



More than 25 years experience

Dr. Fooke Laboratories are dedicated to developing, producing and distributing modern and innovative tests for in-vitro allergy and autoimmune diagnostics. Advanced in-vitro allergy and autoimmune test systems are the result of our developments leading to a product line that offers almost every user a custom tailored solution exactly matching his needs.

A leading allergy diagnostics company

As a medium size high tech. company, we are free to respond fast, flexibly and individually to our customers. We stay at your service, ready to answer any technical or theoretical question concerning immunology, allergy and autoimmune diagnosis and develop new concepts and solutions together with you. Because by giving you this best imaginable service we also gain your practical and precious inputs to stimulate our R & D work.

Quality Management

Since many years our company is certified according to DIN EN ISO 9001 and DIN EN ISO 13485.

Our bioanalytic department is accredited according to DIN EN ISO/IEC 17025.

Our Team

Our team of highly qualified professionals such as biologists, bioengineers and medical device consultants take care of the continuous advancement and optimization of our product range and are available for any questions. Whether it concerns a product demonstration in your lab, practical or theoretical question, we are there for you.

Allergy Lateral Flow Assay

What do you expect from modern allergy diagnostics? With our rapid test ALFA - Allergy Lateral Flow Assay – we offer you a 15-20 minute first line screening test for allergen specific IgE or Total IgE. With the addition of recombinant allergens more detailed information about sensitization patterns and treatment concepts of patients can be provided.

DR FOOKE

ALFA (Allergy Lateral Flow Assay)

Rapid test for the qualitative determination of allergen specific IgE (sIgE) in whole blood, serum or plasma

The worldwide frequency of allergies has increased significantly over the past decades. The term allergy is used for type I hypersensitivity reactions (immediate type reactions), whose symptoms generally occur within 30-60 minutes after contact with the allergen. The most frequent symptoms are: hay fever (rhinitis), conjunctivitis, hives (urticaria), allergic asthma and as the most dangerous manifestation anaphylaxis (the anaphylactic shock). The allergens causing type I hypersensitivity reactions are mostly proteins derived from the natural environment e.g. plant pollen, animal hair, food, mites and insect venoms. A characteristic of type I allergies is the involvement of allergen specific immunoglobulins (antibodies) of class E (sIgE). Hence, the detection of sIgE is an important tool of modern allergy diagnostics.

ALFA (Allergy Lateral Flow Assay) is a rapid test for the qualitative determination of allergen specific Immunoglobulin E (sIgE).

slgE ALFA Specifications

- ▲ Serum, plasma and whole blood applicable
- ▲ Large palette of single allergens and allergen mixtures available (see current list of ALFA allergens)
- ▲ Recombinant and native, highly purified allergen components are available (see current list of recombinant and native allergens)
- ▲ Test results in 20 min
- ▲ Quantitative evaluation and documentation with the help of the LFA (Lateral Flow Assay) Reader in Units (U/mL) and Classes, analog to RAST Classes, possible
- ▲ Excellent correlation with skin prick test and other in-vitro test methods for sIgE (Figure 2 und 3)

ALFA single-strip cassette REF 1800010	▽	20
ALFA eight-strip cassette REF 184000	▽	80

ALFA Test procedure

ALFA consists of a uniform test device - the ALFA Basis Set - in combination with several arbitrary single- or allergen-mixture-solutions (screens).

The sample (serum, plasma or whole blood) is transferred onto the sample application point of the Basis Set. Immediately afterwards the desired allergen solution is added.

After 20 minutes the result can be evaluated based on the test line (T). The functionality of the test is evaluated based on the control line (C).

Two different test formats are available, a single-strip and an eight-strip cassette.

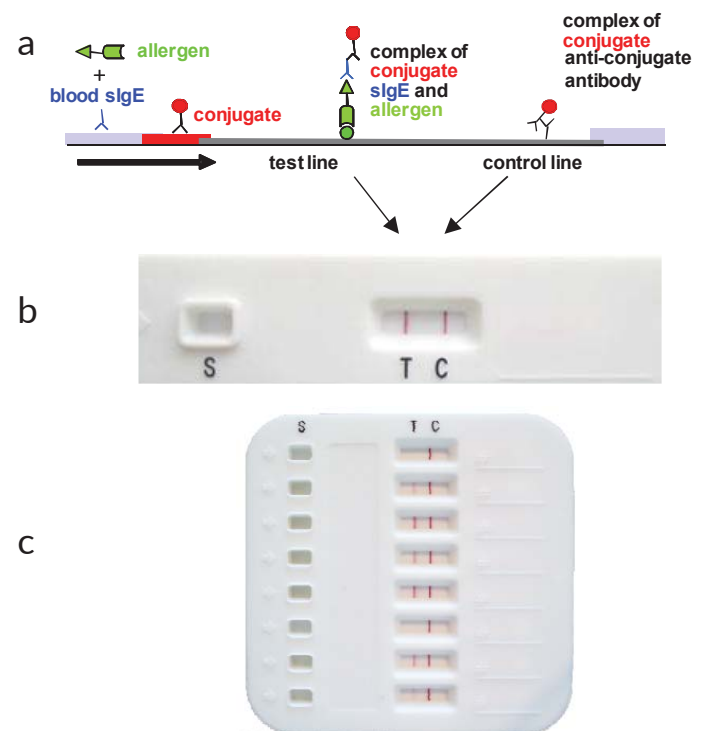


Figure 1
a) Test principle ALFA, b) Positive result (single-strip cassette),
c) Different results (eight-strip cassette).

LIST of ALFA Allergens

ALFA allergens for use in combination with ALFA Basis Set (single or 8-strips)

Panel 1 General screening
PIS Perennial inhalants fx5 food mix e1 Cat e5 Dog

Panel 2 Infant allergy
f2 Cow 's Milk f76 Alpha-Lactalbumin f77 Beta-Lactoglobulin f78 Casein f1 Egg white f68 Ovomuroid fx5 Food mix fx 3 Nut mix

Panel 3 Childhood allergy
d1 D. pteronyssinus d5 Blomia tropicalis e1 Cat e 5Dog i6 German cockroach f252 Egg f2 Milk f13 Peanut

Panel 4 Indoor allergy
d1 D. pteronyssinus d2 D. farinae d5 Blomia tropicalis e1 Cat e 5Dog i6 German cockroach i14 American cockroach mx1 Mould mix

Panel 5 Seasonal allergy (with possible exposure)
g001 Sweet Vernal Grass 黄花草 g002 Bermuda Grass 狗牙根 g004 Meadow fescue 草甸羊茅 g005 Perennial Rye Grass 黑麥草 g006 Timothy Grass 梯牧草 t003 Birch 白樺樹花粉 w001 Ambrosia elatior 豚草 w006 Mugwort 艾蒿

PIS: Der p, Der f, German cockroach, Aspergillus
f5x: cow's milk, cod fist, wheat, peanut, soy, hazelnut
f3x: walnut, hazelnut
mx1: Cladosporium, Aspergillus, Alternaria

Other ALFA allergens

Mite
d005 Blomia tropicalis 熱帶無爪蟎
d002 Dermatophagoides farinae 粉塵蟎
d004 Dermatophagoides Microceras 微角塵蟎
d001 Dermatophagoides pteronyssinus 屋塵蟎
d003 Euroglyphus maynei 梅氏嗜霉蟎
d070 Acarus siro 粗腳粉蟎

Weed Pollens
w015 Scale 龍鬚菜
w019 Parietaria judaica 猶太牆草
w020 Nettle 蕁麻
w021 Parietaria officinalis 牆草
w029 Sunflower 向日葵

Moulds
m001 Penicillium notatum 青霉菌
m002 Cladosporium herbarum 蠟葉芽枝黴
m003 Aspergillus fumigatus 煙曲霉
m004 Mucor racemosus 白色念珠菌
m005 Candida albicans 細鏈格泡
m006 Alternaria alternata 細鏈格泡
m008 Helminthosporium halodes 蟻孢霉
m033 Aspergillus niger 黑曲霉
m046 Saccharomyces ellipsoideus 葡萄汁酵母

Epithelia and Feathers
e001 Cat 貓毛
e005 Dog 狗毛
e010 Parrot 鸚鵡毛
e081 Sheep 羊毛
e082 Rabbit 兔毛
e085 Chicken 雞毛
e003 Horse (Dander) 馬毛
e004 Cow (Dander) 牛毛
e006 Guinea Pig (Hair) 豚鼠毛
e011 Pigeon (Feathers) 鴿子毛
e084 Goldhamster 倉鼠毛
e088 Mouse (Dander+Protein) 老鼠毛

Tree Pollens
t001 Maple 楓樹花粉
t002 Alder 杞木花粉
t003 Birch 白樺樹花粉
t004 Hazel 榛樹花粉
t005 Beech 樺木花粉
t007 Oak 櫟樹花粉
t009 Olive 橄欖樹花粉
t011 Plane 懸鈴木
t012 Willow 柳樹花粉
t014 Poplar 白楊花粉
t015 Ash 白腊樹花粉
t023 Cypress 柏樹花粉

Allergen mix
tx1 (t2, t3, t4)
tx2 (t9, t23)
tx4 (t1, t3, t5, t7, t11, t14)
gx1 (g3, g4, g5, g6, g8)
gx2 (g1, g5, g7, g12, g13)
mx1 (m2, m3, m6)
ex1 (e1, e5)
wx1 (w1, w6, w9)
wx2 (w1, w19, w21)
wx32 (w1, w6, w8, w9)
dx1 (d1, d2, d3, d4)
fx1 (f49, f73, f84)
fx2 (f85, f31)
fx3 (f16, f17)
fx5 (f1, f2, f3, f4, f13, f14, f17)

Insects
i001 Bee 蜜蜂
i003 Wasp 黃蜂
i006 German cockroach 德國蟑螂
i007 Hornet Venom 胡蜂
i071 Mosquito 蚊子
i014 American cockroach 美洲蟑螂

Grass Pollens
g001 Sweet Vernal Grass 黄花草
g002 Bermuda Grass 狗牙根
g003 Orchard Grass 雞腳草
g004 Meadow fescue 草甸羊茅
g005 Perennial Rye Grass 黑麥草
g006 Timothy Grass 梯牧草
g007 Common Reed 蘆葦
g008 June Grass 草地早熟禾
g011 Brome Grass 雀麥草
g012 Rye 黑麥
g013 Holcus lanatus (Velvet grass) 絨毛草
g020 Corn 玉蜀黍
g021 Couch Grass 茅草

Weed Pollens
w001 Ambrosia elatior 豚草
w006 Mugwort 艾蒿
w007 Ox Eye Daisy 牛眼菊
w008 Dandelion 蒲公英
w009 English Plantain 長葉車前草

Others
k082 Latex 乳膠
c001 CCD 交叉反应性碳水化合物决定因子

Food
Milk & Derivatives
f002 Cow 's Milk 牛奶
f076 Alpha-Lactalbumin Alpha 乳清蛋白
f077 Beta-Lactoglobulin Beta 乳清蛋白
f078 Casein 酪蛋白
f081 Cheddar Cheese 切達奶酪
f219 Goat 's milk 山羊奶

Egg & Fractions
f001 Egg White 蛋白
f067 Ovalbumin 卵清蛋白
f068 Ovomucoid 卵類黏蛋白
f075 Yolk 蛋黃
f252 Whole egg 雞蛋

Flour
f004 Wheat flour 麵粉
f005 Rye Flour 黑麥粉
f006 Barley flour 大麥
f007 Oat Flour 燕麥粉
f008 Corn Flour 玉米粉
f009 Rice 米
f011 Buckwheat Flour 小麥麩皮麵粉
f079 Gluten 麩質

Fruits
f029 Banana 香蕉
f030 Pear 梨
f032 Lemon 檸檬
f033 Orange 橙
f034 Tangerine 柑橘
f044 Strawberry 草莓
f049 Apple 蘋果
f050 Grape (white) 白葡萄
f053 Peach 桃
f073 Cherry 櫻桃
f084 Kiwi 奇異果
f091 Mango 芒果
f092 Grapefruit 葡萄柚
f122 Olive green 綠橄欖
f156 Raspberry 覆盆子
f248 Date 棗
f286 Kaki 柿子
f301 Grape (blue) 藍葡萄

Food
Seafood
f003 Cod Fish 鱈魚
f023 Crab 蟹
f024 Syrimp 蝦
f040 Tuna 吞拿魚
f041 Salmon 三文魚
f080 Lobster 龍蝦
f174 Mackerel 鯖魚

Meat
f026 Pork 豬肉
f027 Beef 牛肉
f083 Chicken meat 雞肉
f130 Turkey 火雞肉
f167 Rabbit 兔肉

Nuts & Seeds
f010 Sesame (bruised grain) 芝麻
f013 Peanut 花生
f016 Walnut 核桃
f017 Hazelnut 榛子
f020 Almond 杏仁
f052 Chocolate 巧克力
f144 Pistachio Nut 開心果
f158 Cashew Nut 腰果

Vegetable
f012 Pea 豌豆
f014 Soy 大豆
f015 White Bean 白豆
f025 Tomato 蕃茄
f031 Carrot 胡蘿蔔
f035 Potato 馬鈴薯
f039 Cabbage 捲心菜
f047 Garlic 大蒜
f048 Onion 洋蔥
f061 Cauliflower 椰菜花
f085 Cerleriac 芹菜
f134 Broccoli 西蘭花
f136 Beet Root 紅菜頭
f151 Zucchini 夏南瓜

Recombinant (R) and native (N) allergens
ND 11 ALFA Der p1 (Der. pt.)
ND 12 ALFA Der p2 (Der. pt.)
ND 21 ALFA Der f1 (Der. far.)
ND 22 ALFA Der f2 (Der. far.)
NF131 ALFA Ara h 1 (Peanut)
NF 132 ALFA Ara h 2 (Peanut)
NF 133 ALFA Ara h 3 (Peanut)
NF 136 ALFA Ara h 6 (Peanut)
RF 139 ALFA Ara h 9 (Peanut)
NF 024 ALFA Tropomyosin (Shrimp)
NW 101 ALFA Amb a 1 (Common Ragweed)
RE 11 ALFA Fel d1 (Cat)
RT401 ALFA Cor a 1 (Hazelnut)
RF 171 ALFA Cor a 1 (Hazelnut)
RF 178 ALFA Cor a 8 (Hazelnut)
NF 179 ALFA Cor a 9 (Hazelnut)
Rf 180 ALFA Cyp c1 (Carp)
RF 311 ALFA Dau c1 (Carrot)
RF 419 ALFA Tri a 19 (Wheat)
RF 441 ALFA Fra a 1 (Strawberry)
RF 443 ALFA Fra a 3 (Strawberry)
RF 491 ALFA Mal d1 (Apple)
RF 493 ALFA Mal d3 (Apple)
RF 531 ALFA Pru p 1 (Peach)
RF 533 ALFA Pru p 3 (Peach)
RF 534 ALFA Pru p 4 (Peach)
RG 601 ALFA Phl p1 (Timothy Grass)
RG 612 ALFA Phl p12 (Timothy Grass)
RG 605 ALFA Phl p5 (Timothy Grass)
RG 607 ALFA Phl p7 (Timothy Grass)
RG 620 ALFA Phl p1 and 5 (Timothy Grass)
RG 621 ALFA Phl p7 and 12 (Timothy Grass)
RI 101 ALFA Api m 1 (Bee Venom)
RI 102 ALFA Api m 2 (Bee Venom)
RI 305 ALFA Ves v 5 (Wasp Venom)
RK 825 ALFA Hev b5 (Latex)
RK 826 ALFA Hev b6 (Latex)
RK 827 ALFA Hev b7 (Latex)
RK 828 ALFA Hev b8 (Latex)
RT 301 ALFA Bet v1 (Birch)
RT 302 ALFA Bet v2 (Birch)
RT 304 ALFA Bet v4 (Birch)
RT 901 ALFA Ole e 1 (Olive)
RW 601 ALFA Art v1 (Artemisia vulgaris)

Evaluation of a scanner based allergy lateral flow assay system for the determination of specific IgE within 20 minutes

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Background: Type I hypersensitivity is caused by allergen specific immunoglobulin E (sIgE) and thus sIgE represents a marker for modern allergy diagnosis. ALFA (Allergy Lateral Flow Assay) is a rapid test for the qualitative determination of sIgE in human serum, plasma or whole blood. The use of a special scanner system provides the opportunity of semi-quantitative interpretation of ALFA results (see figure 1). The objective of the study is the evaluation of a rapid test for the semi-quantitative interpretation of sIgE compared with other *in-vitro* and *in-vivo* methods.

Methods: Agreement between ALFA (Dr. Fooke Laboratories) and ImmunoCAP® (ThermoScientific) was investigated using 72 sera tested for specific IgE to *Dermatophagoides pteronyssinus* (d1), *Dermatophagoides farinae* (d2), timothy grass pollen (g6), birch pollen (t3) and hazel pollen (t4). Receiver Operating Characteristic (ROC) analysis and spearman correlations were performed for every single allergen separately and for all five allergens together. Skin Prick test results and/or nasal provocation results (Roxall) of more than 40 patients were compared to both *in-vitro* methods.

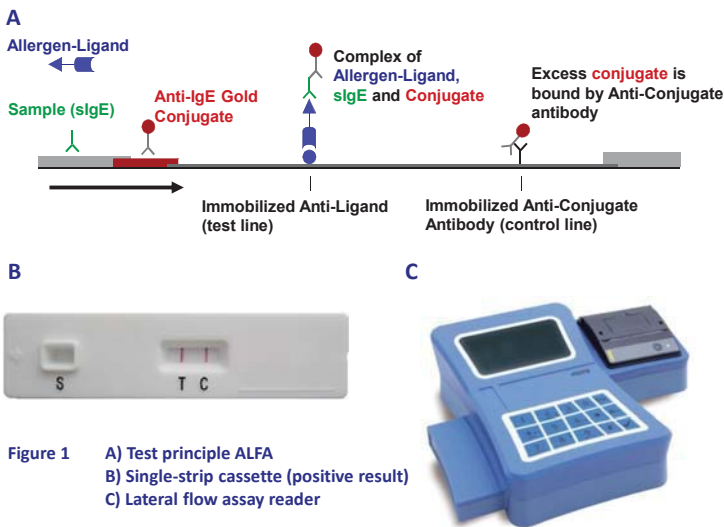


Figure 1 A) Test principle ALFA
B) Single-strip cassette (positive result)
C) Lateral flow assay reader

Results and findings: Excellent agreements were observed between ALFA results and ImmunoCAP® results. Area under the curve (AUC) values were found at > 0.95 for every allergen (see table 1) and 0.97 for all allergens (see figure 2A) compared to ImmunoCAP® results.

Table 1 Agreement between ImmunoCAP® and ALFA results for d1, d2, g6, t3 and t4 (n=72 patient samples).

Allergen	Number of negative / positive results with ImmunoCAP®		ALFA vs ImmunoCAP®		
	neg	pos	AUC	Sensitivity (%)	Specificity (%)
d1 (<i>Der. pteronyssinus</i>)	25	47	0.95	91.5	92.0
d2 (<i>Der. farinae</i>)	26	49	0.97	91.3	96.2
g6 (Timothy Grass)	14	58	0.97	96.6	92.9
t3 (Birch)	19	53	0.97	96.2	89.5
t4 (Hazel)	21	51	0.97	92.2	90.5

Agreements between ALFA and ImmunoCAP® according to Spearman were found at 0.92 for d1 (Confidence interval, CI 0.87-0.95), 0.92 for d2 (CI 0.97-0.95), 0.96 for g6 (CI 0.94-0.98), 0.95 for t3 (CI 0.92-0.97) and 0.91 for t4 (CI 0.86-0.94).

Spearman correlation between ALFA and ImmunoCAP® for all five allergens reveals a coefficient of 0.93 (CI 0.91-0.94, see figure 2B).

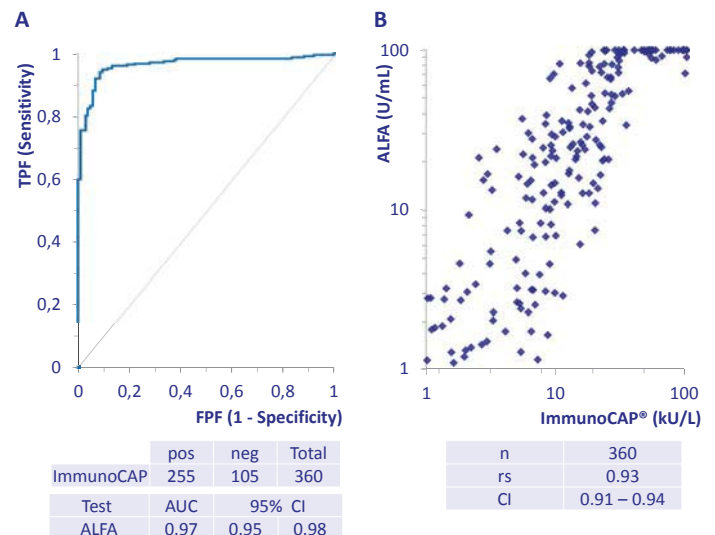


Figure 2 A) ROC analysis for ALFA vs. ImmunoCAP® for five different allergens (d1, d2, g6, t3 and t4) with n=360 results.
B) Spearman correlation between ALFA and ImmunoCAP® for five different allergens (d1, d2, g6, t3 and t4) with n=360 results.

AUC values of both *in-vitro* systems compared to 211 *in-vivo* results were found > 0.95. Compared to *in-vivo* results ALFA show a sensitivity of 0.96 (CI 0.92-0.98) and specificity of 0.85 (CI 0.74-0.92). Sensitivity and specificity between *in-vivo* results and ImmunoCAP® were found at 0.95 (CI 0.90-0.98) and 0.81(CI 0.71-0.89), respectively.

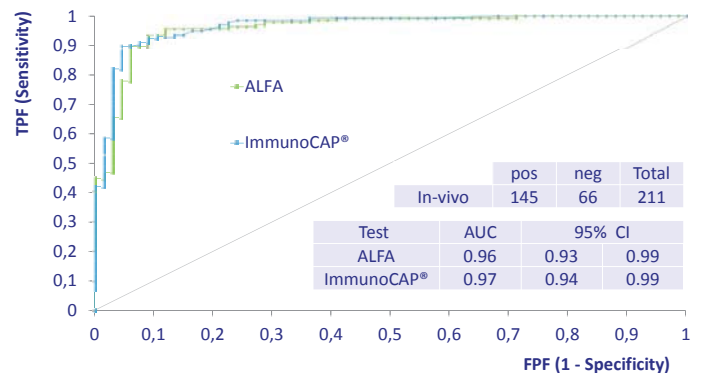


Figure 3 ROC analysis for ALFA (green) and ImmunoCAP® (blue) vs. *in-vivo* results for five different allergens (d1, d2, g6, t3 and t4) with n=211 results.

Conclusion: For the detection of sIgE, ALFA shows results of high sensitivity and specificity when compared to ImmunoCAP® and *in-vivo* results. AUCs of > 0.95 indicates a nearly identical performance between ImmunoCAP® and ALFA. The correlation for ALFA versus ImmunoCAP® is also comparable with spearman's rho ≥ 0.91 for each tested allergen. The high sensitivity of the ALFA is supported by the Lateral Flow Assay Reader, especially for weak positive results.

References:

- Pfender N, Lucassen R, Offermann N, Schulte-Pelkum J, Fooke M, Jakob T. 2012. Evaluation of a Novel Rapid Test System for the Detection of Specific IgE to Hymenoptera Venoms. J Allergy (Cairo) 2012: 862023

In relation to this presentation, we declare that there are no conflicts of interest

Presented at EAACI Helsinki 2017

Lateral Flow Assay Reader

Mobile measuring device for the evaluation and documentation of rapid tests

The LFA (Lateral Flow Assay) Reader is a mobile measuring device for the quantitative evaluation and documentation of ALFA (Allergy Lateral Flow Assay) and AI-LFA (Autoimmune Lateral Flow Assay), rapid tests for the determination of sIgE (ALFA) and autoimmune parameters (AI-LFA)



Figure 1 LFA Reader

LFA Reader REF 190002

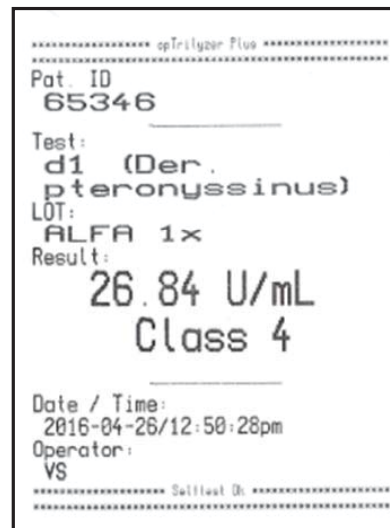


Figure 2
Report printout LFA Reader for ALFA

LFA Reader Specifications

- ▲ Quantitative Evaluation
 - Measuring results in Units for ALFA (U/mL) and AI-LFA (RU)
 - Allocation in classes analog to RAST classes for ALFA
- ▲ Documentation of the results by
 - Printout (provided printer)
 - Storage on the internal memory of the device
 - Export of results
- ▲ Simplified use by an integrated Barcode Scanner for importing allergens, antigens and patient samples
- ▲ Single- and eight-strip cassettes can be read

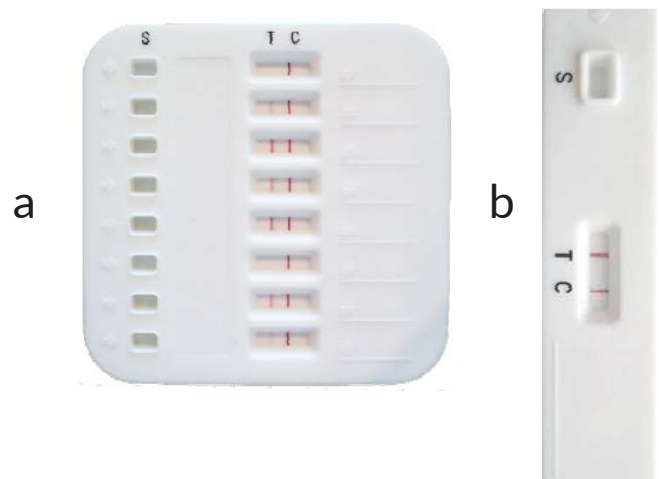


Figure 3
a) different results eight-strip cassette, b) positiv result single-strip cassette

ALFA Total IgE

Rapid assay for the qualitative determination of Total IgE in whole blood, serum or plasma

Allergic reactions of the immediate type (type I allergies) are mediated by allergen specific immunoglobulins of class E (sIgE). The normal serum IgE concentration is age dependent with a peak at the age of 6-15 years. The occurrence of allergen specific IgE is often accompanied by increased titers of total IgE in the blood of the patients. In these cases the titer can increase up to 1000fold. Usually, IgE concentrations are determined in international units per millilitre (IU/mL) whereat 1 IU/mL corresponds to 2.4 ng of IgE. Highest IgE concentrations occur in patients with atopic dermatitis in which they often reach levels of 50.000 IU/mL. Moreover, increased titers of IgE can be observed e.g. in patients with parasitic diseases. Deviations to the normal values have also been described in patients with certain autoimmune disorders

ALFA (Allergy Lateral Flow Assay) Total IgE is a rapid assay for the qualitative determination of total IgE in human serum, plasma or whole blood. ALFA Total IgE is designed as a screening test which allows a fast and easy detection of increased and highly increased Total IgE titers. Furthermore the test can be used in laboratories as validity check and confirmatory test, respectively.

ALFA Total IgE REF 183000 ∇ 20

ALFA Total IgE Test procedure

ALFA Total IgE consists of a test device – the ALFA Total IgE Basis Set – in combination with an Anti-IgE Solution.

Immediately after application of the sample (serum, plasma or whole blood) onto the sample application point of the Basis Set, the Anti-IgE Solution is applied.

After 25-30 min the result of the test line (T) can be assessed by the help of an evaluation card. The functionality of the test is determined by the control line (C).

ALFA Total IgE Specifications

- ▲ Serum, plasma and whole blood can be used
- ▲ Short assay time (Resultat after 25 - 30 min)
- ▲ Very good correlation to Total IgE EIA (08102CP)

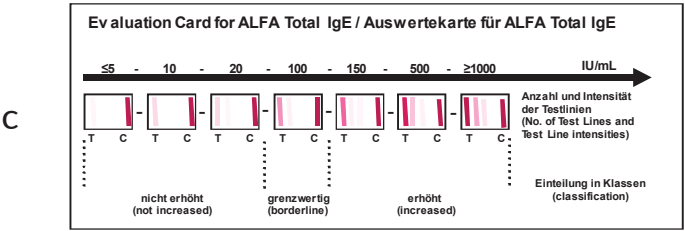
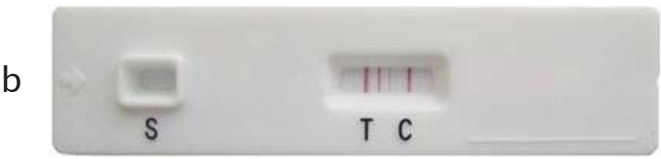
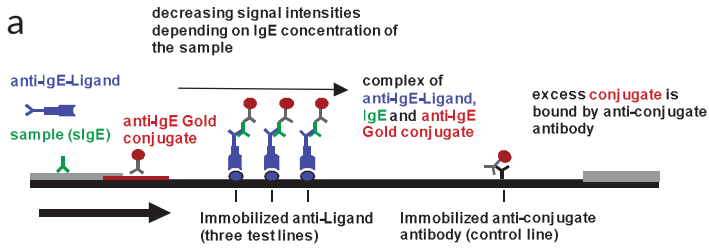


Figure 1
a) Principle of ALFA Total IgE, b) Test Cassette, c) ALFA Total IgE Evaluation Card.

Agreement to Total IgE EIA

Very good agreement between ALFA Total IgE and Total IgE EIA (Pearson's correlation = 0.931).

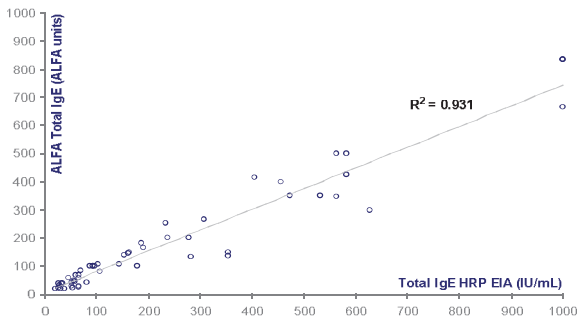


Figure 2

Pearson's correlation (mean of three observers) between ALFA Total IgE and Total IgE ELISA.

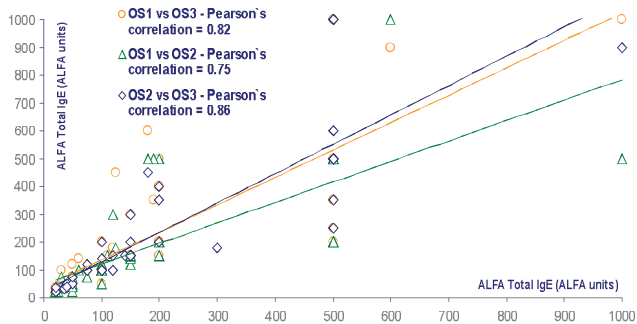


Figure 3

Pearson's correlation of ALFA Total IgE results between observer (OS) 1, 2 and 3.

Literature

1. Antibody IV. Presence of a Unique Immunoglobulin as a Carrier of Reaginic Activity. J Immunol 1966, 97:75-85
2. Wittig H, Bellot J, Fillippi I, and Royal G: Age-related Serum IgE Levels in Healthy Subjects and in Patients with Allergic Disease. J Allergy Clin Immunol 1980, 66:305-313
3. Lucassen R, Mahler M, Fooke M: Development and evaluation of a new rapid assay for semi-quantitative detection of total IgE in human serum and capillary blood. 27th Congress of the European Academy of Allergology and Clinical Immunology held in Barcelona, Spain 2008.

Reproducibility of ALFA Total IgE

Data on the reproducibility of ALFA Total IgE is shown in Table 1.

sample ID	IU/mL Total IgE	ALFA Total IgE VB1				ALFA Total IgE VB2				ALFA Total IgE VB3				Mean CV%
		Assay 1	Assay 2	Assay 3	CV%	Assay 1	Assay 2	Assay 3	CV%	Assay 1	Assay 2	Assay 3	CV%	
1	21	20	20	20	0	20	20	20	0	20	20	20	0	0
2	54	35	35	50	18	50	50	50	0	35	50	50	16	11
3	104	100	100	100	0	100	100	100	0	100	150	100	20	7
4	145	100	150	150	18	150	150	150	0	150	150	100	18	12
5	188	150	200	200	13	200	200	200	0	200	150	200	13	9
6	1000	1000	1000	1000	0	1000	500	1000	28	1000	500	1000	28	19

Table 1

Reproducibility of ALFA Total IgE results (IU/mL, Inter-Assay/ Inter-Batch variation)



Hong Kong and Macau Distributor

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