March 10th 2021

ALEX^2 Instruction for Use

The Allergy Explorer^2 (ALEX^2) is an in-vitro diagnostic test based on Enzyme-Linked Immunosorbent Assay (ELISA) for the quantitative measurement of allergen specific IgE (sIgE)

INTENDED USE

The Allergy Explorer^2 (ALEX^2) is a quantitative in vitro diagnostic test for the measurement of allergen specific IgE (sIgE) and a semi-quantitative in vitro diagnostic test for the measurement of total IgE (tIgE) in human serum or plasma (exception EDTA-plasma). It is to be used by clinical chemistry laboratories, trained laboratory personnel and medical professionals for the purpose of supporting the clinical diagnosis of IgE mediated diseases, in conjunction with other clinical findings or diagnostic test results.

SUMMARY AND EXPLANATION OF THE TEST

Allergic reactions are immediate type I hypersensitivity reactions and are mediated by antibodies belonging to the IgE class of immunoglobulins. After exposure to specific allergens, IgE–mediated release of histamine and other mediators from mast cells and basophils results in clinical manifestations such as asthma, allergic rhino-conjunctivitis, atopic eczema and gastrointestinal symptoms [1]. Therefore, a detailed sensitization pattern to specific allergens assists in the evaluation of allergic patients [2-6].

All major type I allergen sources are covered by ALEX^2. A complete list of ALEX^2 allergen extracts and molecular allergens can be found at the bottom of this instruction. Link

Important information for the user!

For the correct use of ALEX^2, 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 which is not described in this document or for modifications by the user of the test system. Attention: The calibration function stored in the QR barcodes is optimized for the respective intended use. The kit variant 02-2001-01 of the ALEX^2 test is therefore exclusively intended for manual processing and kit variant 02-5001-01 exclusively for automated processing (MAX 45k).

PRINCIPLE OF THE PROCEDURE

ALEX^2 is an immunoassay test based on Enzyme-Linked Immunosorbent Assay (ELISA). Allergens extracts or molecular allergens, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase forming a macroscopic array. First, the particle bound allergens react with specific IgE that is present in the patient's sample. After incubation, non-specific IgE is washed off. The procedure continues by adding an enzyme labelled anti-human IgE detection antibody which forms a complex with the particle bound specific IgE. After a second washing step, substrate is added which is converted to an insoluble, coloured 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 concentration of specific IgE in the patient sample. The lab test procedure is followed by image acquisition and analysis using the ImageXplorer device. The test results are analysed with MADx's Raptor Analysis Software and reported in IgE response units (kU_A/L). Total IgE results are also reported in IgE response units (kU/L).

SHIPMENT AND STORAGE

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

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

WASTE DISPOSAL

Dispose the used ALEX^2 cartridge and unused kit components with laboratory chemical waste. Follow all national, state, and local regulations regarding disposal.

GLOSSARY OF SYMBOLS

The meaning of the symbols stays the same, regardless of colour.

Warning (GHS pictogram)
Refer to safety data sheet for details

Catalogue number
Indicates the manufacturer's catalogue number so that the medical device can be identified.

Contains sufficient for <n> tests
Indicates the total number of IVD tests that can be performed with the IVD.

Do not use if package is damaged
Indicates a medical device that should not be used if the package has been damaged or opened.

CE mark

Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified.

Consult instructions for use
Indicates the need for the user to consult the instructions for use.

Manufacturer
Indicates the medical device manufacturer, as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.

In vitro diagnostic medical device
Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.

Do not re-use
Indicates a test that is intended for one use, or for use on a single patient during a single procedure.

Temperature limit
Indicates the temperature limits to which the test (reagents) can be safely exposed to.

Use-by date
Indicates the date after which the test (reagents) is not to be used.

Important Note

ALEX^2 KIT COMPONENTS

Each component (reagent) is stable until the date stated on each individual component's label. It is not recommended to pool any reagents from different kit lots. For a list of allergen extracts and molecular allergens immobilized on the ALEX^2 array, please contact support@macroarraydx.com.

ALEX^2 kit components REF 02-2001-01	**Content**	**Properties**
ALEX^2 Cartridge	2 Blisters á 10 ALEX^2 for 20 analyses in total. Calibration via master curve - deposited in barcode of each array.	Ready for use. Store at 2-8°C until expiry date.
ALEX^2 Sample Diluent	1 bottle á 9 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, includes CCD inhibitor.
ALEX^2 Washing Solution	2 bottles á 50 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.
ALEX^2 Detection Antibody	1 bottle á 11 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.
ALEX^2 Substrate Solution	1 bottle á 11 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.
ALEX^2 Stop Solution	1 bottle á 2.4 mL	Ready for use. Store at 2-8°C until expiry date. Allow stop solution 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.

ALEX^2 kit components REF 02-5001-01	**Content**	**Properties**
ALEX^2 Cartridge	5 Blisters á 10 ALEX^2 for 50 analyses in total. Calibration via master curve - deposited in barcode of each array.	Ready for use. Store at 2-8°C until expiry date.
ALEX^2 Sample Diluent	1 bottle á 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, includes CCD inhibitor.
ALEX^2 Washing Solution	4 x conc. 1 bottle á 250 mL	Store at 2-8°C until expiry date. Dilute 1 to 4 with purified water before use. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C.
ALEX^2	1 bottle á 30 mL	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room

Detection Antibody		temperature before use. Opened reagent is stable for 6 months at 2-8°C.
ALEX^2 Substrate Solution	1 bottle á 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.
ALEX^2 Stop Solution	1 bottle á 10 mL	Ready for use. Store at 2-8°C until expiry date. Allow stop solution 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.

REQUIRED EQUIPMENT FOR PROCESSING AND ANALYSING ALEX^2

- Arrayholder (optional)
- Lab Rocker (inclination angle 8°, required speed 8 rpm)
- ImageXplorer or MAX45k analyser (only with REF 02-5001-01)
- Incubation chamber (WxDxH – 35x25x2 cm)
- Raptor analysis software or RAPTOR SERVER software
- PC/Laptop
- For fully automated test procedure with ALEX^2 REF 02-5001-01, a MAX 45k instrument and a PC/Laptop with Internet connection is required

Required equipment, not provided by MADx:

- Purified Water
- Pipettes & tips (100 µL & 1000 µL)

Maintenance services according to manufacturer's instructions.

HANDLING OF ALEX^2 ARRAYS

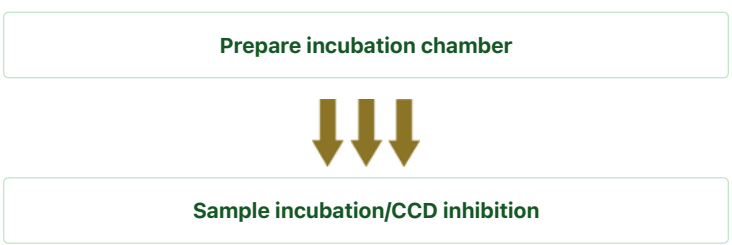
Do not touch the array surface. Any surface defects caused by blunt or sharp objects can interfere with the correct readout of the results. Do not acquire ALEX^2 images before array is completely dry (dry at room temperature).

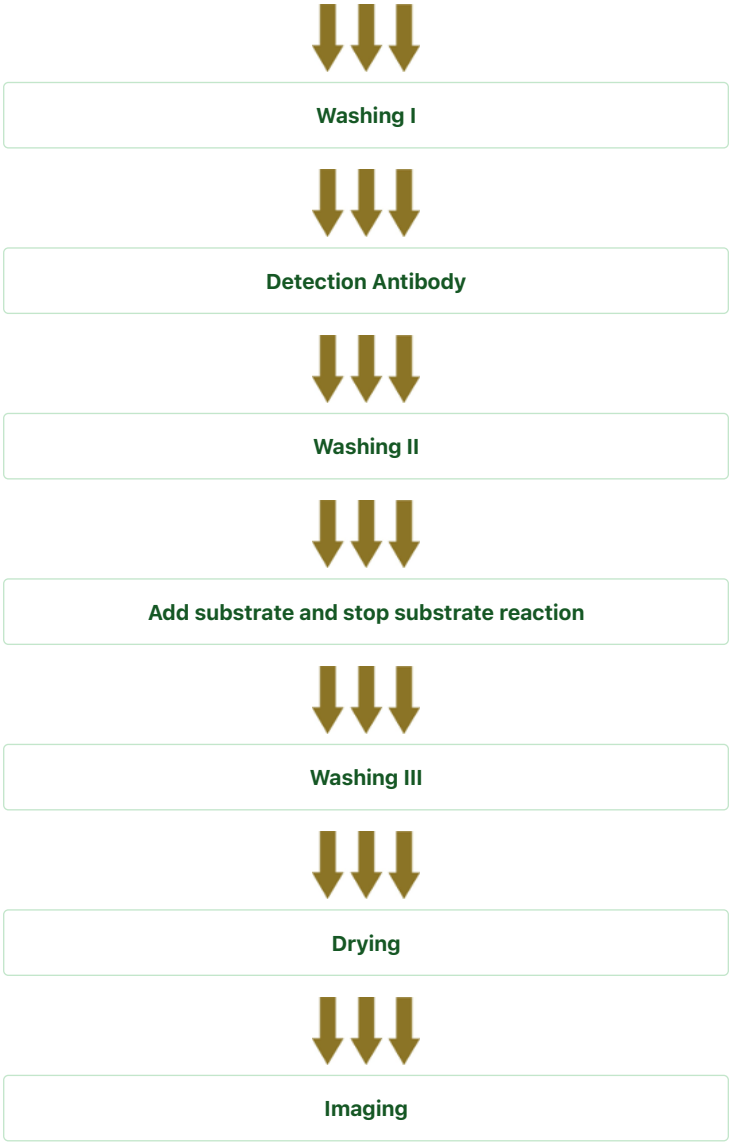
WARNINGS AND PRECAUTIONS

- It is recommended to wear hand and eye protection as well as lab coats and follow good laboratory practices when preparing and handling reagents and samples.
- In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions as Patient samples.
- The 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.
- Sample diluent and washing solution contain sodium azide as a preservative and must be handled with care. Safety data sheet is available upon request.
- ALEX^2 is an ELISA test for in vitro diagnostic use only. Not for internal or external use 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@macroarraydx.com). 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 batches.

ALEX^2 ELISA ASSAY PROCEDURE

Flowchart of ELISA Assay Procedure





Preparation:

Preparation of samples: Serum or plasma (heparin, citrate, no 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 (only for REF 02-5001-01 when used with MAX 45k instrument): Pure the content of 1 vial of Washing Solution intothe washing container of the instrument. Fill destilled water up to the red mark and carefully mix the container several times without generating foam. Store at 2-8°C until expiry date if not in use.

Incubation chamber: Close lid for all assay steps to prevent drop in humidity.

Parameters of Procedure

- 100 µL sample + 400 µL ALEX^2 Sample Diluent
- 500 µL ALEX^2 Detection Antibody
- 500 µL ALEX^2 Substrate Solution
- 100 µL ALEX^2 Stop Solution
- 4500 µL ALEX^2 Washing Solution

Assay time is approximately 3 h 30 min.

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.

ALEX^2 ELISA ASSAY PROCEDURE

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

Prepare incubation chamber

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

1. Sample incubation/CCD inhibition

Take out the needed number of ALEX^2 cartridges and place them into the array holder(s). Add 400 µL of ALEX^2 sample diluent to each cartridge. Add 100 µL patient sample to the cartridges. Ensure that the resulting solution is spread evenly. Place the cartridges onto the lab rocker and start the serum incubation with 8 rpm for 2 hours. Close incubation chamber before starting the lab rocker. After 2 hours, discharge the patient samples into a collection container. Carefully wipe off droplets from the cartridge using a paper towel.

Avoid touching the array surface with the paper towel! Avoid any carry over or cross-contamination of patient samples between individual ALEX^2 cartridges!

Optional or positive Hom s LF (CCD marker): with the standard CCD antibody inhibition protocol (as described in paragraph 2: sample incubation/CCD inhibition) the CCD inhibition efficiency is 85%. If a higher rate of inhibition efficiency is required, prepare a 1 mL sample tube, add 400 µL sample diluent and 100 µL serum. Incubate for 30 minutes (non-shaking) and then proceed with the usual assay procedure.

Note: The extra CCD inhibition step leads in many cases to an inhibition rate for CCD antibodies of above 95%.

1a. Washing I

Add 500 µL ALEX^2 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 of ALEX^2 Detection Antibody to each cartridge.

Make sure that the complete array surface is covered by the ALEX^2 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. Carefully wipe off remaining droplets from the cartridges using a paper towel.

2a. Washing II

Add 500 µL ALEX^2 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 of ALEX^2 Substrate Solution to each cartridge. Start a timer with filling the first cartridge and proceed with the filling of the remaining cartridges. Make sure that the complete array surface is covered by the substrate solution and incubate the arrays for 8 minutes without shaking (lab rocker at 0 rpm and in horizontal position).

After exactly 8 minutes, add 100 µL of the ALEX^2 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. Carefully agitate to evenly distribute the stop solution in the array cartridges, after the stop solution was pipetted onto all arrays. Afterwards discharge substrate/stop solution from the cartridges and wipe off any remaining droplets from the cartridges using a paper towel.

Do NOT SHAKE during substrate incubation!!

4a. Washing III

Add 500 µL ALEX^2 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).

The complete drying is essential for the sensitivity of the test. Only completely dried arrays provide an optimal signal to noise ratio.

Finally, the dried arrays are scanned with the ImageXplorer and analysed with Raptor software (see details in the Raptor software handbook). The Raptor software is only verified in combination with the ImageXplorer instrument, therefore MADx does not take any responsibilities for results, which have been obtained with any other image capture device (like scanners).

Assay Calibration

Systematic variations in signal levels between lots are normalized by heterologous calibration against an IgE reference curve. A curve fit is calculated, and the resulting equation applied to transform arbitrary intensity units into quantitative units. Curve parameters for each lot are adjusted by in-house reference testing against a serum preparation tested on ImmunoCAP (Thermo Fisher Scientific) for specific IgE against several allergens. The ALEX^2 results are therefore indirectly traceable against the WHO reference preparation 11/234 for total IgE. Lot specific calibration parameters are encoded in the barcode. ALEX^2 sIgE test results are expressed as kU_A/L. Total IgE results are semi-quantitative and calculated from an anti-IgE measurement with lot-specific calibration factors encoded in the ALEX^2 barcode.

Measuring Range

Specific IgE: 0.3-50 kU_A/L quantitative
Total IgE: 20-2500 kU/L semi-quantitative

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.

DATA ANALYSIS

For the image analysis of processed arrays, the ImageXplorer is to be used. ALEX^2 images are automatically analysed using MADx's Raptor analysis software and a report is generated summarising the results for the user.

RESULTS

ALEX^2 is a quantitative ELISA test for specific IgE and semi-quantitative method for total IgE. Allergen specific IgE antibodies are expressed as IgE response units (kU_A/L), total IgE results as kU/L. MADx's Raptor analysis software automatically calculates and reports sIgE results (quantitatively) and tIgE results (semi- quantitatively).

LIMITATIONS OF THE PROCEDURE

A definitive clinical diagnosis should only be made in conjunction with all available clinical findings by medical professionals and shall not be based on results of a single diagnostic method only.

In certain areas of application (e.g. food allergy), circulating IgE antibodies may remain undetectable although a clinical manifestation of food allergy against a certain allergen may be present, because these antibodies may be specific to allergens that are modified during industrial processing, cooking or digestion and hence do not exist in the original food for which the patient is tested.

Negative venom results only indicate undetectable levels of venom specific IgE antibodies (e.g. due to long term non-exposure) and do not preclude the existence of clinical hypersensitivity to insect stings.

EXPECTED VALUES

The close association between allergen specific IgE antibody levels and allergic disease is well known and is described thoroughly in literature [1]. Each sensitized patient will show an individual IgE profile when tested with ALEX^2. The IgE response with samples from healthy non-allergic individuals will be below 0.3 kU_A/L for single molecular allergens and for allergen extracts when tested with ALEX^2. Good laboratory practice recommends that each laboratory establishes its own range of expected values.

PERFORMANCE CHARACTERISTICS

Precision (lot-lot variation)

The lot-to-lot variation was determined on 3 cartridge lots in three sperate runs. Multi-sensitized samples were included in the study. The study comprised 319 allergen per sample combinations covering 191 individual allergens at 3 different levels (> 10 kU_A/L, 1-10 kU_A/L and 0.3-1 kU_A/L [7].

Concentration - kU_A/L	Intra CV%	Inter CV%	Total CV%
≥0.3 - <1.0	18.4	26.1	24.7
≥1 - <10	11.6	12.7	12.1
≥10	8.7	10.3	9.6
≥1	10.7	12.0	11.3

Repeatability (within-run precision)

In the repeatability study, multi-sensitized samples were tested 10 times by the same operator on different days. The study comprised 319 allergen per sample combinations covering 165 individual allergens at 3 different levels (>10 kU_A/L, 1-10 kU_A/L and 0.3 - 1 kU_A/L) [7].

Concentration - kU_A/L	Total CV%
≥0.3 - <1.0	25.6
≥1 - <10	13.8
≥10	10.7
≥1	13.5

Analytical Sensitivity

The Limit of Detection was determined in accordance with CLSI guideline EP17-A [8] for representative allergen components and was below 0.3 kU_A/L for all allergen components and all allergen extracts.

Analytical Specificity

There is no detectable cross-reactivity with other human Immunoglobulins (IgA, IgG1, IgG2, IgG3, IgG4 and IgM) at normal physiological concentrations.

Interference

There is no detectable interference with bilirubin, cholesterol/triglycerides and haemoglobin at normal physiological concentrations.

Neither is there an interference with tIgE which was tested in concentrations of up to 3000 kU/L.

WARRANTY

The herein presented performance data were obtained using the procedure outlined in this Instructions for Use. Any change or modification in 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 authorized distributors shall not be liable for damages indirect or consequential in such an event.

Allergen list ALEX^2

Allergen extracts: Aca m, Aca s, Ach d, Ail a, All c, All s, Ama r, Amb a, Ana o, Api m, Art v, Ave s, Ber e, Bos d meat, Bos d milk, Bro p, Cam d, Can f ♂ urine, Can s, Cap a, Cap h epithelia, Cap h milk, Car c, Car i, Car p, Che a, Che q, Chi spp., Cic a, Cit s, Cla h, Clu h, Cor a pollen, Cuc p, Cup s, Cyn d, Dau c, Dol spp., Ecu c milk, Equ c meat, Fag e, Fic c, Fic b, Fra e, Gad m, Gal d meat, Gal d white, Gal d yolk, Hel a, Hom g, Hor v, Jug r, Jun a, Len c, Lit s, Loc m, Lol spp., Lup a, Mac i, Man i, Mel g, Mor r, Mus a, Myt e, Ori v, Ory meat, Ory s, Ost e, Ovi a epithelia, Ovi a meat, Ovi a milk, Pan b, Pan m, Pap s, Par j, Pas n, Pec spp., Pen ch, Per a, Pers a, Pet c, Pha v, Phr c, Pim a, Pis s, Pla l, Pol d, Pop n, Pru du, Pru av, Pyr c, Raj c, Rat n, Rud spp., Sac c, Sal k, Sal s, Sco s, Sec c flour, Sec c pollen, Ses i, Sin, Sol spp., Sola l, Sol t, Sus d epithel, Sus d meat, Ten m, Thu a, Tri fo, Tri s, Tyr p, Ulm c, Urt d, Vac m, Ves v, Zea m flour

Purified natural components: nAct d 1, nAct d 10, nAct d 2, nAct d 5, nApi m 1, nAra h 1, nAra h 3, nBos d 4, nBos d 5, nBos d 6, nBos d 8, nCan f 3, nCor a 11, nCor a 9, nCup a 1, nEqu c 3, nFag e 2, nFel d 2, nGad m 1, nGad m 2 + 3, nGal d 1, nGal d 2, nGal d 3, nGal d 4, nGal d 5, nGly m 6, nGly m 5, nJug r 1, nJug r 2, nJug r 4, nJug r 6, nMac i 2S Albumin, nMal d 2, nOle e 1, nPap s 2S Albumin, nPis v 2, nPis v 3, nPla a 2, nSes i 1, nTri a aA_TI

Recombinant components: rAln g 1, rAln g 4, rAlt a 1, rAlt a 6, rAmb a 1, rAmb a 4, rAna o 2, rAna o 3, rAni s 1, rAni s 3, rApi g 1, rApi g 2, rApi g 6, rApi m 10, rAra h 2, rAra h 6, rAra h 8, rAra h 9, rAra h 15, rArg r 1, rArt v 1.0101, rArt v 3.0201, rAsp f 1, rAsp f 3, rAsp f 4, rAsp f 6, rBer e 1, rBet v 1, rBet v 2, rBet v 6, rBla g 1, rBla g 2, rBla g 4, rBla g 5, rBla g 9, rBlo t 10, rBlo t 21, rBlo t 5, rBos d 2, rCan f 1, rCan f 2, rCan f 4, rCan f 6, rCan f Fel d 1 like, rCan s 3, rCav p 1, rChe a 1, rCla h 8, rClu h 1, rCor a 1.0103, rCor a 1.0401, rCor a 8, rCor a 12 (RUO), rCor a 14, rCra c 6, rCry j 1, rCuc m 2, rCyn d 1, rCyp c 1, rDau c 1, rDer f 1, rDer f 2, rDer p 1, rDer p 10, rDer p 11, rDer p 2, rDer p 20, rDer p 21, rDer p 23, rDer p 5, rDer p 7, rEqu c 1, rEqu c 4, rFag s 1, rFel d 1, rFel d 4, rFel d 7, rFra a 1 + 3, rFra e 1, rGly d 2, rGly m 4, rGly m 8, rHev b 1, rHev b 3, rHev b 5, rHev b 6.02, rHev b 8, rHev b 11, rHom s LF, rJug r 3, rLep d 2, rLol p 1, rMal d 1, rMal d 3, rMala s 11, rMala s 5, rMala s 6, rMer a 1, rMes a 1 (RUO), rMus m 1, rOle e 7 (RUO), rOle e 9, rOry c 1, rOry c 2, rOry c 3, rPar j 2, rPen m 1, rPen m 2, rPen m 3, rPen m 4, rPer a 7, rPhl p 1, rPhl p 12, rPhl p 2, rPhl p 5.0101, rPhl p 6, rPhl p 7, rPho d 2, rPhod s 1, rPis v 1, rPis v 4 (RUO), rPla a 1, rPla a 3, rPla l 1, rPol d 5, rPru p 3, rPru p 7 (RUO), rRaj c Parvalbumin, rSal k 1, rSal s 1, rSco s 1, rSin a 1, rSola l 6, rSus d 1, rThu a 1, rTri a 14, rTri a 19, rTyr p 2, rVes v 1, rVes v 5, rXip g 1, rVit v 1, rZea m 14

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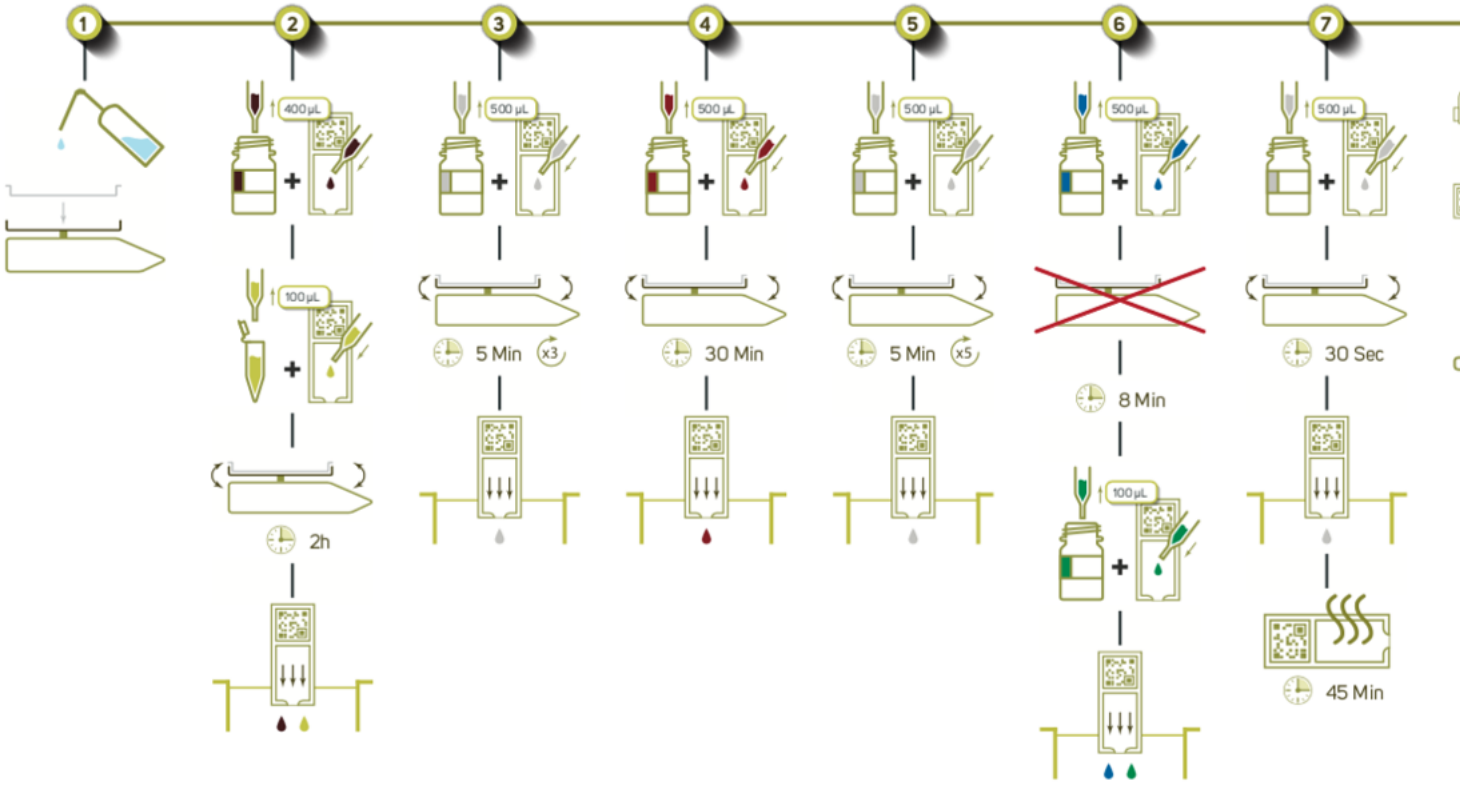
Quick Guide



- **ALEX²** Sample Diluent
- Patient Sample
- **ALEX²** Washing Solution
- **ALEX²** Detection Antibody
- **ALEX²** Substrate Solution
- **ALEX²** Stop Solution