## RIDA qLine® Allergy

Allergy Panels for Quantitative Analysis of Specific IgE in Human Serum or Plasma





### RIDA qLine® Allergy The Next Generation of Allergy In-Vitro-Diagnostics

The prevalence of allergies is increasing worldwide. Only in Europe up to 15% of the population is thought to be afflicted. Allergy-specific laboratory tests are now indispensable tools for the diagnosis of allergies. Patients show often a wide range of varying symptoms and sensitization patterns against several allergens. It is necessary to test a patient's blood whenever an allergic response or severe reaction is suspected.

The most commonly used in vitro allergy diagnostic test systems nowadays are either cost intensive quantitative single allergen tests or more economic and easy to handle semi-quantitative panel test systems. R-Biopharm AG has faced the challenge to develop a sophisticated allergy in vitro test system that combines both a quantitative determination and a very economic and easy handling.

The next generation of allergy in vitro diagnostics has arrived:

## The RIDA qLine® Allergy system



## The Product Quantitative, Efficient and Economic Determination

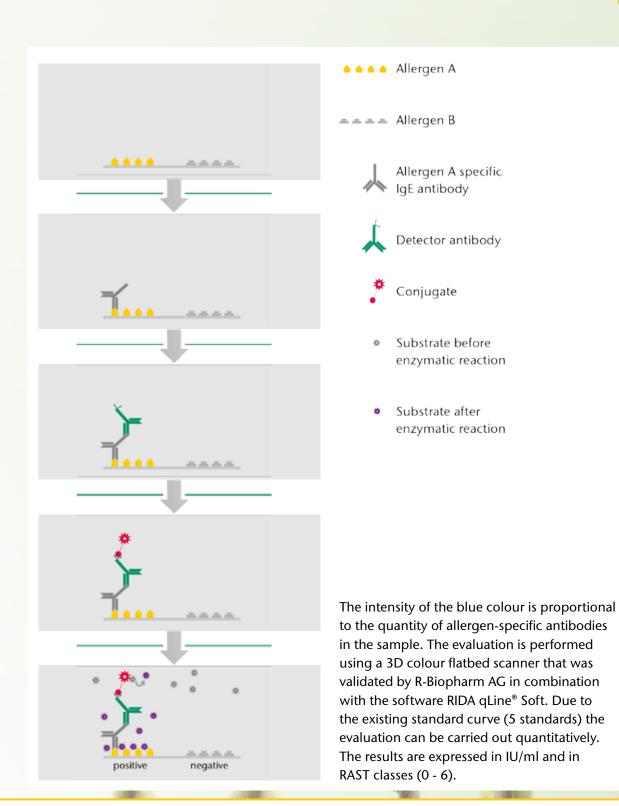
- Enzyme immunoassay on a nitrocellulose membrane (immunoblot)
- Quantitative analysis of a great range of allergens or allergen mixes in one operation
- 5 standards on each strip
- Only 400 µl of serum or plasma (citrate) are needed for 1 strip (up to 20 allergens)
- All necessary reagents are included
- Assay time only 2.5 hours
- Results are given in IU/ml (range 0.00 - 100 IU/ml) and in RAST classes (0-6)

Picture 1 RIDA qLine® Allergy





### Test Principle Immunoblot Technology



# Test Procedure – Easy and Standardized Protocol for Accurate and Reliable Results

#### Place the required number of strips into the strip holder



Follow the standardized washing procedure according to the test instruction



Add **400 µl of patient serum**to the membranes

#### Incubate on an orbital shaker for 30 minutes





Follow the standardized washing procedure according to the test instruction



Add **400 µl of Antibody** to the membranes

#### Incubate on an orbital shaker for 45 minutes





Follow the standardized washing procedure according to the test instruction



Add **400 µl of Conjugate** to the membranes

#### Incubate on an orbital shaker for 20 minutes





Follow the standardized washing procedure according to the test instruction



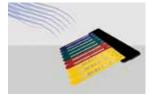
Add **400 µl of Substrate**to the membranes

#### Incubate in the dark on an orbital shaker for 15 minutes





Follow the standardized washing procedure according to the test instruction



Allow the membrane to air dry for at least 30 minutes or with a cold air hair dryer



### Evaluation

### Quantitative Determination by Digital Scanning

The evaluation is performed using a 3D colour flatbed scanner that was validated by R-Biopharm AG in combination with the software RIDA qLine® Soft. The evaluation is based on the standard curve contained on each strip, whereas the intensity of each individual allergen line is related to this standard curve. The results are expressed in IU/ml and in RAST classes (0 - 6).

- Up to 20 strips in one scan
- Plug-and-play (Scanner)
- Digital 3D scanning of immunoblot bands
- Cost effective even for small labs





## RIDA qLine® Soft Easy and Intuitive Handling

- Easy and intuitive handling of software
- Print out and software in different languages available
- Report adaptable individually
- Data and work list import (.csv)
- Connection to LIMS possible







## Report Individually Designable and Clearly Represented Results

#### Individually adaptable letterhead

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R-Biopharm AG An der neuen Bergstraße 64297 Darmstadt





#### Test / Patient data Lab ID: 123456

Panel 1

Name: Doe First name: John Date of Birth: 01.12.1950 28.05.2013 Created: Additional 1: Information 1 Additional 2: Information 2

#### RIDA qLine® Allergy - Assay Report

Additional placeholders for individual data entry

Test and patient data

 Code	Description	IU/ml	RAST	1,	2	3	4	5	6
D1	Dermat. pteronys. (house-dust mite)	45,00	4,8						- St. (1)
D2	Dermat. farinae (dust mite 1)	40,00	4,7		1		i		75000
T2	Alder	2,70	2,7		- 1				Name (
T3	Birch (Wart birch)	0,85	2,1		i				303052
T4	Hazel [Pollen]	0,30	0,8						33.632
GX	Grasmix	0,95	2,1		i				135.00
G12	Rye [Pollen]	73,12	5,7			- 1	- :		31292
W6	Mugwort (Artemisia vulgaris)	29,38	4,4		1				777,4186
W9	Ribwort plantain	0,63	1,8						0.32990
E1	Cat [epithelia/hair]	0,80	2,0						33436
E3	Horse [epithelia/hair]	32,50	4,5						21N/93E
E5	Dog [epithelia/hair]	0,13	0,4						13.00
M6	Alternaria tenuis	20,00	4,1		i	i	i		×93.74
F1	Egg white (albumen)	0,51	1,5				$\overline{}$	- 1	777.2.20%
F2	Milk (pasteurised)	0,58	1,6					Claar	ly represented
F13	Peanuts (Groundnuts) [food]	6,25	3,2		- 1	i			
F17	Hazel nuts [food]	0,80	2,0					resul	ts
F31	Carrots [food]	0,58	1,6					- 1	24.99
F4	Wheat flour [food]	0,24	0,7			- 1			3,750,000
F14	Soy beans [food]	0.47	1.4		1	- 1			775 (200)

Test valid

#### RAST classes

- 0: Not detectable or absent
- 1: Low 2: Elevated
- 3: Significantly elevated
- 4: High 5: Very high 6: Extremly high

#### Signature

Individually adaptable footer

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## Analytical Performance Superior Reproducibility and Sensitivity

#### Reproducibility

Reproducibility							
	CV (RAST)		CV (RAST)				
Intra-Assay (n=20)	< 6 %	Inter-Lot (3 lots each n=20)	< 12 %				
Inter-Assay	< 11 %						
(5 technicians, 10 days each n=2)							

#### **Analytical Sensitivity**

The limit of detection (LoD) was determined by using a positive human serum on a panel of 18 single allergens in different concentrations and a negative human reference serum as the limit of blank.

All LoDs for the tested single allergens were determined < RAST 0,7. Since the limit of detection is allergen specific the itemized LoDs are shown here (mixes were not taken into consideration):

Sensitivity						
Allergen	LOD (RAST)	Allergen	LOD (RAST)			
Dermatophagoides	0.3	Dog	0.7			
pteronyssinus  Dermatophagoides farinae	0.7	Alternaria alternata/tenuis	0.3			
, ,		Egg white	0.3			
Alder	0.7	Milk	0.2			
Birch	0.3	Peanut	0.3			
Hazel	0.3	Hazelnut	0.5			
Rye	0.5	Carrot	0.6			
Mugwort	0.6	Wheat meal	0.5			
Ribwort plantain	0.6					
Cat	0.4	Soya bean	0.7			



## Panel Allergen Compositions A Comprehensive Assortment of Allergens

- Assortment of more than 700 allergens
- 4 standard panels covering the most common inhalative and food allergens

Panel 1	Inhalative and Food Allergens
	Std. 5
	Std. 4
	Std. 3
	Std. 2
	Std. 1
D1	Dermatophagoides pteronyssinus
D2	Dermatophagoides farinae
T2	Alder
T3	Birch
T4	Hazel
GX	Grass mix
G12	Rye
W6	Mugwort
W9	Ribwort plantain
E1	Cat
E3	Horse
E5	Dog
M6	Alternaria alternata/tenuis
F1	Egg white
F2	Milk
F13	Peanut
F17	Hazelnut
F31	Carrot
F4	Wheat flour
F14	Soya bean

1 1 4 4 4 4
nhalative Allergens
Std. 5
Std. 4
Std. 3
Std. 2
Std. 1
Dermatophagoides pteronyssinus
Dermatophagoides farinae
Alder
Birch
Hazel
Oak
Grass mix
Rye
Mugwort
Ribwort plantain
Cat
Horse
Dog
Guinea pig
Golden hamster
Rabbit
Penicillium notatum/chrysogenum
Cladosporium herbarum
Aspergillus fumigatus
Alternaria alternata/tenuis



Panol	3 Food Allergens	Panol	4 Pediatric Allergens
Tarret	Std. 5	Tarier	Std. 5
	Std. 4		Std. 4
	Std. 3		Std. 3
	Std. 2		Std. 2
	Std. 1		Std. 1
F17	Hazelnut	D1	Dermatophagoides pteronyssinus
F13	Peanut	D2	Dermatophagoides farinae
F16	Walnut	T3	Birch
F20	Almond	GX	Grass mix
F2	Milk	E1	Cat
F1	Egg white	<b>E5</b>	Dog
F75	Egg yolk	M6	Alternaria alternata/tenuis
F78	Casein	F2	Milk
F35	Potato	F76	α-Lactalbumin
F85	Celery	F77	β-Lactoglobulin
F31	Carrot	F78	Casein
F25	Tomato	F1	Egg white
F3	Cod	F75	Egg yolk
F23	Crab	E101	Bovine serum albumin = BSA
F33	Orange	F14	Soya bean
F49	Apple	F31	Carrot
F4	Wheat flour	F35	Potato
F5	Rye flour	F4	Wheat flour
F10	Sesame	F17	Hazelnut
F14	Soya bean	F13	Peanut

Individual country specific panels are available or can be produced on demand. Please ask R-Biopharm AG or your local distributor for further information.



## RIDA qLine® Allergy — At a glance

Product	Description	Tests	Matrix	Art. No.	
RIDA qLine® Allergy					
RIDA qLine® Allergy Panel 1 Standard	Quantitative determination of specific IgE against 20 inhalative and food allergens	10	Serum/ Plasma	A6142	
RIDA qLine® Allergy Panel 2 Standard	Quantitative determination of specific IgE against 20 inhalative allergens	10	Serum/ Plasma	A6242	
RIDA qLine® Allergy Panel 3 Standard	Quantitative determination of specific IgE against 20 food allergens	10	Serum/ Plasma	A6342	
RIDA qLine® Allergy Panel 4 Standard	Quantitative determination of specific IgE against 20 pediatric related allergens	10	Serum/ Plasma	A6442	
RIDA qLine® Allergy	Accessories				
RIDA qLine® Incubation Set	Strip holder for 10 strips and cover box for (dark) incubation	1		ZG2701	
RIDA qLine® Orbital Shaker	Validated orbital shaker with 300 rpm and 3 mm orbital diameter	1		ZG2601 ZG2601-V	
RIDA qLine® Soft	Software for evaluation of RIDA qLine® Allergy	1		Z9995	
RIDA qLine® Scanner Template	Template for strip holder for the use in a 3D flatbed scanner	1		ZG1107	
Epson Perfection V600 Photo	3D Flatbed Scanner for evaluation of RIDA qLine® Allergy	1		ZG1106	

Individual panels on request. Please ask your local distributor.

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