

PRODUCT CATALOG
BULK ALLERGENS AS RAW MATERIAL FOR IVD SYSTEMS



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About us

Rekom Biotech, as specialised company in the design and development of biomarkers for infectious diseases, presents a new line of recombinant products, Bioallergens. Our recombinant allergens are biomarkers of non-infectious origin intended for the diagnosis of type I allergic disorders.

A wide variety of protein antigens from our environment are proteins coming from food, dust mites, pollens from trees and grasses; and other natural products. These environmental proteins come primarily from non-pathogenic eukaryotic organisms (animals and plants) and are essentially innocuous. However, in some cases, our immune system reacts to them, unintentionally causing damage to our tissues and vital organs that occasionally generates serious systemic pathologies.

The development of recombinant allergens provides new opportunities for the improvement of the diagnosis of immunoglobulin E (IgE) mediated allergies, given that they present capacity for binding these antibodies in a comparable way to natural allergens and generally show good reactivity in *in vitro* diagnostic test. For this reason, recombinant allergens are of a great interest to both the research field and the development of new diagnostic test for IgE quantification in the clinical routine.

The recombinant allergens developed by Rekom Biotech have been evaluated in an external study carried out at a Spanish hospital by a group of allergists with positive and negative serum samples from patients. In this study, it has been determined the presence of specific IgE in sera that had previously been validated by skin prick testing (SPT) and the UniCAP® test.

For the completion of this evaluation, an ELISA immunoassay was developed at the hospital that allowed the quantification of specific IgE in the patient sera and the collection of incidence data for each biomarker in the analysed population. This incidence was subsequently compared to the data described by bibliography, finding a complete correlation.

The measure of circulating IgE antibodies specific for a determined allergen provides information about the patient sensitisation to this allergen. In general, low IgE levels would indicate a low probability of developing a clinical disease, while high IgE levels would show a high correlation of developing disease.

Through an adequate diagnostic test incorporating our biomarkers, it would be possible to determine the allergen to which the patient is reacting and the levels of specific IgE to this allergen. This quantification will allow to predict more accurately the chance of the patient developing a disease, and thus the need for appropriate treatment.



INDOOR RECOMBINANT ALLERGENS

This group includes the allergens present in the feces of dust mites and cockroaches; and in animal dander.



INDOOR RECOMBINANT ALLERGENS

ANIMAL EPITHELIAL RECOMBINANT ALLERGENS

Dog (*Canis familiaris*)

Allergen name: Can f 1
Group: lipocalin
References: RAL0016

Allergen name: Can f 5
Group: arginine esterase, prostatic kallikrein
References: RAL0014

Horse (*Equus caballus*)

Allergen name: Equ c 1
Group: lipocalin
References: RAL0007

Cat (*Felis domesticus*)

Allergen name: Fel d 1
Group: uteroglobin (chain 1)
References: RAL0023

DUST MITES RECOMBINANT ALLERGENS

American house (*Dermatophagoides farinae*)

Allergen name: Der f 2
Group: NPC2 family
References: RAL0013

European house (*Dermatophagoides pteronyssinus*)

Allergen name: Der p 10
Group: tropomyosin
References: RAL0015

Storage mite (*Lepidoglyphus destructor*)

Allergen name: Lep d 2
Group: tropomyosin
References: RAL0008

POLLEN RECOMBINANT ALLERGENS

Pollen is a fine yellowish powder that is transported from one plant to another by wind, birds, insects and other animals. The spread of pollen helps to fertilize plants and causes innumerable allergies throughout the year in many people. This group contains pollens of trees and grasses.



POLLEN RECOMBINANT ALLERGENS

Mugwort (*Artemisia vulgaris*)

Allergen name: Art v 1
Group: defensin-like protein
References: RAL0005

Allergen name: Art v 3
Group: non-specific lipid transfer protein type 1 (LTP)
References: RAL0006

Silver birch (*Betula verrucosa*)

Allergen name: Bet v 1
Group: pathogenesis-related protein (PR-10)
References: RAL0011

Allergen name: Bet v 4
Group: polcalcic
References: RAL0009

Pellitory-of-the-Wall (*Parietaria judaica*)

Allergen name: Par j 2
Group: phospholipid transfer protein (LTP)
References: RAL0020

Olive (*Olea europaea*)

Allergen name: Ole e 1
Group: proteins similar to Ole e 1
References: RAL0012

Allergen name: Ole e 2
Group: profilin
References: RAL0010

London plane tree (*Platanus acerifolia*)

Allergen name: Pla a 1
Group: invertase inhibitor
References: RAL0019

Allergen name: Pla a 3
Group: non-specific lipid transfer protein type 1 (LTP)
References: RAL0021

Russian thistle (*Salsola kali*)

Allergen name: Sal k 1
Group: pectin methylesterase
References: RAL0018

POLLEN RECOMBINANT ALLERGENS

Timothy grass (*Phleum pratense*)

Allergen name: Phl p 1

Group: beta-expansin

References: RAL0001

Allergen name: Phl p 5a

Group: unkown

References: RAL0003

Allergen name: Phl p 5b

Group: unkown

References: RAL0017

Allergen name: Phl p 7

Group: polcalcin

References: RAL0002

Allergen name: Phl p 12

Group: profilin

References: RAL0004

POLLEN RECOMBINANT ALLERGENS



MOLD RECOMBINANT ALLERGENS

This group contains allergens present in outdoor molds, which live on the trunks and leaves of the trees, and indoor molds, located in warm and humid places such as bathrooms and kitchens.



MOLD RECOMBINANT ALLERGENS

Alternaria rot fungus (*Alternaria alternata*)

Allergen name: Alt a 1

Group: unkown

References: RAL0025

Quality management

Rekom Biotech is committed to ensure the highest quality level in the design and production of recombinant allergens intended for the *in vitro* diagnosis of type I allergic disorders.

Rekom Biotech products are designed, developed, produced and distributed according to our Quality Management System that is certified by ISO 9001 standards. Rekom recombinant allergens are always produced according to Standard Operating Procedures (SOPs) and undergo rigorous quality controls in our laboratories.



Each lot is subjected to various analyses:

- ▶ Concentration detection by spectrophotometry

The measurement of the protein concentration is performed with the theoretical extinction coefficient of the recombinant protein obtained from Gill and vonHippel, 1989.

For proteins which do not contain any Trp residues, experience shows that this could result in more than 10% error in the computed extinction coefficient. Therefore, we measure the protein concentration by using the colorimetric assay based on the interaction between Coomassie brilliant blue and the arginine and aromatic residues (Bradford Method) and its maximum absorption shifts from 470 nm to 595 nm (Bradford, 1976).

- ▶ Purity and integrity determination by SDS-PAGE

- ▶ Aggregates presence analysed by size-exclusion chromatography (SEC)

External validation

Our bioallergens have been evaluated in an external study carried out at a Spanish hospital by a group of allergists with positive and negative serum samples from patients. The evaluation of the recombinant allergens has been performed by means of an *in-house* ELISA assay. In this immunoassay, it has been determined the presence of specific IgE in sera that had previously been validated by skin prick testing (SPT) and the UniCAP® test. The sera panels specific for each group of allergens were composed of 25 positive sera and 10 total IgE negative specimen sera.

The following chart shows the good correlation found between the incidence rates described in bibliography and the incidence rates found in the external study carried out by the hospital with our bioallergens:



GROUP	ALLERGEN	REFERENCE	INCIDENCE RATES	
			BIBLIOGRAPHY	HOSPITAL VALIDATION
Timothy grass	Phl p 1	RAL0001	70%-100%	92%
	Phl p 5a	RAL0003	60%-93%	60%
	Phl p 5b	RAL0017	60%-93%	56%
	Phl p 7	RAL0002	10%	44%
	Phl p 12	RAL0004	20%	36%
Olive	Ole e 1	RAL0012	70%	100%
	Ole e 2	RAL0010	20%-47%	40%
Mugwort	Art v 1	RAL0005	70%	58%
Animal epithelial	Can f 1	RAL0016	90%	84%-100%
	Fel d 1	RAL0023	90%	76%-84%
Dust mites	Der f 2	RAL0013	98%	78%
	Der p 10	RAL0015	5.6%	5.6%
	Lep d 2	RAL0008	>75%	72%

ONGOING RESEARCH FOR OTHER ALLERGEN GROUPS

Allergen manipulation

STORAGE

Protein is shipped with dry ice. Upon arrival, it should be aliquoted in order to avoid repeated freezing and thawing cycles and stored at -20°C to -80°C . Proteins should be maintained frozen at high concentrations.

DEFROST

In order to defrost the protein, maintain the aliquot at 25°C without shaking to avoid aggregation.

MANIPULATION

Before making test dilutions and after the protein has been defrosted, it is recommended to remove possible protein aggregates by centrifuging the stock solution, avoiding alterations in the immobilisation of the biomolecule to the solid surface.

During shipment, small volumes of product will occasionally become entrapped in the seal of the product vial. For products with volumes of $200\ \mu\text{l}$ or less, we recommend tapping the vial on a hard surface or briefly centrifuging the vial in a tabletop centrifuge to dislodge any liquid in the containers cap. Although recombinant allergens are expressed in *Pichia pastoris* and non-pathogenic *E. coli*, in which bacterial integrity is destroyed during purification, the allergen preparation should be handled as potentially infectious.



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Can f 1	3	Phl p 7	6
Can f 5	3	Pla a 1	5
Der f 2	3	Pla a 3	5
Der p 10	3	Sal k 1	5
Equ c 1	3		
Fel d 1	3		
Lep d 2	3		
Ole e 1	5		
Ole e 2	5		



Certain uses of some of these products may violate existing or pending patent claims in a specific country. It is the user's responsibility to determine if the use of this product constitutes such a violation in the country where the recombinant allergen is going to be used. Rekom Biotech is not responsible for patent infringements or other violations that may occur by the use of this product in a specific country.



bioallergens 
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Agencia de Innovación y Desarrollo de Andalucía IDEA
CONSEJERÍA DE ECONOMÍA, INNOVACIÓN, CIENCIA Y EMPLEO



We are ISO 9001 certified
- ensuring commitment to quality standards globally -

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