

RIDA qLine® Allergy

Allergy panels for quantitative analysis of spec. IgE in human serum or plasma

- New** • **Quantitative and reliable**
Standard curve and positive control on each strip
- **Economic and customized**
Individual allergen panels with up to 20 allergens
- New** • **Enhanced and sophisticated**
CCD band on each strip



RIDA qLine® Allergy

Reliable 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 RIDA qLine® Allergy system.**



The product

Quantitative, efficient and economic determination

- Quantitative analysis of a great range of allergens or allergen mixes in one operation
- 5 real standards on each strip
- **New** CCD band
- **New** Positive control
- Only 400 µl of serum or plasma 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 0,0 - 100 IU/ml) and in RAST classes (0 - 6)

Picture 1: RIDA qLine® Allergy



New Two additional bands on RIDA qLine® Allergy

The CCD band is an indicator of the presence of IgE antibodies against cross-reactive carbohydrate side chains in a patient's serum.

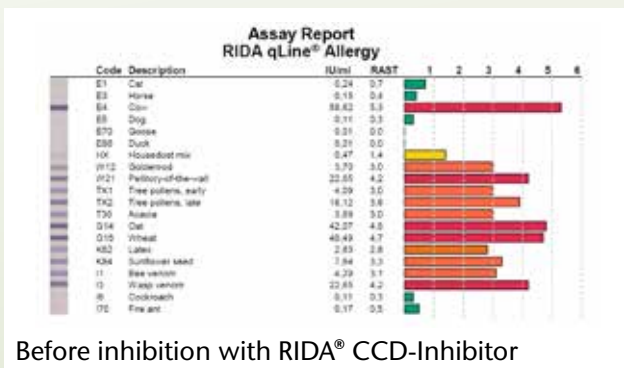
The CCD band consists of purified carbohydrate side chains, which are bound to the nitrocellulose membrane. The CCD band detects specific IgE antibodies against cross-reacting carbohydrate determinants (CCD) in the patient sample.

Specific IgE antibodies are generated by the immune system against real allergens, but also against the carbohydrate side chains of allergens (anti-CCD-IgE) of plant origin, insects, molluscs or latex. These anti-CCD IgEs also result in cross reaction with unrelated proteins and are therefore also called cross-reactive carbohydrate determinants (CCD).

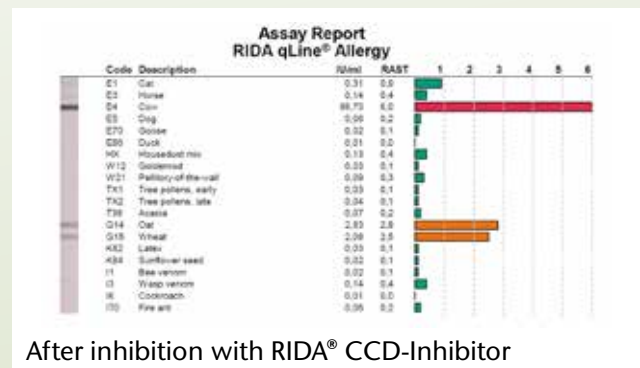
Approximately 25 % of all allergic patients produce anti-CCD IgEs, which, however, do not seem to trigger any allergic symptoms and therefore are not clinically relevant.

Because these cross-reactions lead to positive results in in vitro test systems, they have to be assessed as false positive. If both the result of the CCD band and one or more CCD allergens are positive, it is recommended to repeat the test and block the serum prior to testing with a CCD inhibitor (Art. No. ZA0601) to prevent binding to CCDs in in vitro tests.

For further information about the RIDA® CCD-Inhibitor (Art. No. ZA0601) please see also our brochure "RIDA® CCD-Inhibitor Reliable inhibition of IgE antibodies against cross-reactive carbohydrate determinants (CCD) in RIDA qLine® Allergy testing" or visit <http://products.r-biopharm.com/qline/>.



Before inhibition with RIDA® CCD-Inhibitor

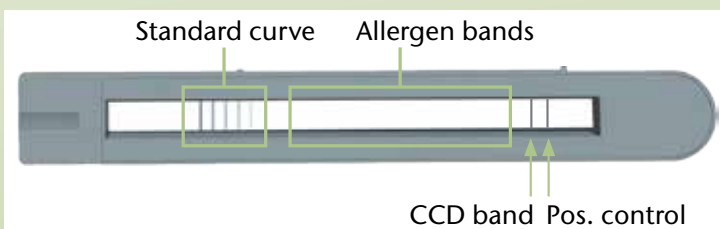


After inhibition with RIDA® CCD-Inhibitor

Positive control

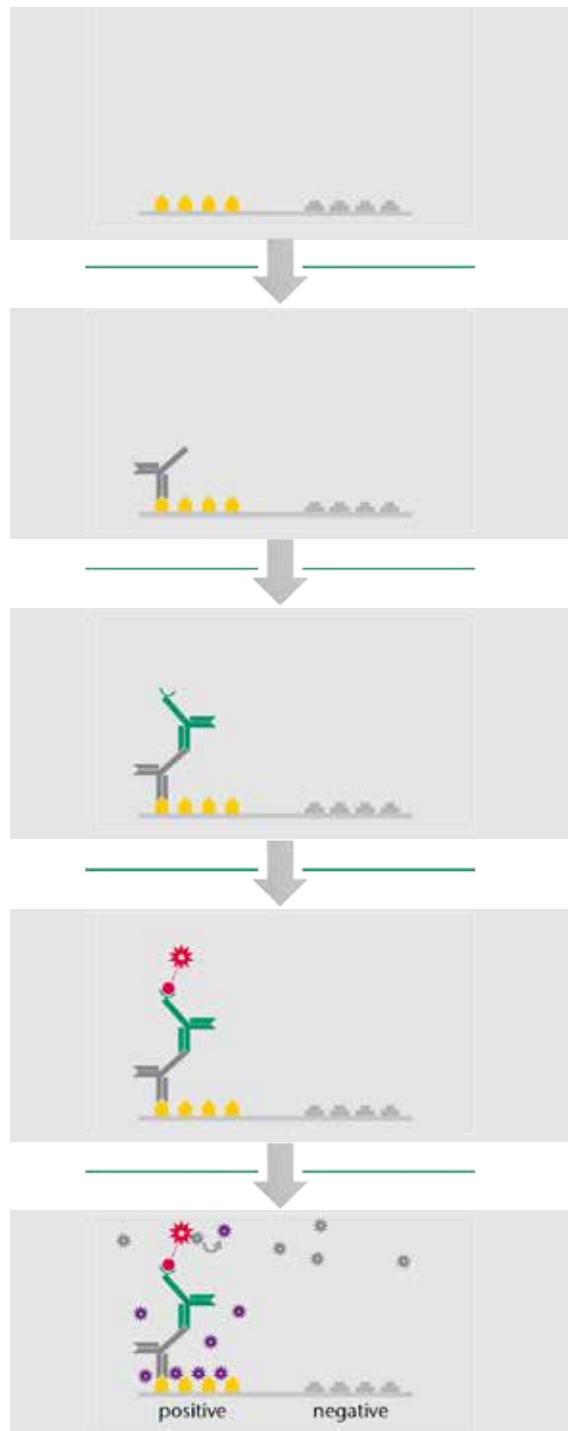
The positive control is used to check the entire system. The expected value can be obtained only when the strips are processed correctly, the measuring system is recognizing correctly and the software performs the analysis correctly.

A positive control and a CCD band:



Test principle

Immunoblot technology



▲▲▲▲ Allergen A

■ ■ ■ ■ Allergen B

Y Allergen A specific IgE antibody

Y Detector antibody

★ Conjugate

⊗ Substrate before enzymatic reaction

⊕ Substrate after enzymatic reaction

The intensity of the blue colour is proportional to the quantity of allergen-specific antibodies in the sample. 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. Due to the existing standard curve (5 standards) the evaluation can be carried out quantitatively. The results are expressed in IU/ml and in RAST classes (0 - 6).

Evaluation

Quantitative determination by digital scanning

The evaluation is performed using either RIDA qLine® Scan (IVD/CE) or 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 7 RAST classes.

RIDA qLine® Scan (Art. No. ZG1109)

- Up to 10 strips in one scan
- Digital 3D scanning of immunoblot bands
- IVD and CE marked
- Software RIDA qLine® Soft (Art. No. Z9995)



3D colour flatbed scanner (Art. No. ZG1106)

- Up to 20 strips in one scan
- Cost effective even for small labs
- Software RIDA qLine® Soft (Art. No. Z9995)



RIDA qLine® Soft

Easy and intuitive handling

- Easy and intuitive handling of software
- Print out and software in different languages available
- Data and work list import (.csv)
- Bidirectional connection with LIS possible

Easy and intuitive handling of the software

The screenshot displays the software interface with several key components:

- Navigation Bar:** Includes icons for Requests, Worklists, iChart, Results, and Settings.
- Filters:** Shows 'Measured' and date ranges from 09.05.2017 to 08.06.2017.
- Patient Data Table:**

Date	Lab ID	Status
08.06.2017 09:13:05	123456	Measured
06.06.2017 09:30:59	Histogram 10	Measured
06.06.2017 09:30:52	Histogram 9	Measured
06.06.2017 09:30:44	Histogram 8	Measured
06.06.2017 09:30:38	Histogram 7	Measured
06.06.2017 09:30:27	Histogram 6	Measured
06.06.2017 09:30:20	Histogram 5	Measured
06.06.2017 09:30:09	Histogram 4	Measured
06.06.2017 09:30:01	Histogram 3	Measured
06.06.2017 09:29:50	Histogram 2	Measured
06.06.2017 09:29:21	Histogram 1	Measured
- Test Results Table:**

Code	CCD	Intens	Units	RAST
D1	X	79	100,30	6,2
D2	X	10	2,70	2,7
T2	X	1	0,12	0,3
T3	X	3	0,35	1,0
T4	X	6	1,10	2,1
G1	X	14	4,97	3,1
G12	X	4	0,33	1,5
W1	X	5	0,70	2,0
W3	X	13	4,24	3,0
E1	X	68	80,95	5,6
E3	X	13	4,24	3,0
E5	X	38	28,33	4,3
M6	X	2	0,23	0,6
F1	X	54	33,87	5,0
F2	X	18	6,45	3,2
F13	X	89	121,58	6,4
F17	X	7	1,30	2,2
F31	X	92	127,38	6,5
F4	X	53	51,93	5,0
F34	X	69	82,89	5,6
CCD	X	4	0,53	1,5
- Visual Display:** A bar chart showing results for various codes (D1, T2, T3, T4, G1, G12, W1, W3, E1, E3, E5, M6, F1, F2, F13, F17, F31, F4, F34, CCD) across five lanes (1-5). A 'New' callout indicates 'Visual display of validity of the positive control'.
- Recommendations:** A 'New' callout with a question mark icon states: 'The CCD test is positive. This may affect all allergens which are marked as CCDs. We recommend that the test be repeated.' Below this, another 'New' callout says 'Recommendations regarding CCD band evaluation'.
- Standard Curve:** A line graph showing a curve with points labeled 3, 5, 12, 31, and 53. A 'Standard curve' callout points to this graph.
- Results in IU and RAST classes:** A callout points to the RAST column in the test results table.

New LIS connection now available with software version RIDA qLine® Soft 1.2 or higher. If you are interested in establishing a LIS connection please ask R-Biopharm AG for further information.



Report

Individually designable and clearly represented results

Individually adaptable
letterhead

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



R-Biopharm
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64297 Darmstadt
Germany

Test / Patient data
 Lab ID: 54987
 Test: Standard 1+
 Panel 1 Standard
 Last name: Doe
 First name: John
 Date of Birth: 19.01.1966
 Created: 18.05.2017
 Additional 1: Information 1
 Additional 2: Information 2

Test and patient data

Assay Report RIDA qLine® Allergy

Additional placeholders
for individual data entry

Code	Description	IU/ml	RAST	1	2	3	4	5	6
D1	Dermatophagoides pteronyssinus	94,16	5,8	[Red bar]					
D2	Dermatophagoides farinae	0,58	1,6	[Yellow bar]					
T2	Alder	0,26	0,7	[Green bar]					
T3	Birch	62,36	5,2	[Red bar]					
T4	Hazel	72,96	5,4	[Red bar]					
GX	Grass mix	> 100	6,0	[Red bar]					
G12	Rye	1,32	2,2	[Orange bar]					
W6	Mugwort	1,32	2,2	[Orange bar]					
W9	Ribwort plantain	1,63	2,3	[Orange bar]					
E1	Cat	12,56	3,6	[Red bar]					
E3	Horse	3,50	2,9	[Orange bar]					
E5	Dog	> 100	6,0	[Red bar]					
M6	Alternaria alternata/tenuis	0,17	0,5	[Green bar]					
F1	Egg white	17,50	4,0	[Red bar]					
F2	Milk	2,88	2,7	[Orange bar]					
F13	Peanut	2,57	2,6	[Orange bar]					
F17	Hazelnut	3,50	2,9	[Orange bar]					
F31	Carrot	44,35	4,8	[Red bar]					
F4	Wheat flour	1,94	2,4	[Orange bar]					
F14	Soya bean	18,91	4,0	[Red bar]					
CCD	CCD	0,09	0,2	[Green bar]					

Clearly represented
results

RAST classes

IU/ml	RAST	Description
0,00 - 0,34	0,0 - 0,9	Not detectable or absent
0,35 - 0,69	1,0 - 1,9	Low
0,70 - 3,49	2,0 - 2,9	Elevated

IU/ml	RAST	Description
3,50 - 17,49	3,0 - 3,9	Significantly elevated
17,50 - 49,99	4,0 - 4,9	High
50,00 - 99,99	5,0 - 5,9	Very high
>= 100	6	Extremely high

Test valid

Signature

Individually adaptable
footer

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Comparison with a quantitative in vitro IgE reference system

In order to determine the concordance of the RIDA qLine® Allergy with a quantitative IgE reference system (Phadia ImmunoCap, Thermo Scientific, USA) 50 sera have been tested on 42 allergens of

the RIDA qLine® Allergy standard panels 1 - 4 with both assays. The resulting RAST classes of both test systems have been compared. A difference between the assays of $\Delta\text{RAST} \leq 1$ is regarded as concordant.

Comparison to the IgE reference system

	qLine/IgE reference system
Concordance ($\Delta \leq 1$ RAST)	1904
Discrepancy ($\Delta > 1$ RAST)	196
Measurements in total	2100
% Concordance	90.7 %
% Discrepancy	9.3 %



Panel allergen compositions

A comprehensive assortment of 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
CCD	CCD band
PosCo	Positive control

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
CCD	CCD band
PosCo	Positive control



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
CCD	CCD band
PosCo	Positive control

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	α -Lactalbumin
F77	β -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
CCD	CCD band
PosCo	Positive control

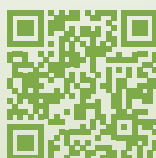
Individual country specific panels are available or can be produced on demand.
Please ask R-Biopharm AG or your local distributor for further information.

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
RIDA qLine® Soft	Software for evaluation of RIDA qLine® Allergy (in combination with RIDA qLine® Scan (ZG1109) and flatbed scanner (ZG1106))	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
RIDA qLine® QC-Kit	10 strips for function control of ZG1106 and ZG1109	1		ZG1108
RIDA qLine® CCD-Inhibitor	Accessory for the inhibition of false positive results by cross-reactive anti-CCD IgE in human serum and plasma in in vitro diagnostics	25	Serum/ Plasma (citrate)	ZA0601
RIDA qLine® Scan	Reader for RIDA qLine® Allergy (CE/IVD)			ZG1109

Individual panels on request. Please ask your local distributor.

For further information regarding RIDA qLine® Allergy please visit:



For further information or orders please contact R-Biopharm AG

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