ARTHUS-sIgE Controls

Artificial human sera (ARTHUS) for use in in-vitro systems for the determination of human specific IgE

For the development, production, evaluation, standardization and quality control of allergy in-vitro test systems, the availability of well-defined quality controls (positive sera) is required. However the availability of human control sera for different allergens is limited. Human control sera from commercial serum banks (often serum pools) are partly associated with variable quality and mostly with high costs.

Another challenge is the fact that allergen extracts in allergen-specific IgE assays may differ because of variations in the allergen source material, manufacturing process, storage conditions and acceptance criteria. No standardized reference controls for the determination of allergen-specific immunoglobulin (IgE) is available. The use of artificial human sera improves the quality of allergens used in in-vitro systems and provides a step towards standardization of systems for the allergy in-vitro diagnostic.

ARTHUS-sIgE controls are designed for the development, production, evaluation, standardization and quality control of allergy in-vitro test systems for the determination of human specific IgE (sIgE).

REF 07Axxxxx-01	∇̄Σ	1mL
REF 07Axxxxx-10	∇̄	10 mL

Available ARTHUS Controls

ARTHUS specific for	Allergen-Code	REF
Penicilloyl G	c1	07Ac0001 -01 / -10
Dermatophagoides pteronyssinus	d1	07Ad0001 -01 / -10
Peanut	f13	07Af0013 -01 / -10
Hazelnut	f17	07Af0017 -01 / -10
Alpha - Lactalbumin	f76	07Af0076 -01 / -10
Beta – Lactoglobulin	f77	07Af0077 -01 / -10
Phospholipase A	i11	07Ai0011 -01 / -10
Hevea brasiliensis	k82	07Ak0082 -01 / -10
Aspergillus fumigatus	m3	07Am0003 -01 / -10
Ves v 5 wasp venom	ri305	07ARI305 -01 / -10
Bet v 1 birch	rt301	07ART301 -01 / -10

Further ARTHUS-sIgE Controls on request!

Handling

ARTHUS-sIgE controls should be treated like patient sample and run in accordance with the instructions of the kit manufacturer.

Assingment of values

The target values for each lot are specified in the quality control certificates (QCC). The tests were performed by the manufacturer and/or independent laboratories.

Advantages of ARTHUS-sIgE

- ◢ solve the limited availability of human control sera even for rare allergens
- ◢ big volumes in constant quality available
- ◢ clean sera, no serum pools
- ◢ high stability of the controls
- ◢ long shelf life
- ◢ controls for recombinant allergens and allergen extracts available
- ◢ controls for almost all proteins possible

Performance data

A set of ARTHUS-sIgE controls specific to different allergens was evaluated in three established assay methods ImmunoCAP, ALLERG-O-LIQ and ALFA. Allergen-specific IgE concentrations and the corresponding class were calculated for each ARTHUS-sIgE control.

Source	Allergen	ImmunoCAP		Allerg-O-LIQ		ALFA	
		KU/L	Class	IU/mL	Class	U/mL	Class
Mites	d1	13,3	3	33,31	4	18,48	4
		3,61	3	14,61	3	6,78	3
		4,39	3	17,25	3	4,7	3
		3,16	2	7,4	3	8,98	3
	d2	12,5	3	12,26	3	6,33	3
		3	2	6,12	3	2,68	2
		3,73	3	4,82	3	1,75	2
		3	2	10,58	3	2,15	2
Trees	Bet v 1	7,7	3	4,31	3	9,37	3
		3,1	2	1,09	2	1,76	2
	t3	8,86	3	4,05	3	6,86	3
		3,98	3	1,43	2	1,57	2
Food	f17	8,22	3	21,96	4	6,52	3
		3,77	2	8,02	3	1,57	2
	f76	4,07	3	6,36	3	5,78	3
		1,88	2	1,16	2	2,28	2
	f77	16,8	3	12,89	3	19,31	4
		7,57	3	4,66	3	8,74	3
Occupation	k82	23,3	4	10,03	3	16,37	3
		6,93	3	3,42	2	2,38	2
Molds	m3	2,74	2	8,69	3	4,12	3
		0,83	2	3,2	2	1,16	2
Drugs	c1	11,4	3	16,84	3	13,97	3
		4,84	3	5,47	3	3,49	2

Figure 2
ARTHUS-sIgE controls in three established assay methods: ImmunoCAP (Thermo Scientific), ALLERG-O-LIQ and ALFA (Dr. Fooke Laboratorien).
d1: Dermatophagoides pteronyssinus, house dust mite; d2: Dermatophagoides farinae, house dust mite; t3: Betula verrucosa, birch; f17: Corylus avellana, hazelnut; f76 and f77: Bos domesticus, cow´s milk; k82: Hevea brasiliensis, latex; m3: Aspergillus fumigatus, mold; c1: Penicilloyl G.

Titrations of ARTHUS-sIgE controls specific to d1, f17 and Bet v 1 were performed in three established diagnostic systems (ImmunoCAP, ALLERG-O-LIQ and ALFA). Correlation coefficients were calculated by Pearson correlation between the results from ALLERG-O-LIQ and ALFA vs ImmunoCAP. Correlation coefficients reach from 0,98 to 1,00.
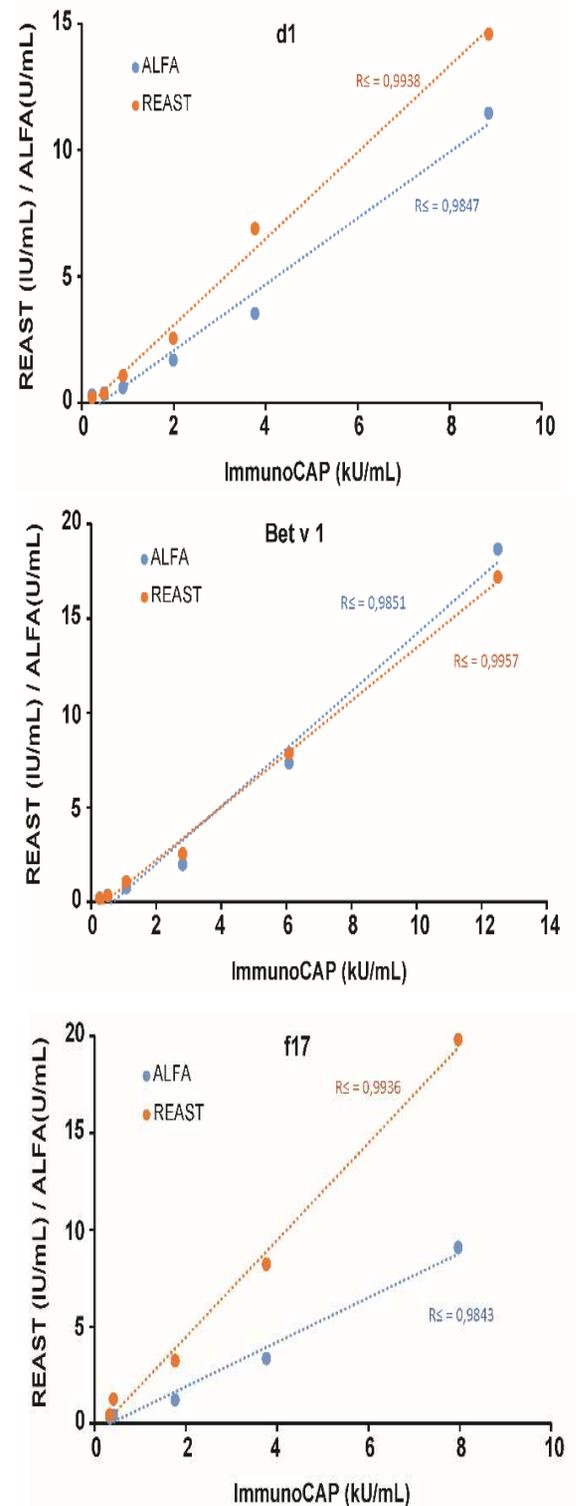
Figure 3
Pearson correlation of different ARTHUS-sIgE titrations tested with ImmunoCAP, ALLERG-O-LIQ and ALFA (2).

Literature

1. Pawankar R. 2014. Allergic diseases and asthma: a global public health concern and a call to action. World Allergy Organ J 7: 12
2. Offermann N, Plum M, Hubner U, Rathloff K, Braren I, Fooke M, Spillner E. 2016. Human serum substitution by artificial sera of scalable allergen reactivity based on polyclonal antibodies and chimeras of human FcgammaRI and IgE domains. Allergy 71: 1794-9

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