Dr. Fooke-Achterrath Laboratorien GmbH, Habichtweg 16, D-41468 Neuss

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17.11.2023

Annex to the Declaration of Conformity

To whom it may concern:

Dr. Fooke-Achterrath Laboratorien GmbH, Habichtweg 16, 41468 Neuss, Germany declares that the following list of allergens is the detailed information of the Product Name "Allergen-coupled Discs (Single Allergen, Allergen Mixes)" with the Product Number "Allergen Code", mentioned in the Declaration of Conformity.

Item code	Description
c 00068	Articaine
c 00082	Lidocaine
c 00088	Mepivacaine
c 00196	Epinephrine
c 00108	Ciprofloxacine
c 00125	Dexametazone
c 00056	Amoxiciline
c 00055	Cephalosporin
c 00153	Metronidazol
c 00089	Bupivacain
c 00172	Ketoprofen
c 00194	Azithromycin
c 00170	Clarithromycin
c 00083	Procain
c 00210	Tetracain

Sincerely,

DR FOOKE LABORATORIEN GMBH Habichtweg 16 · 41468 Neuss Tel (0 21 31) 29 84-0 · Fax (0 21 31) 29 84-184

Dr. Margrit Fooke-Achterrath
General Manager

Dr. Fooke-Achterrath Laboratorien GmbH, Habichtweg 16, D-41468 Neuss

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EC-Declaration of Conformity

For the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices

Product Name: **Allergene-coupled Discs (Sinlge Allergens, Allergen Mixes)**

Product Number: **Allergene Code**

The product is designed and manufactured for the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices in the sole responsibility of:

DR. FOOKE-ACHTERRATH Laboratorien GmbH
Habichtweg 16
D-41468 Neuss
Germany

The product meets all applicable requirements of Directive 98/79/EC.
The conformity assessment procedure followed Directive 98/79/EC Annex III.

This declaration is valid until 25th May 2027.

Neuss, 18th May 2022

DR. FOOKE-ACHTERRATH Laboratorien GmbH

Dr. Margrit Fooke-Achterrath
- General Manager -

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EG-Konformitäts-Erklärung

im Sinne der Richtlinie 98/79/EG über In-vitro-Diagnostika

Product Name: **Quantitative Reference System with 6 Standards**

Product Number: **076000PQ**

The declaration of conformity is valid for the kit and the components included in the kit.

Produkt-Name		Produkt-Nummer
Quantitative Reference System with 6 Standards		**076000PQ**
Anti-IgE Reference discs	CALDISC	760007
Calibrator (0,35 IU/mL)	CAL	760001
Calibrator (0,7 IU/mL)	CAL	760002
Calibrator (3,5 IU/mL)	CAL	760003
Calibrator (17,5 IU/mL)	CAL	760004
Calibrator (50 IU/mL)	CAL	760005
Calibrator (100 IU/mL)	CAL	760006

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Neuss, 18th May 2022

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EC-Declaration of Conformity

For the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices

Product Name: **Specific IgE EAST – Conjugat Kit**

Product Number: **0560200PKL, 0561000PKL**

The declaration of conformity is valid for the kit and the components included in the kit.

Product Name		Product Number	
Specific IgE EAST – Conjugat Kit		**0560200PKL**	**0561000PKL**
Anti IgE Enzyme-Conjugate	CONJ AP E	560202	561002
Concentrated Washing Buffer (50x)	WASHBUF C 50x	560201	561001
Substrate Buffer	SUBBUF	560203	561003
Stop Solution (1 N NaOH)	STOP NAOH	560204	561004

The kit and its components were designed and manufactured for the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices in the sole responsibility of:

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Neuss, 18th May 2022

DR. FOOKE-ACHTERRATH Laboratorien GmbH

Dr. Margrit Fooke-Achterrath
- General Manager -

Certificate

mdc medical device certification GmbH
certifies that

Dr. Fooke-Achterrath Laboratorien GmbH
Habichtweg 16
41468 Neuss
Germany

for the scope

development, manufacturing and distribution of in vitro diagnostics for allergy and auto immune diagnosis as well as in vitro diagnostics for the determination of parameters in the infection serology

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-07-28
Valid until	2025-07-27
Registration no.	D1060800022
Report no.	P22-00403-230765
Stuttgart	2022-07-28

Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
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Phone: +49-(0)711-253597-0
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Internet: http://www.mdc-ce.de

CE IVD 2°C 8°C

Please read instructions for use before starting the assay

Specific IgE EAST

Enzym-Allergo-Sorbent-Test for the quantitative determination of allergen-specific IgE in human serum or plasma

REF 0560200PKL Σ 200 Determinations

REF 0561000PKL Σ 1000 Determinations

BACKGROUND

The worldwide frequency of allergies has increased significantly over the past decades. The term allergy is often 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.

The characteristics 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.

INTENDED USE

The Specific IgE EAST is intended for the quantitative determination of sIgE in human serum or plasma. The results add to the diagnosis of type I allergies.

PRINCIPLE

The Specific IgE EAST for the quantitative measurement of specific IgE is carried out in mircotiterplates. During the first incubation step patient specimens are incubated on allergen coupled discs. Surplus serum components are removed from the well by washing whereas allergen specific IgE remains bound. Subsequently, alkaline phosphatase (AP)-labelled antibody is added forming allergen/-sIgE/anti-IgE conjugate complexes.

The wells are washed again, and the substrate solution p-nitrophenyl-phosphat (pNPP) is added and incubated, resulting in the development of a yellow colour if conjugate is present.

After stopping the enzymatic reaction with Sodium hydroxide (NaOH) the optical density (OD) of the coloured reaction product is measured spectrophotometrically at 405 nm (reference wave length 620 nm). The sIgE concentration of the patient sample is proportional to the OD. Calibrators with defined concentrations of IgE (calibrated against WHO) are assayed simultaneously with the patient samples to generate a calibration curve. Unknown IgE concentrations of the test samples are calculated from this curve.

KIT COMPONENTS

Enzyme kit	REF	**0560200PKL 0561000PKL**
Anti IgE Enzyme-Conjugate	CONJ AP E	1 x 10.4 mL 1 x 52 mL
Concentrated Washing Buffer (50x)	WASHBUF C 50x	1 x 30 mL 1 x 160 mL
Substrate Buffer	SUBBUF	1 x 50 mL 1 x 250 mL
Substrate Tablets	SUB PNPP	10 x 5 mg 50 x 5 mg
Stop Solution (1 N NaOH)	STOP NAOH	1 x 10 mL 1 x 52 mL

MATERIAL NEEDED, BUT NOT INCLUDED IN THE KIT

1. Reference unit	REF	**076000PQ**
Anti-IgE Reference discs	CALDISC	75 pieces
Calibrators (0.35, 0.7, 3.5, 17.5, 50, 100 IU/mL)	CAL (1-6)	6 x 0.8 mL

2. Allergen discs	REF	**Allergen-code**

3. Controls	REF	**07001/ 07002**
Positive Control	CONTROL +	1 x 0.5 mL
Negative Control	CONTROL −	1 x 0.5 mL

LABORATORY EQIUPMENT:

pipettes 10-100 µL, 200-1000 µL, Multipette, pipette tips, tubes for dilution of the specimens, graduated glass cylinder, ELISA-reader, covering foil, microplate-washer, incubator (optional), lab watch, distilled water.

SPECIMEN COLLECTION & PREPARATION

Either serum or plasma can be used in this test. No additives or preservatives are necessary to maintain the integrity of the specimen.
Specimens should be stored at 2-8°C and assayed within 48 hours after collection. If the assay cannot be performed within 48 hours or if the specimen has to be shipped, cap the specimen and keep it frozen. Repeated freezing and thawing should be avoided. Frozen specimens should be thawed at room temperature (RT, 20-25°C) and mixed thoroughly by gentle inversion before assaying. Samples should be tested undiluted. The use of haemolysed or lipemic specimens is not recommended.

PREPARATION OF REAGENTS

Allow all reagents to come to RT before use.
Enzyme conjugate: ready to use
Substrate Solution: to be prepared freshly
Stop Solution: ready to use
Calibrators and Controls: ready to use
Concentrated Washing Buffer:
The concentrated Washing Buffer has to be diluted 1:50 in distilled water. (Example: For 2 strips 10 mL of Washing Buffer is required. Therefore 200 µL concentrated Washing Buffer have to be diluted to a final volume of 10 mL with distilled water). The resulting Washing Buffer is stable for one week at RT.

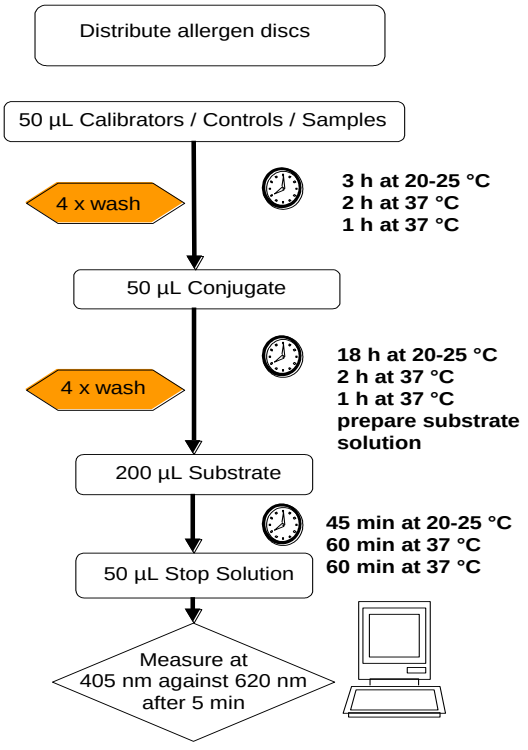
ASSAY PROCEDURE

1. Prepare a protocol for the assay run. It is recommended to test the calibrators and controls in duplicate determination.
2. Using plastic forceps, put reference- and allergen discs into test wells on the plate according to your protocol.
3. Pipette exactly 50 µL calibrator-, control- and patient samples directly onto the respective disc. Cover plate and incubate according to Table 1.
4. Following completion of the incubation time wash each well of the plate with an appropriate ELISA Plate Washer 4 x 1000 µL in “overflow”-modus with diluted Washing Buffer.
5. Pipette exactly 50 µL Anti-IgE-Conjugate onto each disc. Cover plate and incubate according to Table 1.
6. Prepare substrate solution approximately 1 h before use and store in the dark until use. Use one tablet for 5 mL Substrate Buffer.
7. Repeat washing as described in step 4.
8. Pipette 200 µL Substrate Solution into each well and incubate according to Table 1.
9. Add 50 µL Stop Solution to each well in the same order and interval as used for the substrate solution. It is recommended to mix the colour solution in the wells by knocking on the frame. Incubate plate for 5 min at RT. Read OD at 405 nm in a microplate reader (reference wavelength 620 nm) and calculate the results of the samples and controls as described on page 3.

Table 1: Incubation scheme

	Assay description		
	Long-time	**Short-time**	**Abbreviated**
Serum-incubation	3 h RT	2 h 37 °C	1 h 37 °C
Conjugate-incubation	18 h RT	2 h 37 °C	1 h 37 °C
Substrate-incubation	45 min RT	1 h 37 °C	1 h 37 °C

TEST SCHEME
Specific IgE EAST



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CALCULATION OF RESULTS

It is recommended to use validated software for the calculation of the results. For manual calculation, the mean OD [Δ 405 nm – 620 nm] values are calculated from the calibrators and controls. Generate a graph from the mean OD values of the six calibrators on half logarithmic paper (Abscissa: log IU IgE/mL; Ordinate: linear OD Δ 405 nm - 620 nm) to create a standard curve. The sIgE concentration and class of the patient sample is determined on the basis of this standard curve. The OD is mapped on the Ordinate and the result can be read out on the Abscissa. The standard curve and the controls should be in the acceptance range given in the Quality-Control-Certificates delivered with the kit. Otherwise, the test conditions should be verified and the test should probably be repeated.
The results are interpreted as follows:

Class	IU/mL sIgE	Interpretation
6	> 100	extremely high
5	50 -100	strongly high
4	17.50 - 50	very high
3	3.50 - 17.50	high
2	0.70 - 3.50	moderate
1	0.35 - 0.70	low
0	< 0.35	non detectable

EXPECTED VALUES

The clinical relevance of a positive test result varies significantly among the different allergens. Therefore, it is highly recommended for each laboratory to determine the normal range for each allergen individually. The above listed values can be used as a guideline for the interpretation.

HSA coupled allergens

Low molecular substances (Haptens) e.g. Penicillin and Isocyanates are coupled to the discs by a protein (Human Serum Albumin / HSA). In rare cases patient samples can contain HSA specific IgE. Therefore reaction against HSA itself has to be tested for each patient sample by running the HSA-Control Disc test and comparing the results to the Allergen-HSA-Conjugate.

Recommended interpretation:

The sIgE concentration against the HSA Conjugate is measured in parallel to sIgE to HSA. The concentration obtained from the HSA disc has to be subtracted from the concentration obtained from the respective HSA conjugate.

Alternative interpretation:

The result for the Allergen-HSA-Conjugate is calculated by multiplying the OD-Value of the HSA Control Disc by the factor 2.

Cut off = OD (HSA control disc) X 2

OD Allergen-HSA-Conjugate > Cut off: positive result.

MEASURING RANGE

This ELISA detects IgE concentrations in the range between 0.35 and 100 IU/mL. Samples with IgE concentrations above 100 IU/mL should be diluted and retested to obtain the exact concentration.

PRECISION

Variability and Reproducibility

1. ***Intra***-Assay-Variability

Specimen	Mean [IU/mL]	CV (%)
1 (n=10)	22,57	7,45
2 (n=10)	10,48	7,14
3 (n=10)	11,57	9,54

2. ***Inter***-Assay-Variability

Specimen	Mean [IU/mL]	CV (%)
1 (n=17)	23,41	7,91
2 (n=20)	10,49	7,54
3 (n=20)	10,93	10,79

LINEARITY

Five randomly selected sera show a linear behaviour (≤ ±20%) in three consecutive dilution steps. Based on the heterogeneity of human serum or plasma samples varying results can not be excluded.

SPECIFICITY

In physiological concentrations no cross-reactivity to other Ig-classes could be observed using this sIgE test.

LIMITATIONS OF THE METHOD

This sIgE test shows the following limitations:

- A negative test result does not exclude a Type I allergy
- The test result has to be considered in the context of the patient's history and the clinical findings

LITERATURE

1. Ishizaka K, Ishizaka T, und Hornbrook MM: **Physicochemical Properties of Human Reaginic Antibody IV. Presence of a Unique Immunoglobulin as a Carrier of Reaginic Activity** *J Immunol* 1966, **97**:75-85.
2. Hamilton R: **Radioimmunoassay in the Assessment of Allergic Disease***, Ligand Quarterly* 1979, **2**:13-19.
3. Johansson S, Bennich H, Berg T: **The Clinical Significance of IgE**, *Progress in Clin. Immunol* 1972, **1**.
4. Kjellman M: **Immunoglobulin IgE and Atopic Allergy in Childhood.** *Linkpoing University Medical Dissertations* No 36 1976.
5. Wittig H, Bellot J, Fillippi I, Royal G: **Age-related Serum IgE Levels in Healthy Subjects and in Patients with Allergic Disease.** *J Allergy Clin Immunol* 1980, **66**:305-313.
6. Gleich G, Averbeck A and Swedlund H: **Measurement of IgE in Normal and Allergic Serum by Radioimmunoassay**. *J Lab and Clin Med* 77 (1971) 690-698.
7. Arbeitsgruppe der Deutschen Diagnostika Gruppe e.V. (DDG). **Gute Labordiagnostische Praxis GLDP, Konzept einer „Guten Labordiganostischen Praxis".** *Clin Lab* 1999, **45**: 569-80.

PRECAUTIONS FOR USERS

1. In compliance with annex I of European directive 98/79/EC the use of *in-vitro* diagnostic medical devices is intended to secure suitability, performance and safety of the product by the manufacturer. Therefore the test procedure, information, precautions and warnings stated in the instructions for use have to be followed strictly. The kit has only to be used as described on page 1 (intended use).
2. The test must be performed according to this instruction, which contains all necessary information, precautions and warnings. The use of the test kit with analyzers and similar equipment has to be validated. Any change in design, composition of the test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes resulting in false results and other incidents. The manufacturer is not liable for any results obtained by visual analysis of patient samples.
3. The kit is intended for use by trained and qualified professionals carrying out research or diagnostic activities only. Pregnant women should not perform the test.
4. Laboratory equipment has to be maintained according to the manufacturer's instructions and must be tested for its correct function before use.
5. For *in-vitro* diagnostic use only. Use only once. Do not use components exceeding the expiry date. Do not combine reagents of other suppliers or kit components of different lots (unless specified on page 1) with this kit.
6. Do not use kit components when the package of the component is damaged. Please check all solutions prior to use for microbiological contamination. Cap vials tightly immediately after use to avoid evaporation and microbiological contamination. Do not interchange screw caps of the reagent vials.
7. The kit was evaluated for use at the temperatures specified in the Testing scheme (see page 2). Higher or lower temperatures may result in values not meeting the quality control ranges.
8. The washing procedure is absolutely important. Improper washing will cause erroneous results. It is recommended to use a multichannel pipette and an automated washer.
9. To avoid cross-contamination and false-positive results it is recommended to perform all pipetting steps properly. Use only clean pipette tips, dispensers and lab ware.
10. Test components based on human serum were tested using a CE marked method for the presence of antibodies against HIV 1 / HIV 2, Anti-HBc, and Anti-HCV as well as for hepatitis antigen HBsAg and were found to be negative. Nevertheless, material based on human serum should be handled as potentially infectious (BIOHAZARD).
11. Some kit components may contain bovine serum albumin, of which according to the manufacturer no infectious potential is known. Due to the eventual occurrence of undetectable infectious agents we recommend to handle any product of animal origin as potentially infectious.
12. The following safety rules should be followed with all reagents:
    - Do not get in eyes, on skin, or on clothing (P262). Do not breathe spray (P260). Pipetting should never be done by mouth, but with suitable pipetting devices.
    - IF SWALLOWED: rinse mouth. Do NOT induce vomiting (P301/330/331)
    - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower (P303/361/353).
    - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing (P303/340).
    - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P305/351/338)
    - Don't eat, drink or smoke while performing the test. Keep away from food, feed and beverage.
    - Wear protective gloves/protective clothing/eye protection (P280). Wash hands thoroughly after handling (P264) and care for your skin.
    - Material safety data sheet is available on request.
13. Stop Solution and SubBuf cause severe skin burns and eye damage (H314).
14. TMB in high concentrations may be potentially mutagenic. Due to the low concentration of TMB in this substrate solution a mutagenic effect can be ruled out, if it is properly used.
15. p-NPP is harmful if swallowed (H302). Diethanolamin (SubBuf) may cause damage to organs through prolonged or repeated exposure (H373). Get medical advice/attention if you feel unwell (P314).
16. The preservatives (Bronidox) are toxic to aquatic life, but their concentration is not hazardous to environment anymore. On disposal, flush large volumes of reagents with plenty of water.
17. Waste containing serum must be collected in separate containers containing an appropriate disinfectant in sufficient concentration. This material has to be treated according to national biohazard and safety guidelines or regulations.
18. We refer to the national regulations of medical devices regarding *in-vitro* diagnostic test kits.

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LOT	CE	IVD	2 °C 8 °C		REF					Σ		
Lot- Number	European conformity	For *in-vitro* diagnostic use	Temperature Limit	Use before	Catalogue Number	Consult instructions for use	Refer accompanying documents	Do not use when package is damaged	Do not Re-use	Sufficient for <n> tests	Manufactured by	Biohazard

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EC-Declaration of Conformity

For the purpose of 98/79/EC Directive on *in vitro* diagnostic medical devices

Product Name: **Allergene-coupled Discs (Sinlge Allergens, Allergen Mixes)**

Product Number: **Allergene Code**

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Neuss, 18th May 2022

DR. FOOKE-ACHTERRATH Laboratorien GmbH

Dr. Margrit Fooke-Achterrath
- General Manager -