIPTION

The FOX Food Xplorer is an Enzyme-Linked Immunosorbent Assay (ELISA) – based test for the semi-quantitative measurement of specific immunoglobulin G (IgG) and is intended for research use only. It detects all four IgG subtypes (IgG1-4) and reports a combined total value, without distinguishing between individual subtypes.

These Instructions for Use are applicable for the following products:

Basic UDI-DI	REF	Product
91201229280KC	80-5001-02	FOX for 50 Analyses
	80-0001-02	FOX for up to 250 Analyses

III. INTENDED PURPOSE

The Food Xplorer (FOX) is an ELISA – based test for the semi-quantitative measurement of specific immunoglobulin G (IgG) against 286 food antigens and is intended for research use only. The Food Xplorer is suitable for use with serum or plasma. The processing of FOX should always be carried out by qualified researchers in a laboratory environment.



IV. SUMMARY AND EXPLANATION OF THE TEST

The Food Xplorer covers all food groups. The complete list of FOX food extracts can be found at the end of the instructions for use.

There is no restriction on the test population. When developing IgG assays, age and sex are typically not considered as critical factors because IgG levels, which are measured in these assays, do not significantly vary based on these demographics.

Important information for the user!

For the correct use of FOX, it is necessary for the user to carefully read and follow these instructions for use. The manufacturer assumes no liability for any use of this test system not described in this document or for modifications by the user of the test system. This test is for research use only and not intended for the diagnosis or treatment of diseases.

All further product information can be found in the corresponding instructions for use: <https://www.madx.com/extras>.

V. PRINCIPLE OF THE PROCEDURE

FOX is a solid-phase immunoassay test based on ELISA. Food extracts, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase forming a macroscopic array. First, the particle-bound proteins react with specific IgG that is present in the blood sample. After incubation, non-specific IgG is washed off. The procedure continues by adding an enzyme-labelled anti-human IgG detection antibody which forms a complex with the antigen bound specific IgG. After a second washing step, substrate is added, which is converted to an insoluble, colored precipitate by the antibody-bound enzyme. Finally, the enzyme-substrate reaction is stopped by adding a blocking reagent. The amount of precipitate is proportional to the reactivity of specific IgG in the blood sample. The lab test procedure is followed by image acquisition and analysis using the manual system (ImageXplorer) or the automated system (MAX 9k or MAX 45k). The test results are analyzed with RAPTOR SERVER Analysis Software and reported in IgG classes. RAPTOR SERVER is available in version 1, for the full four-digit version number please refer to the RAPTOR SERVER imprint available at www.raptor-server.com/imprint.

VI. SHIPMENT AND STORAGE

The shipment of FOX takes place at ambient temperature conditions. Nevertheless, the kit must be stored immediately upon delivery at 2-8 °C. Stored correctly, FOX and its components can be used until the indicated expiry date.



	Kit reagents are stable for 6 months after opening (at the indicated storage conditions).
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VII. WASTE DISPOSAL

Dispose the used FOX cartridge and unused kit components with laboratory chemical waste. Follow all national, state, and local regulations regarding disposal.

VIII. GLOSSARY OF SYMBOLS

	Warning (GHS pictogram) Consult the Safety Data Sheet for more information.
	Catalogue number
	Sufficient for <n> tests
	Do not use if packaging is damaged
	For Research Use only
	Lot code
	Consult instructions for use
	Manufacturer



	Date of manufacture
	Do not re-use
	Cartridge
	Use-by date
	Temperature limit
	Caution
	Unique device identifier
	MacroArray Diagnostics (MADx)

IX. KIT COMPONENTS

New Nomenclature for Reagent Lots

Attention: We are introducing a new lot nomenclature for all MADx reagents (the nomenclature for the cartridges is not affected).

FOX kits with lot number 80DAA01 and subsequently produced lots will be affected by this change.

Key Details:

- **No change for cartridge labels**
- The specific reagents of one reagent lot will show the same label nomenclature and can be combined with different cartridge lots.



We will only vary **position 1 and 2** of our **three-letter code** for the reagents. For instance:

- Reagents with labels **DAA** can be combined with the cartridge lots **DAA, DAB, DAC, DAD,... up to DAT**.
- Reagents with labels **DBA** can be combined with the cartridge lots **DBA, DBB, DBC, DBD,... up to DBT**.
- The RAPTOR SERVER Analysis Software has already been updated to reflect these changes. **No action is required from customers.**
The RAPTOR SERVER will recognize and combine the correct cartridges with the corresponding reagents.

Each component (reagent) is stable until the date stated on each individual component's label. Do not combine or mix reagents from different reagent lots (different first two letters). For a list of antigen extracts and molecular antigens immobilized on the FOX array, please contact pm@macroarraydx.com.

Kit Components REF 80-5001-02	Content	Properties
FOX Cartridge	5 Blisters à 10 FOX for 50 analyses in total	Ready for use. Store at 2-8°C until expiry date. Opened blister is stable for 6 months at 2-8°C.
FOX Sample Diluent	1 bottle à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2- 8°C.
Washing Solution	4 x conc. 1 bottle à 250 ml	Store at 2-8°C until expiry date. Dilute 1 to 4 with demineralized water before use (250 ml Washing Solution + 750 ml demineralized water). Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C.
FOX Detection Antibody	1 bottle à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2- 8°C.
FOX Substrate Solution	1 bottle à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2- 8°C.
(FOX) Stop Solution	1 bottle à 10 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C. May appear as a turbid solution after



Kit Components REF 80-5001-02	Content	Properties
		prolonged storage. This has no effect on results.

Kit Components REF 80-0001-02	Content	Properties
FOX Cartridge	5 Blisters à 50 FOX for 250 analyses in total.	Ready for use. Store at 2-8°C until expiry date. Opened blister is stable for 6 months at 2-8°C.
FOX Sample Diluent	5 bottles à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2- 8°C.
Washing Solution	4 x conc. 5 bottles à 250 ml	Store at 2-8°C until expiry date. Dilute 1 to 4 with demineralized water before use (250 ml Washing Solution + 750 ml demineralized water). Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C.
FOX Detection Antibody	5 bottles à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2- 8°C.
FOX Substrate Solution	5 bottles à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2- 8°C.
(FOX) Stop Solution	5 bottles à 10 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C. May appear as a turbid solution after prolonged storage. This has no effect on results.



X. REQUIRED EQUIPMENT FOR PROCESSING AND ANALYSING

Manual Analysis:

- ImageXplorer (REF 11-0000-02)
- Arrayholder (optional)
- Lab Rocker (inclination angle 8°, required speed 8 rpm)
- Incubation chamber (WxDxH – 35x25x2 cm)
- RAPTOR SERVER Analysis Software
- PC/Laptop

Required equipment, not provided by MADx:

- Demineralized water
- Pipettes & tips (100 µl & 100 - 1000 µl)

Automatic Analysis:

- MAX device (MAX 9k or MAX 45k – REF 17-0000-02 or REF 16-0000-02)
- Washing Solution (REF 00-5003-02)
- Stop Solution (REF 00-5007-02)
- RAPTOR SERVER Analysis Software
- PC/Laptop

Maintenance services according to manufacturer's instructions.

XI. HANDLING OF ARRAYS

Do not touch the array surface. Any surface defects caused by blunt or sharp objects can interfere with the results. Do not acquire FOX images before array is completely dry (dry at room temperature).

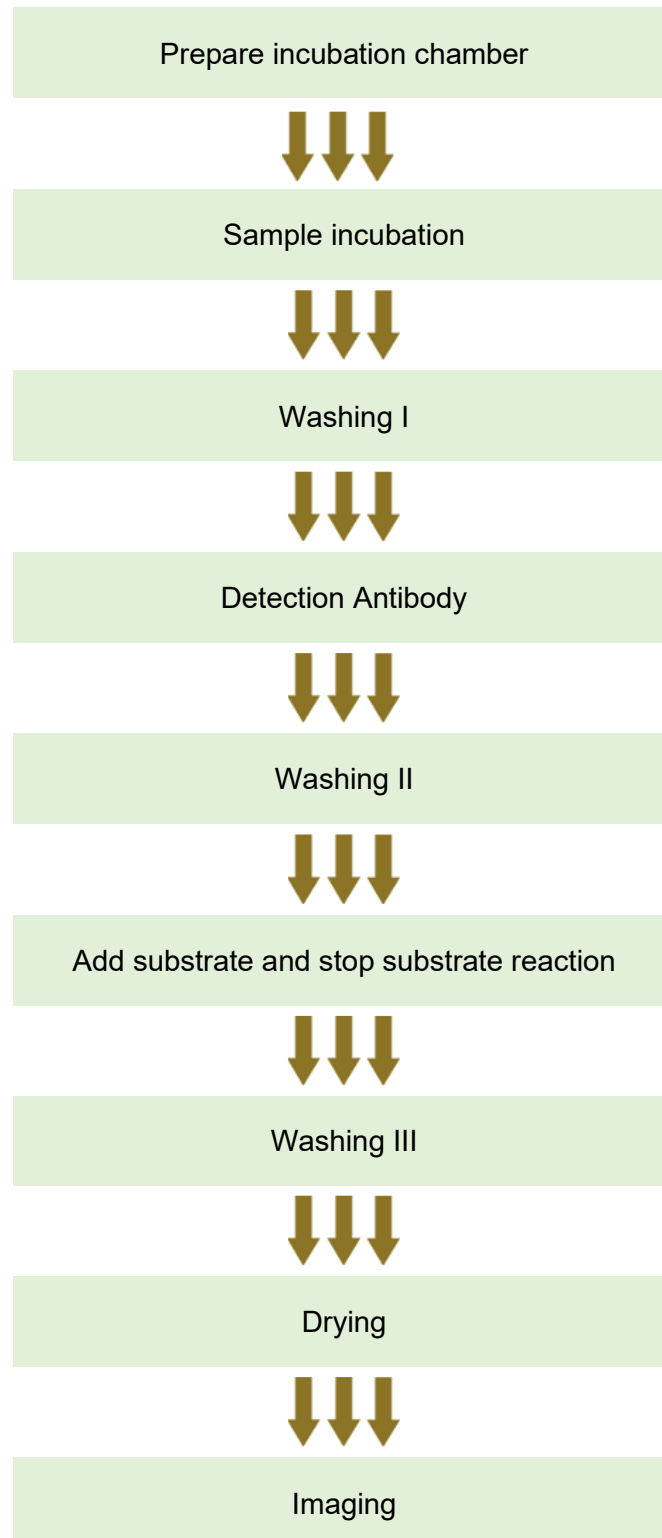


XII. WARNINGS AND PRECAUTIONS

- This product must be used FOR RESEARCH USE ONLY.
- It is recommended to wear hand and eye protection as well as lab coats and follow good laboratory practice when preparing and handling reagents and samples.
- In accordance with good laboratory practice, all blood source material (e.g. ingredients in reagents or other components) should be considered potentially infectious and handled with the same precautions as blood samples.
- The FOX Sample Diluent is partially prepared from human blood sources. The product was tested non-reactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C (HCV) and antibodies to HIV-1/HIV-2.
- The FOX Sample Diluent and Washing Solution contain sodium azide as a preservative and must be handled with care. The safety data sheet is available upon request.
- The (FOX) Stop Solution contains Ethylenediaminetetraacetic acid (EDTA)-Solution and must be handled with care. The safety data sheet is available upon request.
- This test is for research use only and not for the diagnosis or treatment of diseases in humans or animals.
- Only personnel trained in laboratory practice should use this kit.
- Upon arrival, check the kit components for damage. If one of the components is damaged (e.g. buffer bottles), contact MADx (support@madx.com) or your local distributor. Do not use damaged kit components, as their use may lead to poor kit performance.
- Do not use reagents beyond their expiry dates.
- Do not mix reagents from different lots.



XIII. ASSAY PROCEDURE





Preparation

Preparation of samples: Serum or plasma (heparin, citrate, EDTA) samples from capillary or venous blood can be used. Blood samples can be collected using standard procedures. Store samples at 2–8 °C for up to one week. Keep serum and plasma samples at -20 °C for prolonged storage. Shipment of serum/plasma samples at room temperature is applicable. Always allow samples to reach room temperature before use.

Preparation of Washing Solution (for REF 80-5001-02 und REF 80-0001-02): Pour the content of 1 vial of Washing Solution into the washing container of the instrument. Fill demineralized water up to the mark and carefully mix the container several times without generating foam. The opened reagent is stable for 6 months at 2-8°C.

Personnel using the automated procedure of FOX must be trained in handling MAX devices (MAX45k or MAX9k). Instructions on how to run a test are provided in MAX IFU subchapters XVII.7-10 and must be followed.

Automatically processed FOX tests **must be prediluted manually**. Requirements and instructions for dilutions are available in the MAX IFU chapter XXI (Technical Specification).

The current version of the MAX IFU (Systems) can be found here:
<https://www.madx.com/de/extras>

	The minimum sample volume required for FOX test using only Low Volume tubes is 600 µl, which consists of 12 µl serum mixed with 588 µl Sample Diluent.
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Incubation chamber: Close lid for all assay steps to prevent drop in humidity.

Parameters of manual procedure:

- 10 µl sample + 490 µl FOX Sample Diluent
- 500 µl FOX Detection Antibody
- 500 µl FOX Substrate Solution
- 100 µl (FOX) Stop Solution
- 4500 µl Washing Solution

Assay time is approximately 3 h 30 min (without drying of processed array).

It is not recommended to run more assays than can be pipetted in 8 min. All incubations are performed at room temperature, 20-26 °C.

	All reagents are to be used at room temperature (20-26 °C). The assay must not be performed in direct sunlight.
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Prepare incubation chamber

Open the incubation chamber and place paper towels on the bottom part. Soak paper towels with demineralized water until no dry parts of the paper towels are visible.

1. Sample incubation

Predilute 10 µl sample with 490 µl FOX Sample Diluent in a separate tube. Take out the needed number of FOX cartridges and place them into the array holder(s). Add 500 µl of the prediluted sample to the cartridges. Ensure that the resulting solution is spread evenly. Place the cartridges in the prepared incubation chamber and put the incubation chamber with the cartridges on the lab rocker so that the cartridges rock along the long side of the cartridge. Start the serum incubation at 8 rpm for 2 hours. Close the incubation chamber before starting the lab rocker. After 2 hours, discharge the samples into a collection container and vigorously tap the cartridges on a stack of dry paper towels to remove droplets.



Avoid touching the array surface with the paper towel! Avoid any carry over or cross-contamination of samples between individual FOX cartridges!

1a. Washing I

Add 500 µl Washing Solution to each cartridge and incubate on the lab rocker (at 8 rpm) for 5 minutes. Discharge the Washing Solution into a collection container and vigorously tap the cartridges on a stack of dry paper towels.

Repeat this step 2 more times.

2. Add Detection Antibody

Add 500 µl FOX Detection Antibody to each cartridge.



Make sure that the complete array surface is covered by the FOX Detection Antibody solution.

Place the cartridges into the incubation chamber on the lab rocker and incubate at 8 rpm for 30 minutes. Discharge the Detection Antibody solution into a collection container and vigorously tap the cartridges on a stack of dry paper towels.



2a. Washing II

Add 500 µl Washing Solution to each cartridge and incubate on the lab rocker at 8 rpm for 5 minutes. Discharge the Washing Solution into a collection container and vigorously tap the cartridges on a stack of dry paper towels.

Repeat this step 4 more times.

3+4. Add Substrate Solution and stop substrate reaction

Add 500 µl FOX Substrate Solution to each cartridge. The timer should be started upon filling the first cartridge, followed by the filling of the remaining cartridges. Make sure that the complete array surface is covered by the Substrate Solution and incubate the arrays for exactly 8 minutes without shaking (**lab rocker at 0 rpm and in horizontal position**).

After exactly 8 minutes, add 100 µl of the (FOX) Stop Solution to all cartridges, starting with the first cartridge to assure that all arrays are incubated for the same time with the Substrate Solution. After the (FOX) Stop Solution has been pipetted onto all arrays, gently agitate the cartridge to ensure even distribution of the solution. Afterwards discharge (FOX) Substrate/Stop Solution from the cartridges and vigorously tap the cartridges on a stack of dry paper towels.



The Lab Rocker must NOT SHAKE during substrate incubation!

4a. Washing III

Add 500 µl Washing Solution to each cartridge and incubate on the lab rocker at 8 rpm for 30 seconds. Discharge the Washing Solution into a collection container and vigorously tap the cartridges on a stack of dry paper towels.

5. Image analysis

After finishing the assay procedure, air dry the arrays at room temperature until they are completely dry (can take up to 45 min). If the arrays require an extended drying period, they should be stored in a light-protected environment until analysis.



The complete drying is essential for optimal assay performance. Only completely dried arrays provide consistent signal quality for research applications.



Finally, the dried arrays are scanned with the ImageXplorer or a MAX device and analyzed with RAPTOR SERVER Analysis Software (see details in the RAPTOR SERVER IFU). The RAPTOR SERVER Analysis Software is designed to be used in combination with the ImageXplorer instrument or the MAX devices, therefore MADx does not take any responsibilities for results, which have been obtained with any other image capture device (like scanners).

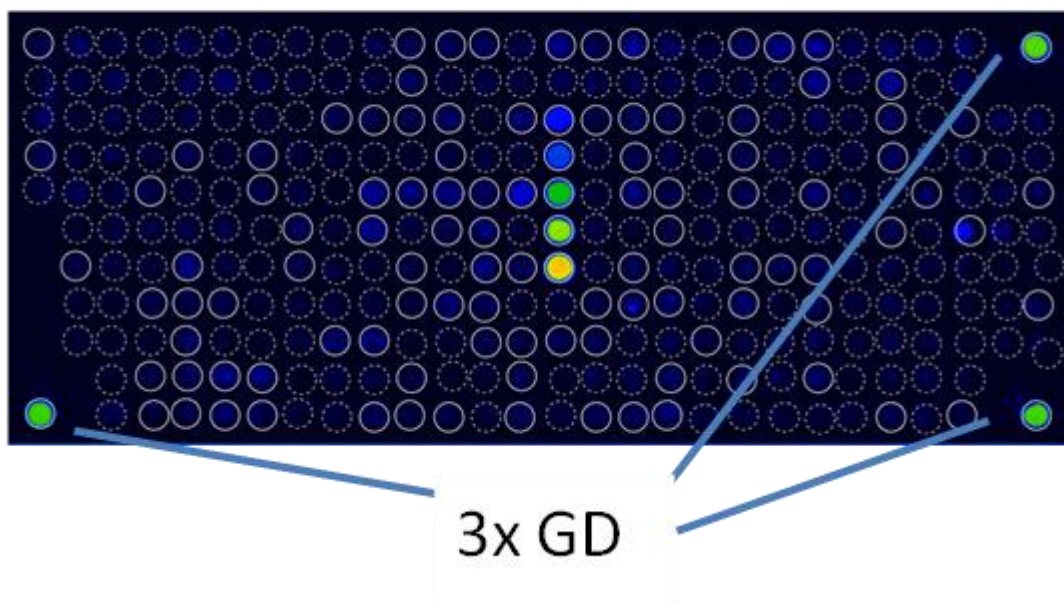
The array with the grid is displayed in the analytical image area. The software automatically locates the array by detecting the Guide Dots (GD). FOX contains three Guide Dots for this purpose.

After processing, the Guide Dots have to be easily visible with the naked eye. Please also verify their correct orientation as shown in the image for FOX below. If they are not visible, please contact your local distributor or MADx support on how to proceed. In case the Guide Dots are visible, the cartridge can be further analyzed.

During the image acquisition of a FOX cartridge, RAPTOR SERVER evaluates the signal of all Guide Dots as well as the background signal of the membrane surface. If all quality criteria are fulfilled, the “automatic QC” field under the image is set to “OK”.

In order to exclude the influence of artifacts in the automated image analysis (satellite spots, sample contaminations, dust, smeared spots, ...), the images must be checked by a trained operator before the results are approved in order to exclude false results. In case of discrepancies between the processed array and the image acquired by the RAPTOR SERVER please consult your local distributor or MADx Support.

FOX





Assay Calibration

Semi-quantitative evaluation of the test results is based on a heterologous calibration against an IgG reference curve. Curve parameters are determined from the standard features of the test panel. A curve fit is calculated, and the resulting equation applied to transform arbitrary intensity units into quantitative units. The standard curve for each lot is adjusted by in-house reference testing against serum samples tested on a reference test system for specific IgG against several antigens. Lot specific calibration parameters are provided by the RAPTOR SERVER Analysis Software and selected according to the lot-specific QR codes. FOX sIgG test results are expressed as µg/ml.

Measuring Range

Specific IgG 5.0 - 50.0 µg/ml

XIV. QUALITY CONTROL

Record keeping for each assay

According to good laboratory practice it is recommended to record the lot numbers of all reagents used.

Control Specimens

According to good laboratory practice it is recommended that quality control samples are included within defined intervals.

XV. DATA ANALYSIS

For the image analysis of processed arrays, the ImageXplorer or a MAX device has to be used. FOX images are automatically analyzed using RAPTOR SERVER Analysis Software and a report is generated summarizing the results for the user.

XVI. RESULTS

FOX is a semi-quantitative ELISA method for specific IgG. Specific IgG antibodies are expressed as IgG response units (µg/ml). RAPTOR SERVER Analysis Software automatically calculates and reports sIgG results semi-quantitatively as classes (negative, low, intermediate and highly elevated).



XVII. LIMITATIONS OF THE PROCEDURE

False-positive test results may occur due to cross-reactivity of the tested antigen with epitopes of other antigens. Antigenic epitopes may be lost during the production of food extracts, which may lead to false-negative results. IgG antibodies to food antigens that occur only during industrial preparation, food preparation, or digestion may not be detectable in the blood sample.

XVIII. EXPECTED VALUES

Good laboratory practice recommends that each laboratory establishes its own range of expected values.

XIX. WARRANTY

Any change or modifications to the procedure may affect the results and MacroArray Diagnostics disclaims all warranties expressed (including the implied warranty of merchantability and fitness for use) in such an event. Consequently, MacroArray Diagnostics and its local distributors shall not be liable for any indirect or consequential damages arising from such modifications.

XX. ABBREVIATIONS

FOX	Food Xplorer
EDTA	Ethylenediaminetetraacetic acid
ELISA	Enzyme-Linked Immunosorbent Assay
IgG	Immunoglobulin G
MADx	MacroArray Diagnostics
REF	Reference number
rpm	Rounds per minute
slgG	Specific IgG
µl	Microliter



ANTIGEN LIST FOX

Vegetables: Artichoke, Arugula, Avocado, Bamboo sprouts, Broccoli, Brussels sprouts, Cabbage, Caper, Carrot, Cauliflower, Celery bulb, Celery stalk, Chard, Chicorée, Chinese cabbage, Chives, Cucumber, Eggplant, Endive, Fennel (bulb), Garlic, Green cabbage, Horseradish, Kiwano, Kohlrabi, Lamb's lettuce, Leek, Nettle leaves, Olive, Onion, Parsnip, Pok-Choi, Potato, Pumpkin (butternut), Pumpkin (hokkaido), Radicchio, Radish, Red beet, Red cabbage, Romanesco, Savoy, Shallot, Spinach, Sweet potato, Tomato, Turnip, Watercress, White Asparagus, White cabbage, Wild garlic, Zucchini

Fish & Seafood: Abalone, Atlantic cod, Atlantic herring, Atlantic redfish, Carp, Caviar, Cockle, Common mussel, Crab, Eel, European anchovy, European pilchard, European plaice, Gilt-head bream, Haddock, Hake, Lobster, Mackerel, Monkfish, Noble crayfish, Northern pike, Northern prawn, Octopus, Oyster, Razor shell, Salmon, Scallop, Sepia, Shrimp mix, Sole, Squid, Swordfish, Thornback Ray, Trout, Tuna, Turbot, Venus clam

Fruits: Apple, Apricot, Banana, Blackberry, Blueberry, Cherry, Cranberry, Date, Elderberry, Fig, Gooseberry, Grape, Grapefruit, Kiwi, Lemon, Lime, Lychee, Mango, Melon, Mulberry, Nectarine, Orange, Papaya, Passion fruit, Peach, Pear, Physalis, Pineapple, Plum, Pomegranate, Raisin, Raspberry, Red currant, Strawberry, Tangerine, Watermelon

Spices: Anise, Basil, Bay leaf, Caraway, Cardamom, Cayenne pepper, Chili (red), Cinnamon, Clove, Coriander, Cumin, Curry, Dill, Fenugreek, Ginger, Juniper berry, Lemongrass, Marjoram, Mint, Mustard, Nutmeg, Oregano, Paprika, Parsley, Pepper (black/white/green/red/yellow), Rosemary, Sage, Tarragon, Thyme, Turmeric, Vanilla

Cereals & Seeds: Amaranth, Barley, Buckwheat, Chickpea, Corn, Durum, Einkorn, Emmer, Gluten, Hempseed, Linseed, Lupine seed, Malt (barley), Millet, Oat, Pine nut, Polish wheat, Poppy seed, Pumpkin seed, Quinoa, Rapeseed, Rice, Rye, Sesame, Spelt, Sunflower, Wheat, Wheat bran, Wheat gliadin, Wheatgrass

Novel Foods: Almond milk, Aloe, Aronia, Baobab, Chia seed, Chlorella, Dandelion root, Ginkgo, Ginseng, Greater burdock root, Guarana, House cricket, Maca root, Mealworm, Migratory locust, Nori, Safflower oil, Spirulina, Tapioca, Wakame, Yacón root

Egg & Milk: Buffalo milk, Buttermilk, Camel milk, Camembert, Cottage cheese, Cow milk, Egg white, Egg yolk, Emmental, Goat cheese, Goat milk, Gouda, Mozzarella, Parmesan, Quail egg, Sheep cheese, Sheep milk

Meat: Beef, Boar, Chicken, Duck, Goat, Horse, Lamb, Ostrich, Pork, Rabbit, Stag, Turkey, Veal, Venison

Nuts: Almond, Brazil nut, Cashew, Coconut, Coconut milk, Hazelnut, Kola nut, Macadamia, Pecan nut, Pistachio, Sweet chestnut, Tigernut, Walnut

Coffee & Tea: Chamomile, Cocoa, Coffee, Hibiscus, Jasmine, Moringa, Peppermint, Tee (black), Tee (green)



Legumes: Green bean, Lentil, Mung bean, Pea, Peanut, Soy, Sugar pea, Tamarind, White bean

Edible Mushrooms: Boletus, Chanterelle, Enoki, French horn mushroom, Oyster mushroom, White mushroom

Other: Agar agar, Aspergillus niger, Baker's yeast, Brewer's yeast, Elderflower, Honey, Hops, M-Transglutaminase (meat glue), Cane sugar, Cross-reactive Carbohydrate Determinants

Molecular antigens: Bos d 4, Bos d 5, Bos d 8



CHANGE HISTORY

Version	Description	Replaces
02	Document created based on 80-IFU-01-EN-8.1 FOX	01



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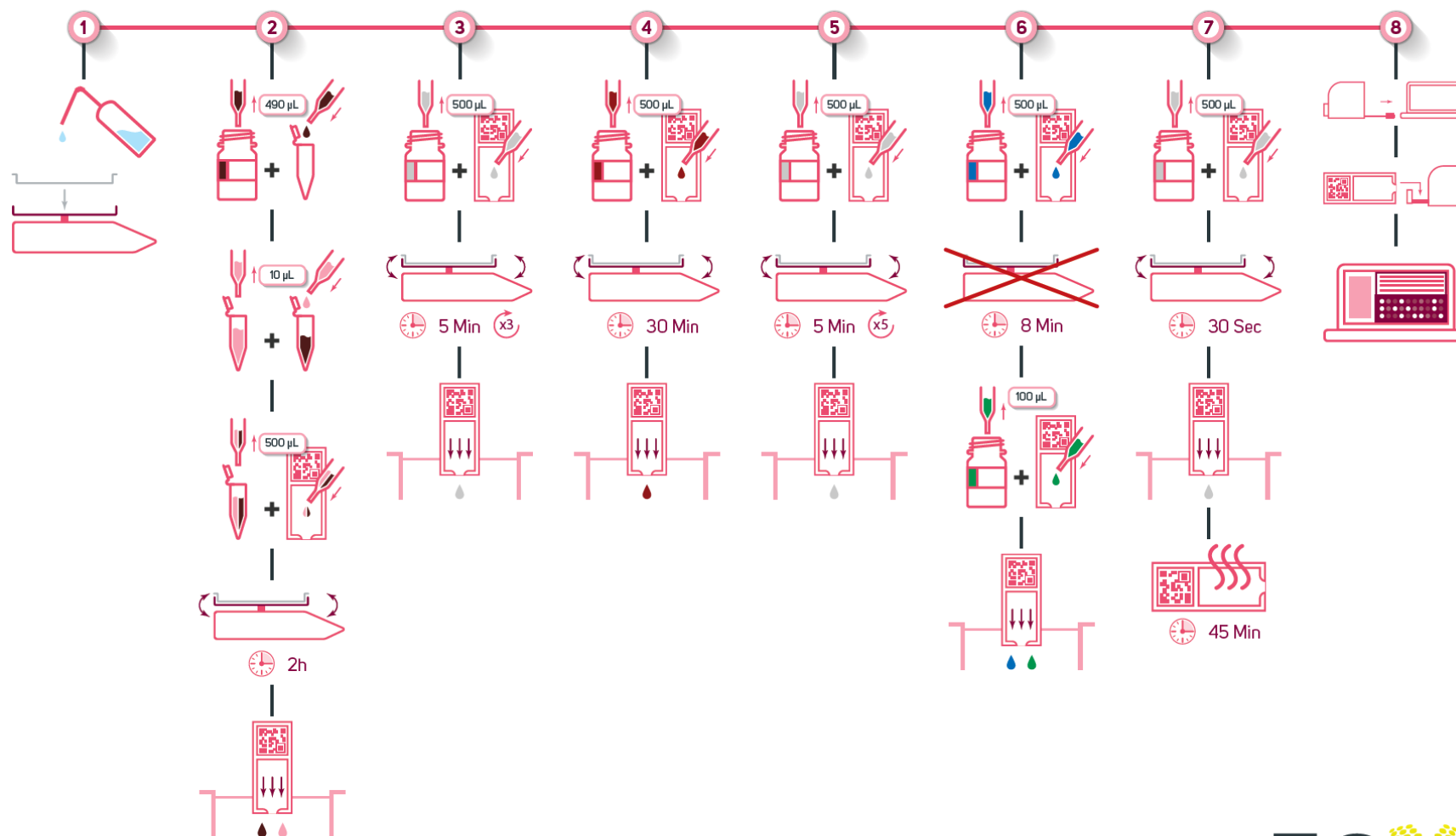
<https://www.madx.com>

Version number: 80-IFU-02-EN-02

Released: 07-2026



Quick Guide



● **FOX** Sample Diluent

● Patient Sample

● **FOX** Washing Solution

● **FOX** Detection Antibody

● **FOX** Substrate Solution

● **FOX** Stop Solution

