

# RIDA qLine<sup>®</sup> Allergy

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

## The New Standard for Economic Quantitative Allergy Diagnostics

- **Quantitative**  
standard curve on each strip
- **Economic**  
allergen panels with up to 20 allergens  
for effective diagnostics
- **Reliable**  
standard curve calibrated against the  
international reference preparation  
“1<sup>st</sup> WHO IRP 67/86 for human IgE”
- **Customized**  
customer-specific allergen  
compositions for flexible  
and individual diagnostics
- **Individual**  
software evaluation  
with individually  
designable report



## ● **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

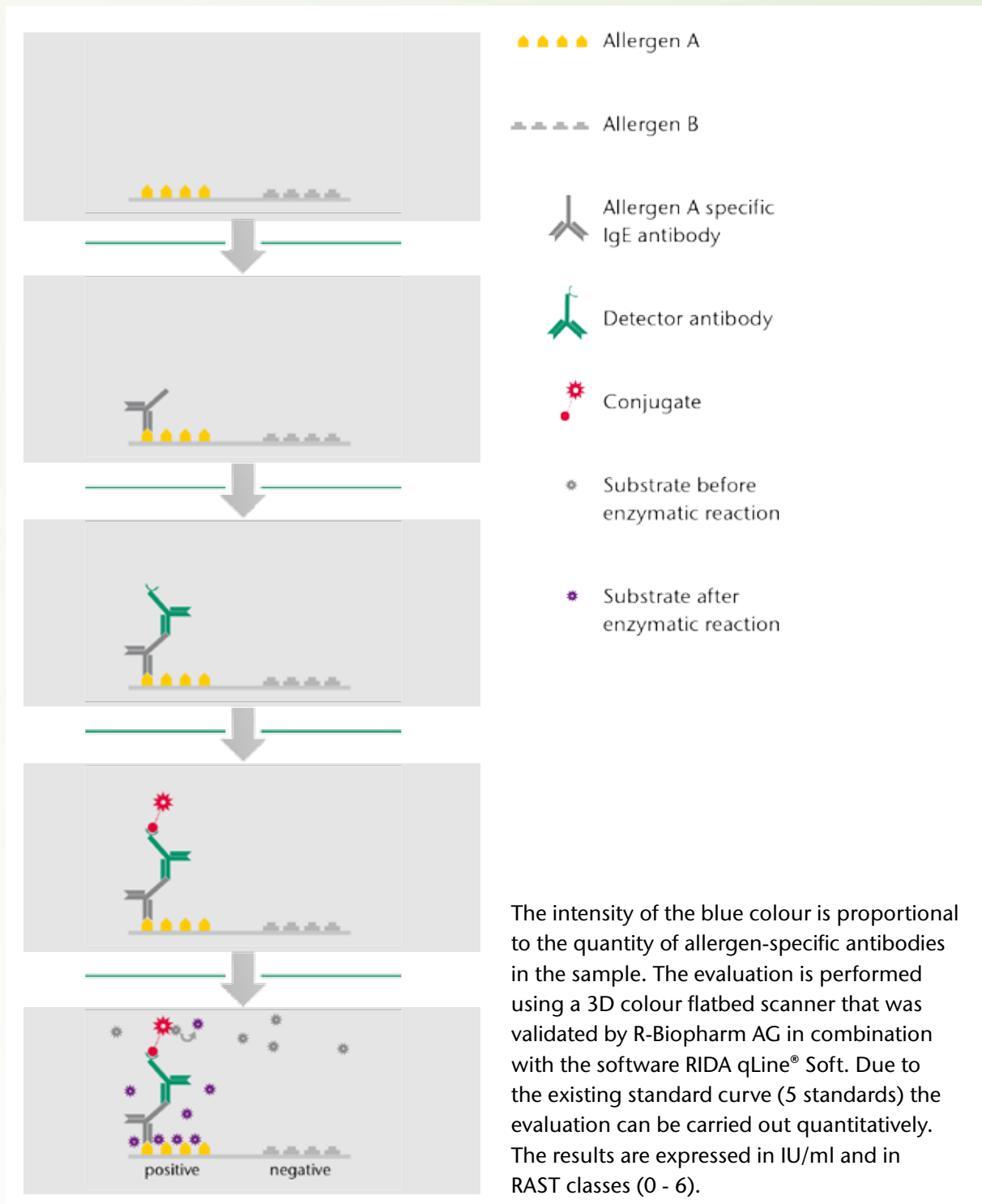
# Quantitative, Efficient and Economic Determination

- 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

1



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

2



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

3



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

4



Follow the standardized washing procedure according to the test instruction



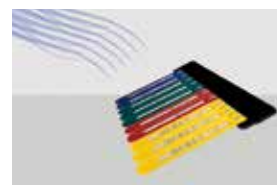
Add **400 µl** of **Substrate** to the membranes

Incubate in the dark on an orbital shaker for 15 minutes

5



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

**Picture 2** 3D Flatbed Scanner and RIDA qLine® Scanner Template (Art. No. ZG1107)



# 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



Easy and intuitive handling of the software

Patient data

The screenshot displays the software interface with the following components:

- Navigation:** Requests, Worklists, Measurement, Results (selected), Settings...
- Filters:** Measured, Refresh, Print
- Patient Data Table:**

Date	Lab ID	Status
16.09.2013 13:45:12	123456	Measured
16.09.2013 13:46:19	3574654	Measured
16.09.2013 13:46:34	24634735	Measured
16.09.2013 13:46:57	23623625	Measured
16.09.2013 13:47:06	255234123	Measured
16.09.2013 13:47:12	153151	Measured
16.09.2013 13:47:17	14212414	Measured
- Scan of the strip:** A horizontal bar chart showing results for various codes (D1, D2, T2, T3, T4, T7, GX, G12, W6, W9, E1, E3, E5, E6, E84, E82, M1, M2, M3, M6) across 5 lanes. Results are shown in IU and RAST classes.
- Standard curve:** A line graph plotting IU (0-140) against a logarithmic scale (1-10). Points are labeled with values: 3, 10, 46, 100, 133.

Scan of the strip

Results shown in IU and RAST classes

Standard curve

# Report

## Individually Designable and Clearly Represented Results

Individually adaptable  
letterhead

R-Biopharm AG • An der neuen Bergstraße 17 • 64297 Darmstadt



R-Biopharm AG  
An der neuen Bergstraße  
64297 Darmstadt

**Test / Patient data**  
Lab ID: 123456  
Test: Panel 1

Test and patient data

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

### RIDA qLine® Allergy - Assay Report

Additional placeholders  
for individual data entry

Code	Description	IU/ml	RAST	1	2	3	4	5	6
D1	Dermat. pteronys. (house-dust mite)	45,00	4,8	[Bar chart showing RAST result 4.8]					
D2	Dermat. farinae (dust mite 1)	40,00	4,7	[Bar chart showing RAST result 4.7]					
T2	Alder	2,70	2,7	[Bar chart showing RAST result 2.7]					
T3	Birch (Wart birch)	0,85	2,1	[Bar chart showing RAST result 2.1]					
T4	Hazel [Pollen]	0,30	0,8	[Bar chart showing RAST result 0.8]					
GX	Grasmix	0,95	2,1	[Bar chart showing RAST result 2.1]					
G12	Rye [Pollen]	73,12	5,7	[Bar chart showing RAST result 5.7]					
W6	Mugwort (Artemisia vulgaris)	29,38	4,4	[Bar chart showing RAST result 4.4]					
W9	Ribwort plantain	0,63	1,8	[Bar chart showing RAST result 1.8]					
E1	Cat [epithelia/hair]	0,80	2,0	[Bar chart showing RAST result 2.0]					
E3	Horse [epithelia/hair]	32,50	4,5	[Bar chart showing RAST result 4.5]					
E5	Dog [epithelia/hair]	0,13	0,4	[Bar chart showing RAST result 0.4]					
M6	Alternaria tenuis	20,00	4,1	[Bar chart showing RAST result 4.1]					
F1	Egg white (albumen)	0,51	1,5	[Bar chart showing RAST result 1.5]					
F2	Milk (pasteurised)	0,58	1,6	[Bar chart showing RAST result 1.6]					
F13	Peanuts (Groundnuts) [food]	6,25	3,2	[Bar chart showing RAST result 3.2]					
F17	Hazel nuts [food]	0,80	2,0	[Bar chart showing RAST result 2.0]					
F31	Carrots [food]	0,58	1,6	[Bar chart showing RAST result 1.6]					
F4	Wheat flour [food]	0,24	0,7	[Bar chart showing RAST result 0.7]					
F14	Soy beans [food]	0,47	1,4	[Bar chart showing RAST result 1.4]					

Clearly represented  
results

Test valid

**RAST classes**  
0: Not detectable or absent  
1: Low  
2: Elevated  
3: Significantly elevated  
4: High  
5: Very high  
6: Extremely high

Signature

Individually adaptable  
footer

R-Biopharm AG  
Festsamschwil  
An der neuen Bergstraße 17, 64297 Darmstadt  
Stz: Pfungstadt  
Telefon Zentrale: +49 (0) 61 51 - 01 02 0  
Fax Zentrale: +49 (0) 61 51 - 01 02 40  
Fax Bestellverwaltung: +49 (0) 61 51 - 01 02 20  
E-Mail: info@rbiopharm.de  
www.rbiopharm.com

Vorsitzender des Aufsichtsrats:  
Detrich Müller  
Vorstand:  
Dr. Ralf M. Dierke (Vors.), Dr. Carsten Bunnig,  
Eckhard Heuch, Dr. Peter Schubert  
Reg.-Bez.: Amtsgericht Darmstadt  
HRB 8321  
Steuer-Nr.: 62262 / 00 088  
MRGD-Nr.: DE 111 657 400

Sparkasse Darmstadt  
Bankleitzahl: 500 501 50  
Konto-Nr.: 711 200  
SWIFT-BIC: HELADEF1654  
BIC: DE 21 5185 0150 0000 7117 40  
Deutscher Bank  
Bankleitzahl: 550 200 00  
Konto-Nr.: 333 211, SWIFT: DEUTDE33  
BAN: DE99 5507 0040 0033 3211 00

Optional: printout of a second page containing the standard curve.



# ● 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 (5 technicians, 10 days each n=2)	< 11 %		

### 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 pteronyssinus	0.3	Dog	0.7
Dermatophagoides farinae	0.7	Alternaria alternata/tenuis	0.3
Alder	0.7	Egg white	0.3
Birch	0.3	Milk	0.2
Hazel	0.3	Peanut	0.3
Rye	0.5	Hazelnut	0.5
Mugwort	0.6	Carrot	0.6
Ribwort plantain	0.6	Wheat meal	0.5
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

### Panel 2 Inhalative Allergens

	Std. 5
	Std. 4
	Std. 3
	Std. 2
	Std. 1
D1	Dermatophagoides pteronyssinus
D2	Dermatophagoides farinae
T2	Alder
T3	Birch
T4	Hazel
T7	Oak
GX	Grass mix
G12	Rye
W6	Mugwort
W9	Ribwort plantain
E1	Cat
E3	Horse
E5	Dog
E6	Guinea pig
E84	Golden hamster
E82	Rabbit
M1	Penicillium notatum/chrysogenum
M2	Cladosporium herbarum
M3	Aspergillus fumigatus
M6	Alternaria alternata/tenuis

### Panel 3 Food Allergens

	Std. 5
	Std. 4
	Std. 3
	Std. 2
	Std. 1
F17	Hazelnut
F13	Peanut
F16	Walnut
F20	Almond
F2	Milk
F1	Egg white
F75	Egg yolk
F78	Casein
F35	Potato
F85	Celery
F31	Carrot
F25	Tomato
F3	Cod
F23	Crab
F33	Orange
F49	Apple
F4	Wheat flour
F5	Rye flour
F10	Sesame
F14	Soya bean

### Panel 4 Pediatric Allergens

	Std. 5
	Std. 4
	Std. 3
	Std. 2
	Std. 1
D1	Dermatophagoides pteronyssinus
D2	Dermatophagoides farinae
T3	Birch
GX	Grass mix
E1	Cat
E5	Dog
M6	Alternaria alternata/tenuis
F2	Milk
F76	$\alpha$ -Lactalbumin
F77	$\beta$ -Lactoglobulin
F78	Casein
F1	Egg white
F75	Egg yolk
E101	Bovine serum albumin = BSA
F14	Soya bean
F31	Carrot
F35	Potato
F4	Wheat flour
F17	Hazelnut
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.
<b>RIDA qLine® Allergy</b>				
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
<b>RIDA qLine® Allergy Accessories</b>				
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.

## R-Biopharm contacts:

### Product Manager Allergy Diagnostics:

Joachim Zehender  
Phone: +49 (0) 61 51 - 81 02-45  
Fax: +49 (0) 61 51 - 81 02-40  
E-mail: j.zehender@r-biopharm.de

### Product Specialist Allergy Diagnostics:

Hannah Gören  
Phone: +49 (0) 61 51 - 81 02-429  
Fax: +49 (0) 61 51 - 81 02-40  
E-mail: h.goeren@r-biopharm.de

### Order Department:

Phone: +49 (0) 61 51 - 81 02-0  
Fax: +49 (0) 61 51 - 81 02-20  
E-mail: orders@r-biopharm.de

### Clinical Sales International:

Jens-Uwe Wunsch (Director)  
Phone: +49 (0) 61 51 - 81 02-995  
E-mail: j.u.wunsch@r-biopharm.de

Dieter Gernet (Asia, Middle East)  
Phone: +49 (0) 61 51 - 81 02-28  
E-mail: d.gernet@r-biopharm.de

Otto Mannherz (Europe, Africa)  
Phone: +49 (0) 61 51 - 81 02-446  
E-mail: o.mannherz@r-biopharm.de

Anatolii Buk (Ex CIS)  
Phone: +49 (0) 61 51 - 81 02-19  
E-mail: a.buk@r-biopharm.de

Andreas Key (Latin America)  
Phone: +55 - 12 - 811 25 944  
E-mail: andreas\_key@yahoo.com

### Sales Support:

Carsten Müller  
Phone: +49 (0) 61 51 - 81 02-440  
E-mail: c.mueller@r-biopharm.de

Martina Scheidenberger  
Phone: +49 (0) 61 51 - 81 02-52  
E-mail: m.scheidenberger@r-biopharm.de

Andrea Becker  
Phone: +49 (0) 61 51 - 81 02-531  
E-mail: a.becker@r-biopharm.de