Clinical diagnostic of allergy diseases



AllergyScreen® AlleisaScreen®



MEDIWISS Analytic GmbH



Content

How allergies work AllergyScreen®/AlleisaScreen®

- Development
- Advantages
- Test principles
- Usage
- Directory of available allergens Professional production Improvio Family CubeScreen Reader Beeblot 12 and Beeblot 36 Comparative studies



12

14

24

How allergies work

Allergy is the fifth leading chronic disease in the U.S. and the third most common chronic disease among children under 18 years old.



- T-lymphocytes recognize the foreign substances in the body and release chemical cytokines that stimulate the B-lymphocytes
- B-lymphocytes produce immunoglobulin E (IgE) to destroy the substance
- TH1 and TH2 combat the foreign substances
- Mast cells and basophiles (white blood cells) produce mediator chemicals such as histamine and leukotriene

The role of IgE

Class E immunoglobulin (IgE) was first identified in 1964 and plays an important role in Type I allergic reactions. Everyone has IgE antibodies in small amounts to protect the body from parasites. However, allergic persons produce IgE in abnormally elevated quantities. When stimulated by the appropriate foreign allergen, helper and suppresser cells (sub classes of the T-lymphocytes) stimulate B-lymphocytes to transform into Plasma-cells. Plasma-cells secrete antibodies of various classes which circulate in the blood and are responsible for immunity in the humours. If this regulation fails, a B-lymphocyte can also be converted by a normally harmless antigen. These immunoglobulins migrate via the blood stream to the basophiles and mast cells where they are bound to specific receptors within their Fc region. If the organism has further contact with the specific allergen, it migrates directly to the anchored IgE and links two neighbouring molecules with epitopes via the antigen-binding Fc region. This link formation liberates different vasoactive amines from the mast cells, which together with other highly active mediators can lead to the typical symptoms of a Type | allergic reaction.

The most common allergic conditions include hay fever (allergic rhinitis), asthma, allergic conjunctivitis, allergic eczema, hives (urticaria) and allergic shock (also anaphylaxis and anaphylactic shock).

Common allergy triggers

Airborne allergens: pollen, animal dander, mites and mold

Often pet allergies are triggered by exposure to proteins found in animal skin cells, saliva or urine and are commonly associated with cats, dogs, horses and rodents. Inhaling mold spores can also cause an allergy with incidents typically reported between July and late summer. The most common triggers are Alternaria, Cladosporium, Aspergillus, Penicillium, Mucor and Rhizopus. A wide variety of tree, grass and weed pollen cause an allergic reaction, the intensity of which is influenced by pollen seasons, location, weather and other environmental factors.

📕 Foods

For adults, the most common triggers of food allergies include shellfish, peanuts, tree nuts, fish and eggs, whereas young children tend to experience allergies to eggs, milk and peanuts. Food intolerance is often confused with food allergy as they share similar symptoms.



Insect venoms

Insect stings inject chemicals into the body which can cause allergic reactions, in most cases resulting from stings/bites from bees, wasps and fire ants. Mosquitos, flies and fleas can cause milder reactions.

Latex

Repeated or prolonged exposure to latex is one of the most common causes of allergic contact dermatitis. Normally harmless, latex is a natural rubber used in a wide range of items: medical supplies (such as gloves and catheters), balloons, children's toys or shoe soles.

Medication

Some people develop allergies to certain medications, the most common of which include penicillin and related antibiotics. Reactions range from mild localized rashes or hives to life-threatening severe allergic reaction (anaphylaxis).

Changing the testing paradigm

AllergyScreen[®]/AlleisaScreen[®]



Allergy diagnostics and the identification of a sensitization against allergens is an interdisciplinary challenge that incorporates knowledge gained through medical science, biochemistry and biology.

Long years of experience and work done with single test systems in allergological labs have shown that only a few key allergens are responsible for the patient's disorders. And so, a question emerged: Why not collect all these key allergens and combine them in one single reaction trough?

AllergyScreen[®]: Quick and efficient testing of up to 20 allergens per strip

Mediwiss Analytic has vast experience in the extraction of allergens from raw material and extensive know-how of western blot protein analysis. This led to the idea of binding high quality, self-extracted, lyophilised allergens to a nitrocellulose membrane with the help of a contact plot printer.

The required antibody and substrate for the visualization of the specific IgE/allergen reaction were available and well known from western blot analysis. It was only necessary to develop a plastic reaction trough in which the membrane strips could be glued. This resulted in a ready-to-use test for the determination of specific IgE in human serum. The original contact plot printer used pencils filled with a special protein solution. New sophisticated equipment was developed featuring up to 21 micro dispensing pumps which can be individually programmed according to variable and individual parameters with minimal divergence.

Supportive hardware and software systems were also developed for a camera that photographs the membrane and allows a semi-quantitative analysis of the results: Initially, up to 20 allergens could be measured per membrane.

AlleisaScreen[®]: Precise testing of up to 30 flexible allergens in a single procedure

The wish for more allergen lines on a single membrane surface led to AlleisaScreen®, a bigger biochip with a maximum capability of 30 allergens on one test strip that is glued in a ready-to-use reaction trough. The fact that these new biochips required a higher camera resolution resulted in the development of a new analysis system.

What started as a simple qualitative visual test strip has been developed into a highly innovative, semiquantitative nitrocellulose chip system for the determination of specific IgE, IgG4 and IgG in human serum with customized, high resolution scanner systems.

Clear advantage over single determination tests AllergyScreen[®]/AlleisaScreen[®]



AllergyScreen[®] and AlleisaScreen[®] are two test systems to detect allergen-specific immmunoglobulins in human serum. Customers can be provided with the necessary test strips and the corresponding hard and software (camera, scanner, testing equipment, robotics).

Testing multiple allergens offers a more detailed and extensive analysis

It is extremely important for allergic persons to identify their sensitizations in order to establish an appropriate life plan - even when, from a clinical point of view, not all of these sensitizations are current. Labs can either use single or multiple allergens for the determination of allergic sensitization. In both cases the allergens are extracted in the same way. Single allergen test systems usually test only allergens based on the patient's complaints and clinical history. By contrast, test membranes with multiple allergens make it possible to test different allergen groups, thereby determining sensitization with no clinical currency at the time of the test. Since most sensitizations are cross-reactive, key allergens in particular are always present. One trough with several key allergens allows for a rapid detection of all possible antigens in a single lab test. This type of approach is naturally cheaper than single tests, uses less lab materials and less patient's serum. The use of allergen specific test strips with multiple food allergens or test panels with multiple respiratory allergens also lead to a more detailed and extensive patient analysis,

AllergyScreen



AllergyScreen®

This immunoblot test combined with our evaluation software enables:

- Easy test procedure
- Quick testing and evaluation in just 2.5 hours
- Flexible, customized and country-specific panels
- Testing of 20 allergens per strip with only 250 µl serum

AlleisaScreen[®]

This test offers you all the advantages of our well established AllergyScreen® test, as well as:

- Testing of 30 allergens per strip with only 300 µl serum
- The best price-allergen ratio of all screening systems in allergy diagnostics on the market

Mediwiss Analytic produces its own antigens/allergens and optimizes them for use on the test strips.



Precise testing methods

AllergyScreen[®]/AlleisaScreen[®]

Overview of the AllergyScreen®/AlleisaScreen® processes

- (1) Different allergens are bound to a nitrocellulose membrane as lines.
- (2) Specific IgE antibodies of the patient serum bind to their respective allergen.
- (3) The biotinylated detector antibody, an anti-IgE antibody, binds to the specific IgE antibodies.
- (4) The alkaline phosphatase binds via its streptavidin tag to the biotin group of the detector antibody.
- (5) The colorless substrate (BCIP/NBT) is modified enzymatically, resulting in a blue precipitate.





- Substrate (BICIP/NBT) before enzymatic reaction
- Substrate (BICIP/NBT)
 after enzymatic reaction

Key test principles

The AllergyScreen® and the AlleisaScreen® systems are semi-quantitative in vitro systems to determine the presence of allergen-specific IgE antibodies in human serum. A blood sample from the patient is necessary for this test. Liquid allergens, produced for in vitro diagnostic purposes, are passively bound as test lines to a nitrocellulose membrane and the membrane strips are glued into the reaction troughs. Customers can select up to 20 allergens using AllergyScreen® and up to 30 different allergens using AlleisaScreen®.

Test principles

1. Different allergens are bound as test lines to the surface of a nitrocellulose membrane.

2. To determine allergen-specific IgE antibodies, patients sera (250 µl for AllergyScreen® and 300 µl for AlleisaScreen®) is pipetted into the reaction trough and incubated for 45 minutes at room temperature. During this time the allergen-specific IgE antibodies bind to the specific allergens on the membrane. Nonbound IgE antibodies are removed by washing.

3. In a next step, polyclonal anti-human IgE antibody (AllergyScreen®) or a mix of a monoclonal and a polyclonal anti-human IgE antibody (AlleisaScreen®) is pipetted into the reaction trough and incubated for another 45 minutes at room temperature. These biotin coupled detector antibodies bind to the allergen-specific IgE from the patient serum. Nonbound detector antibodies are removed by washing. 4 The membrane is then incubated with a streptavidin tagged alkaline phosphatase (streptavidin-conjugate) for 20 minutes at room temperature. The streptavidin tag binds to the biotin of the detector antibody. Nonbound streptavidin-conjugate is removed by washing.

5. Now the substrate (color solution) is added to the membrane and incubated at room temperature for 20 minutes. An enzymatic reaction of the alkaline phosphatase takes place, resulting in a blue band on the respective allergen line. The reaction is stopped by washing. The coloration is directly proportional to the amount of the specific antibody in the serum sample.

6. After thoroughly drying the membrane, an evaluation of the coloration of the allergen lines is carried out by one of our systems: Improvio scanners, CubeScreen Reader or RapidReader. The concentration of specific IgE in the serum sample is determined and results are given in classes (from 0 to 6) and iU/ml (range 0 to > 100 iU/ml).

Simplicity combined with quick, concise results AllergyScreen[®]/AlleisaScreen[®]



You will need: A washing bottle, a graduated cylinder, a ScreenShaker, a comb (trough holder), an incubation box, a 100 µl – 1000 µl pipette, a timer and some gloves.

Precautions: Sera and all solutions must be at ambient temperature (20°C-22°C). Dilute the washing buffer concentrate (1:25).





(2) Pipette 250 µl serum (AllergyScreen®) or 300 µl serum (AlleisaScreen®)

into the troughs, taking care that the membranes are completely covered.

Carefully slide the comb into the incubation box. Place the incubation box

onto the ScreenShaker. Incubate for 45 minutes at ambient temperature.





(3) Carefully take the comb out of the box. Remove the sera by rinsing the troughs with the washing buffer. Rinse each membrane five times, thereby shake the washing buffer in the troughs for some seconds. Remove the surplus by gently tapping the comb on paper towels.



(4) Pipette 250 µl (AllergyScreen®) or 300 µl (AlleisaScreen®) detection antibody in each trough. Slide the comb into the incubation box and incubate for another 45 minutes on the ScreenShaker at ambient temperature.



(5) Wash the membranes as described in step (3).



ScreenShaker.





20 minutes at ambient temperature on the incubation shaker.



stay purple.





(6) Pipette 250 µl (AllergyScreen®) or 300 µl (AlleisaScreen®) of the streptavidin conjugate into each reaction trough. Replace the comb into the incubation box and incubate for exactly 20 minutes on the

(7) Wash the membranes as described in step (3), but this time rinse each membrane 10 times.

(8) Pipette 250 µl (AllergyScreen®) or 300 µl (AlleisaScreen®) of the substrate into each reaction trough. Slide the comb into the incubation box and replace it on the ScreenShaker. Incubate for exactly

(9) Rinse each membrane several times under running water. Remove the washing buffer by gently tapping the trough on a paper towel. Leave the membranes to air dry or use a conventional hair dryer. The background of the membranes will turn white, while the control line and positive tested allergens will



Mediwiss Analytics provides our customers worldwide with a wide range of allergens and allergen mixtures for diagnostic testing. In order to obtain exceptional results, our own allergens are manufactured from certificated raw materials to gain the highest quality standards. The allergens are controlled at every stage of production.

Standard and highly customized allergen-specific panels are available for the testing of multiple allergen combinations. Three samples of customized panels are provided at the end of this directory.

If you have any questions about our allergens or about how we support our customers with specific allergen combinations, please contact us.

Sample panels

Multiple combinations of allergens Worldwide customized panels

Panel CHN Multi (20 allergen Control	
Derm. pteronyssinus (d1)	
House dust (h1)	_
Mulberry (t70)	-
Cat (e1)	
Dog (e5)	_
Cockroach (i6)	
Pigweed (w14)	
Egg white (f1)	
Milk (f2)	
Shrimp (f24)	
Beef (f27)	
Mussel (f37)	
Crab (f23)	
Mango (f91)	
Cashew nut (f202)	
Pineapple (f210)	
Mould fungi mixture (mx3)	
Weed mixture CHN (wxCHN)	
Tree mixture CHN (txCHN)	
Total IgE	

Panel 30 Peru Pedi (30 allerge
Control
Grass mix (gx)
Birch (t3)
Mugwort (w6)
Derm. pteronyssinus (d1)
Derm. farinae (d2)
Cat (e1)
Dog (e5)
Horse (e3)
Cladosporium herbarum (m2)
Aspergillus fumigatus (m3)
Egg white (f1)
Egg yolk (f75)
Cow's milk (f2)
Codfish (f3)
a-Lactalbumin (f76)
B-Lactoglobulin (f77)
Casein (f78)
BSA (e204)
Wheat flour (f4)
Rice (f9)
Soy bean (f14)
Peanut (f13)
Hazelnut (f17)
Carrot (f31)
Potato (f35)
Apple (f49)
Bromelain (CCD1)
Horseradish Peroxidase (CCD2)
Ascorbat Oxidase (CCD3)

30 allergens)

um (m2) (m3)

Panel 12 RUS (12 allergens) Control



Food:

Food	A-B	
f498	Agar-Agar	
f20	Almond	
F76	Alpha-Lactalbumin	
f100	Amaranth Flour	
f313	Anchovy	
F449	Angler	
f271	Anise	
f49	Apple	
f237	Apricot	
f230	Argan Tree Seeds	
f445	Artichoke	
f261	Asparagus	
f448	Atlantic Jackknife Clam	
f262	Aubergine	
f96	Avocado	
f 92	Banana	
f6	Barley Flour	
f269	Basil	
f27	Beef	
f224	Beet	
f319	Beetroot	
f77	Beta-Lactoglobulin	
f467	Black Seabream	
f211	Blackberry	
288	Blueberry	- 1
f490	Bonito	
f18	Brasilnut	
f483	Brie	
f500	Broad Beans	
f260	Broccoli	
f217	Brussels Sprouts	
f11	Buckwheat	

_	Doctoriou
Food	С
f216	Cabbage
f93	Cacao
f480	Camembert
f462	Camomile
F187	Cantaloupe
f31	Carrot
f78	Casein
f202	Cashewnut
f291	Cauliflower
f470	Caviar
f85	Celery
f440	Chard
f494	Cheddar
F400	Cheese
f242	Cherry
f83	Chicken
_f309	Chickpea
f443	Chicory
f497	Cinnamon
f268	Clove
f450	Cockle
f36	Coconut
f3	Codfish
f221	Coffee
f317	Coriander
f8	Corn Flour
444	Courgette

{ 454	Cous-Cous
f23	Crab
f244	Cucumber
f485	Cumin
f281	Curry
F447	Cuttlefish

Food	D - G
f289	Date
f277	Dill
f475	Duck
f508	Edam Cheese
f1	Egg White
f75	Egg Yolk
f496	Emmental Cheese
f477	Endive
f276	Fennel
f328	Fig
f333	Flaxseed
f442	Gardencress
f47	Garlic
f270	Ginger
f499	Ginseng
f79	Gluten
f300	Goat Milk
f504	Goose
f506	Gooseberry
f482	Gorgonzola
F492	Gouda
1259	Grape
f209	Grapefruit
f315	Green Bean
f509	Groundnut
f410	Grouper
f463	Guinea Fowl
Food	H-L
1170	1 1 1 1 1

f178	Haddock
f307	Hake
 f17	Hazelnut
 f205	Herring
f247	Honey
f324	Hops
f321	Horse Meat
f473	Iridescent Shark
f453	Kamut
 f505	Kangaroo
f487	Kefir
 f287	Kidney Beans
f84	Kiwi
f459	Kumquats
f334	Lactoferrin

f88 Lamb f278 Laurel

f484 Leek

f208 Lemon f464 Lemongrass f235 Lentil

f215 Lettuce f472 Licorice f306 Lime f80 Lobster

f275 Lovage

f348 Lychee

Food	_ M	
f345	Macadamia	
f206	Mackerel	
495	Manchego	
f302	Mandarin	
91	Mango	
489	Mascarpone	
f87	Melon	
2	Milk	
2MP	Milk, powdered	
457	Mixed Mushrooms	
401	Mozzarella	
491	Mulberry	
212	Mushroom	
37	Mussel	
89	Mustard	

-		
Food	N - 0	

f486	Nectarine	
F469	Northern Pike	
f282	Nutmeg	
f7	Oat Flour	
f59	Octopus	
f458	Olive	
f48	Onion	
f33	Orange	
f283	Oregano	
f466	Ostrich	
f290	Oyster	

ood	P -	

1293	Рарауа
f218	Paprika
f493	Parmesan Cheese
f86	Parsley
f294	Passion Fruit
f12	Pea
f95	Peach
f13	Peanut
f94	Pear
f201	Pecan
f263	Pepper, green
f332	Peppermint
f503	Pheasant
f460	Physalis
f210	Pineapple
f253	Pinenut
f203	Pistachio
f254	Plaice
f255	Plum
f452	Pomegranate
f26	Pork
f502	Pork Liver
f35	Potato
f501	Poultry Liver
f507	Prickly Pear
1225	Pumpkin
226	Pumpkin Seed
f465	Quail
f347	Quinoa

adish aisin ape Seed aspberry ed Cabbage ed Currant ice
ape Seed aspberry ed Cabbage ed Currant
aspberry ed Cabbage ed Currant
ed Cabbage ed Currant
ed Currant
ice
icotta
ocket
oquefort
osemary
unner Beans
ye Flour

Food R

Food	S
f344	Sage
1476	Salicornia
f41	Salmon
f160	Sardine
f10	Sesame
F479	Sheep's Milk Cheese
f24	Shrimps
f314	Snail
f82	Soft-Cheese Mix
f337	Sole, Common
f14	Soy Beans
f4d	Spelt Flour
f214	Spinach
f451	Spring Onion
f258	Squid
F44	Strawberry
f114	Sunflower Seed
f299	Sweet Chestnut
f54	Sweet Potato
f312	Sword Fish

Food	T - Y	
1272	Tarragon	
f273	Thyme	
f478	Tofu	
f25	Tomato	
f204	Trout	
f40	Tunafish	
f510	Turbot	
f284	Turkey	
f234	Vanilla	
f474	Veal	
f207	Venus Shell	
f2.56	Walnut	
f329	Watermelon	
f4	Wheat Flour	
236	Whey	
236	Whey	
15	White Beans	
f228	Wild Pig	
f468	Wolffish	
f45	Yeast	

Non-Food:

Carbo	hydrate
CCD :	3 Ascorbate Oxidase
CCD	l Bromelain
CCD 2	2 Horseradish Peroxidas

_			
derma	c/A	nim al	Ducks
uerma	IS/A	nimat	Prote

Epide	rmals/Animal Protein
e204	Albumin BSA
e77	Budgerigar Droppings
e78	Budgerigar Feathers
e79	Budgerigar Serum
e17	Camel Epithelium
e300	Canary Droppings
e201	Canary Feathers
e401	Canary Serum
el	Cat Epithelium
e20	Chicken Droppings
e85	Chicken Feathers
e304	Chicken Serum
e301	Cockatiel Droppings
e95	Cockatiel Feathers
e92	Cockatiel Serum
e4	Cow Epithelium
e4 e2	Dog Dander
e2 e5	Dog Epithelium
e100	
e100 e86	Duck Droppings Duck Feathers
	Duck Feathers Duck Serum
e108	
e19	Goose Droppings
e70	Goose Feathers
e90	Goose Serum
e6	Guinea Pig Epithelium
e99	Guinea Pig Urine
e84	Hamster Epithelium
e3	Horse Epithelium
e71	Mouse Epithelium
e76	Mouse Serum
e72	Mouse Urine
e303	Parrot Droppings
e213	Parrot Feathers
e16	Parrot Serum
e215	Pigeon Droppings
ell	Pigeon Feathers
e91	Pigeon Serum
e82	Rabbit Epithelium
e211	Rabbit Urine
e73	Rat Epithelium
e75	Rat Serum
e74	Rat Urine
e81	Sheep Epithelium
	D //
	Pollen
g201	Barley
g90	Bentgrass, creeping
g2	Bermuda Grass
g202	Corn
g8	Kentucky Bluegrass

g4	Meadow Fescue
g16	Meadow Foxtail
g14	Oat
g3	Orchard Grass
g21	Quitch
g9	Redtop
g7	Reed
g12	Rye
g5	Ryegrass
g11	Smooth Brome
g10	Sweet Sorghum
gl	Sweet Vernal Grass
g71	Tall Oat Grass
g6	Timothy Grass
g13	Velvet Grass
g15	Wheat Pollen

Місго	organism
m6	Alternaria

m6	Alternaria alternata
m40	Asp. amstelodami
m47	Aspergillus flavus
m3	Aspergillus fumigatus
m30	Aspergillus nidulans
m207	Aspergillus niger
m29	Aspergillus repens
m36	Aspergillus terreus
m19	Aspergillus versicolor
m7	Botrytis cinerea
m5	Candida albicans
m208	Chaetomium globosum
m2	Cladosporium
m17	Curvularia spicifera
m14	Epicoccum purpura.
m9	Fusarium moniliforme
m212	Micropolyspora faeni
m4	Mucor mucedo
m23	Neurospora sitophila
m54	Penicillium chrysog.
m196	Penicillium notatum
m31	Penicillium viridicatum
m90	Pityrosporum ovale
m12	Pullularia pullulans
m11	Rhizopus nigricans
m210	Sporobolomyces
m80	Staph. Enterotox A
m81	Staph. Enterotox B
m226	Staph. TSS Tox. 1
m10	Stemphylium bot.
m213	Thermoactinomyces
m300	Wallemia sebi

Miscel	laneous/Parasites
01	Cotton
0207	Daphnia
O203	Fish Food TetraMin
D20	Grassland Cut
O21	Hayfield Cut
p4	Anisakis simplex

Mite d70	Acarus siro
d202	Blomia tjibodas
d201	Blomia tropicalis
d300	Cheyletus eruditus
d206	Chortoglyphus arcuatus
d2	Derm. farinae
d3	Derm. microceras
d1	Derm. pteronyssinus
dm 1	Environmental Mix
d74	Euroglyphus maynei
d75	Euroglyphus longior
d77	Glycophagus genic.
hx	House Dust
d71	Lepidoglyphus dest.
d76	Tyrophagus entomoph.
d72	Tyrophagus putrescent.

Occup	ational
k87	Alpha-Amylase
k214	Beech Wood
k220	Fir Tree Wood
k82	Latex
k217	Limba Wood
k218	Maranti Wood
k219	Mohogany Wood
k213	Oak Wood
k212	Obeche Wood
k216	Pine Wood
k74	Silk
k215	Spruce Wood

Tree F	
t35	Acacia
t2	Alder
t15	Ash Tree
t5	Beech
t3	Birch
†78	Black Locust
t17	Cedar
t203	Chestnut
125	Cypresst
214	Datepalm
t205	Elder
t8	Elm Tree
t18	Eucalyptus
t4	Hazel
t6	Juniper
t208	Linden Tree
t1	Maple
t20	Mesquite Tree
t70	Mulberry Tree
t7	Oak
t9	Olive Tree
t77	Paper Mulberry Tree
t16	Pine
111	Plane
t14	Poplar

t210	Privet
t201	Spruce
t10	Walnut Pollen
t12	Willow
	-
Weed	
w5	Absinthe
w1	Ambrosia elatior, Ragweed
w2	A. psilostachys, Ragweed
w3	A. trifida, Ragweed
w206	Camomile
w7	Ox-Eye Daisy
w13	Cocklebur
w33	Dahlia
w8	Dandelion
w17	Firebush
w12	Goldenrod
w22	Hops
w17	Kochia
w10	Lambs Quarter
w15	Lens-Scale
w41	Lucerne
w16	Marshelder
w6	Mugwort
w20	Nettle
w21	Pellitory
w14	Pigweed
w9	Plantain
w203	Rape
w11	Russian Thistle
w18	Sorrel
w204	Sunflower

Venon	ns & Insects
i52	Aedes ssp.
i1	Bee Venum
i53	Black Fly
i73	Bloodworm
i10	Bumble Bee Venom
i21	Cat Flea
i6	Cockroach, B.germanica
i6OR	Cockroach, B.orientalis
i6PE	Cockroach, Periplaneta
i50	Culex ssp.
i21	Dorypterix domestica
i22	Dorypterix longipennis
i9	Flour Beetle
190	Fly (Musca)
120	Liposcelis bostrichophila
i50	Mosquito
i70	Red Fire Ant Venum
i51	Sandfly
i3	Wasp Venum
i39	Wheat Weevil



Mediwiss Analytic manufactures high quality allergen extracts from certificated raw materials. About 500 different allergens are available for manifold combinations on our AllergyScreen® and AlleisaScreen® test strips.

The production of each allergen extract adheres to the following procedures:

- Homogenization of raw material in special buffers
- Purification by dialysation
- Centrifugation and filtration
- Lyophilisation of the extract for long term storage

The potency of each allergen extract is determined by a special in-house reference serum and additional positive/negative patient sera.

High qualitative allergens are dispensed as lines on a nitrocellulose membrane by a Biodot printing device with high resolution syringe pumps.

After drying and blocking, a Biodot cutting device precisely cuts the nitrocellulose membranes into test strips. The final test strips are glued into reaction troughs and sent to our customers worldwide.





A new generation of Allergy Screening The Improvio Family

Improvio C

-	Scans 1–36 test strips at a time	26.10 26.10	
irrania.	Print out and program in all langue	ages avail	al
	Data export via Windows-Excel™ o	or CSV	
, 	Data import via CSV		
	Data transfer to LIMS possible		
J	Integrated self-control of the system	by	
	Fuji™ gray scale	All address	
		Parent (2) State	- 740-0 - 7400 - 7400

ble



	Improvio C	Improvio M	Improvio L
Strips scanned at a time	1-2 strips	1–10 strips	1–36 strips
Dimensions (h x l x w)	7.5 x 29.5 x 23 cm	7.7 x 29.5 x 43 cm	10.5 × 60 × 35
Weight	2.9 kg	5.1 kg	25 kg
Plastic contents	2 housing parts	2 housing parts	3 housing parts
Drawer	mechanical drawer	mechanical drawer	mechanical drawer
AllergyScreen [®] /AlleisaScreen [®]	yes	yes	yes
Minimized shadowing	yes	yes	yes
Free position of test strips	yes	yes	yes
Easy to clean	yes	yes	yes
Contamination prevention	yes	yes	yes
Integrated image acquisition and analyzation	no	yes	no
Footprint	small	medium	large
Simplified setup	yes	completely installed	yes
Calibration card	yes	yes	yes
Computer connection	USB 2.0	2 x USB 2.0, 1 x HDMI, 1 x DVI RJ45 LAN	USB 2.0
Keyboard	no	yes	no
Mouse	no	yes	no
Power supply	1 x external power supply, CE certified	2 x external power supply, CE certified	1 x external power supply, CE certified
Input	220 V-240 V 50 Hz, 0.4 A	220 V-240 V 50 Hz, 0.4 A	220 V-240 V 50 Hz, 0.4 A
Output	10V-1A	10V- 1A	10V-1A



A new generation of Allergy Screening The CubeScreen Reader

CubeScreen Reader

	arreaded	Server 12 F2miParel 2	1
	2 and 23 C2 3192	Annuale Annuale (2012)	1
	ates terms	An interest	
		413 33 diplomity transact 4131 32 displaying transact 1238 42 displaying transact 4146 43 displaying transact 4146 43 displaying	1
	RSE Reconstruct RSE Adapted RSE Reconst RSE End Special	1000 827 - 2000-000-000 6120 825 - 2000-000 1000 825 - 2000-000 1000 825 - 2000-000 1000 825 - 2000	
11 A	10 Earlander 10 Million auflag 11 Million auflag 12 Earlan anglau char 13 Kalima harana auglau	AUX 4.4 Map 500 50 million and a second 500 50 million and a second 500 50 million and a second	1
	Balmaniae Pelitikan esperat Celtopenar Autoriae Aperplas temperat Annesis plantes	 R.M. 243. Nature Versity Language R.M. 249. Napol Applications, Incommun. R.M. 247. Napol Applications, Incommun. 	
	Autorizat	Diff. diff. and in both present	/

Scans one test strip at a time
 Print out and program in all languages available
 Data export via Windows-Excel™ or TXT
 Data transfer to LIMS possible
 Micro-stepping software-controlled drawer
 Sony sensor: 600 dpi
 Quiet operation

Strips scanned at a time Dimensions $(h \times | \times w)$ Weight Plastic contents Drawer AllergyScreen[®]/AlleisaScreen[®] Minimized shadowing Free position of teststrips Easy to clean Contamination prevention Integrated image acquisition and analyzation Footprint Simplified setup Calibration card Computer connection Keyboard Mouse Power supply Input Output



CubeScreen Reader

1 strips 17 x 15 x 15 cm 2.5 kg 2 parts of acetal body automatic drawer yes yes no yes yes no small yes no USB 2.0 no no 1 x external power supply, CE certified 100-240 V, 50-60 Hz, 0.7 A

16-21 V DC, 1.56-1.19A



The AllergyScreen® and AlleisaScreen® systems can be used in combination with an optional automated processor in two different model sizes: Beeblot 12 and Beeblot 36.

Bee Robotics Ltd., located in the UK, designed and manufactured the 'BeeBlot' system especially to support blot strip-based assays like AllergyScreen®. The technology of scientific blot analysis integrated into the routine of automated in-vitro laboratories results in enhanced efficacy and eases the operating process.

The Bee36 automated processor makes it possible to automatically process up to 36 diagnostic membranes within 2.5 hours, whereas the smaller Beel 2 model can process up to 12 membranes. The only manual step is the pipetting of the serum (depending on the test system used, this requires only 250 or 300 µl of the patient's sera). The rest is completed by the processor. The results can be directly evaluated with the Improvio L Scanner by transferring the tray with 36 test strips from the Bee36 to the scanner. We recommend our Improvio M Scanner for evaluating the results of the Bee12 process as it lets you measure 10 membranes simultaneously.

Product highlights

- III Up to 12 or 36 membranes can be worked off per process
- I Required assay protocol pre-installed
- Application support
- User-friendly Windows-based software
- Easy maintenance
- Test duration of only 2.5 h
- Only 250 µl/ 300 µl serum needed
- Usable for AllergyScreen® and AlleisaScreen® test strips





Weight: 23 kg Reagent save feature Easy walk away system Acoustical signals Color coding Quiet-running

Weight: 45 kg Reagent save feature Acoustical signals Color coding Quiet-running

Beeblot 12 - Specifications

Capacity: minimum 2, maximum 12 samples per run Dimensions: 400mm(w) x 480mm(d) x 500mm(h) Dispensing accuracy: less than or equal to 10% Display unit: LCD with 2 rows of 16 digits

Beeblot 36 – Specifications

Capacity: minimum 2, maximum 36 samples per run Dimensions: 640 mm(w) \times 620mm (d) \times 450mm(h) Dispensing accuracy: less than or equal to 10% Display unit: LCD with 2 rows of 16 digits Easy walk away system

Food

Sensitivity:

Specifity:

Accuracy:

Sensitivity:

Specifity:

Accuracy:

Comparison of a single allergen determination

system (SADS), skin-prick test and

AllergyScreen[®] (Inhalative allergens

142 sera tested) (Kersten, 2002)

lqG4



76.8 %

77.5 %

77.1 %

79.6 %

75.0 % 79.1 %

95.1 % 95.8 %

84.3 %

AllergyScreen[®] in comparison with a single allergen determination system (internal studies)

Latex

Sensitivity:		
Specifity:		
Accuracy:		
Bee		
Sensitivity		

Sensitivity:	
Specifity:	
Accuracy:	

Wasp

wash		
Sensitivity:	95.7 %	Sensitivity
Specifity:	78.6 %	Prick-test/AllergyScreen®:
Accuracy:	89.2 %	Prick-test/SADS:
		SADS /AllergyScreen®:

92.9 %

100.0 %

92.9 %

93.8 %

100.0 %

97.2 %

Specificity Prick-test/AllergyScreen®: 80.2 % Prick-test/SADS: 76.1 % 95.0 % SADS/AllergyScreen®:

Accuracy

Prick-test/AllergyScreen®:	88.3%
Prick-test/SADS:	87.5%
SADS/AllergyScreen®:	90.6%

Inter-assay and Intra-assay

variations - IgE and IgG4 (n=10)	
Inter-assay variation IgG4	4.0 %
Intra-assay variation IgG4	1.7 %
Inter-assay variation IgE	3.9 %
Intra-assay variation IgE	4.5 %
Inter-batch variation IgE	8,8 %

A comparison with an established single allergen determination system (SADS) and skin test has shown that the Allergy-Screen® system offers a highly effective method for determining a patient's comprehensive specific sensitisation pattern. The sensitivity and specificity of the system is very similar to skin testing, and corresponds to a conventional single allergen system.

What's more, the Allergy-/Alleisa-Screen® systems achieve precise results at a low cost and with a minimum material expenditure.

A complete study overview is available on our website: www.mediwiss-analytic.de. Simply register and you will be provided with a login-password. You are also welcome to contact us directly for further information.

Kersten, W. (2002). Allergologie, Band 25(4): 203-208.

MEDIWISS Analytic GmbH

MEDIWISS Analytic GmbH has been developing, manufacturing and selling their own medical products since the foundation in 1999 in Moers, Germany. Our experience in allergologic in vitro diagnostics, developments and technologies have transformed us into a worldwide company that plays an important role in allergy screening diagnostics.

Our guiding objective is to provide a complete system for the allergy screening of specific IgE antibodies and further developed areas such as IgG4 and IgG antibody detection with test panels, hardware, software and customer support. Team members are certified biologists and are regularly trained in the latest medical requirements in the field of allergy and immunology.

Our aim is to simplify professional allergy diagnostics with concomitant sensitivity and specificity. To this end, our products are developed and manufactured to meet the highest standards. Customer suggestions and requirements are taken into consideration since their input ensures the optimal support of customers and distributors around the world.

Our pursuit of quality is demonstrated by our quality control system ISO 9001 from 2008 and ISO 13485 from 2003 as well as a certification for in vitro test systems in allergology from March 2011.



MEDIWISS Analytic GmbH Gesellschaft für angewandte in-vitro Analytic mbH Uerdinger Straße 3 47441 Moers Germany Phone: +49 (0)28 41/8 89 04-70 Fax: +49 (0)28 41/8 89 04 72 E-mail: pwahl@mediwiss-analytic.de www.mediwiss-analytic.de certificated acc.: ISO 9001 (2008) and ISO 13485 (2003)