Certificate

mdc medical device certification GmbH
certifies that

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49 - 51
55129 Mainz
Germany

with the locations listed in the attachment

for the scope

design, development, manufacturing and distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases

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:2016 - ISO 13485:2016

Valid from	2019-04-01
Valid until	2022-03-31
Registration no.	D1227900020
Report no.	P18-01487-133131
Stuttgart	2019-04-01

Head of Certification Body

Digitally signed by Ceaicovschi Tudor
Date: 2021.03.31 09:10:35 EEST
Reason: MoldSign Signature
Location: Moldova

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

mdc medical device certification GmbH
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Attachment of the certificate

No. D1227900020 date 2019-04-01 Page 1 of 1

Location	Scope
ORGENTEC Diagnostika GmbH Carl-Zeiss-Straße 49 – 51 55129 Mainz Germany	design, development, manufacturing and distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases
ORGENTEC Austria GmbH Hausfeldstraße 90 A2232 Deutsch-Wagram Austria	distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases
ORGENTEC Hungary Kft. Aradi Vértanúk utca 45 H2060 Biscske Hungary	distribution of in-vitro diagnostic test kits, reagents, controls and analyzers/instruments used in the diagnosis of autoimmune and infectious diseases

medical device certification mdc

Head of Certification Body

mdc medical device certification GmbH
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ORGENTEC

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"GBG-MLD" SRL
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Moldova

09 December 2020

LETTER OF AUTHORIZATION

This is to certify that ORGENTEC Diagnostika GmbH originally manufactures IVD (in vitro diagnostics) assays and reagents as well as the fully automated analyzer Alegria®. All ORGENTEC facilities, including research, development and production, are located in Mainz, Germany.

ORGENTEC Diagnostika GmbH certifies that the respective products (diagnostic assays, reagents, controls and the Alegria® analyser) comply with the essential requirements of European Directive on In Vitro Diagnostic Medical Devices (IVDD 98/79/EC).

We, ORGENTEC Diagnostika GmbH, hereby authorize and entitle **"GBG-MLD" SRL** to purchase all our ORGENTEC products (ELISA and additional reagents) from ORGENTEC, Mainz/Germany and to register, import, promote, quote and sell those products in Moldova.

ORGENTEC Diagnostika GmbH certifies that **"GBG-MLD" SRL** is the nonexclusive agent in Moldova for the ORGENTEC Diagnostika ELISA product line for the next 12 months.

This certificate expires 31 December 2021 and may then be extended on review.

This certificate and its scope is fully understood and confirmed by the agent via signature.

ORGENTEC Diagnostika GmbH

ORGENTEC Diagnostika GmbH Carl-Zeiss-Str. 49, 55129 Mainz, GERMANY ORGENTEC CE and ISO-approved

Ralf Wehen
CFO & Managing Director

"GBG-MLD" SRL

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" S.R.L. REPUBLICA MOLDOVA

signature authorized representative

CEO Director Ceaicovschi

name of signatory (capital letters)

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Geschäftsführer
Ralf Wehen

ORGENTEC
ANCA and Vasculitis Diagnostics
english

Product Overview

Diagnostics of Autoimmune Diseases

Rheumatology Diagnostics

- ANA Detect
- ANA-9-Line
- ANAcombi
- ANAscreen
- Anti-alpha-Fodrin IgG/IgA
- Anti-C1q
- Anti-CCP *hs (high sensitive)*®
- Anti-Centromere B
- Anti-dsDNA IgG, IgM, IgA, Screen
- Anti-Histone
- Anti-Jo-1
- Anti-MCV®
- Anti-Nucleosome
- Anti-Rib-P
- Anti-RNP/Sm
- Anti-RNP-70
- Anti-Scl-70
- Anti-Sm
- Anti-SS-A 52
- Anti-SS-A 60
- Anti-SS-A
- Anti-SS-B
- Anti-ssDNA
- DNase Activity
- ENA-4-Profile
- ENA-6-Profile
- ENAcombi
- ENAscreen
- Myositis plus
- Nucleo-9-Line
- Rheumatoid Factor IgG, IgM, IgA, Screen

Thrombosis Diagnostics

- Anti-Annexin V IgG/IgM
- Anti-beta-2-Glycoprotein I IgG/IgM, IgA, Screen
- Anti-Cardiolipin IgG/IgM, IgA, Screen
- Anti-Phosphatidic Acid IgG/IgM
- Anti-Phosphatidyl Inositol IgG/IgM
- Anti-Phosphatidyl Serine IgG/IgM
- Anti-Phospholipid Screen IgG/IgM
- Anti-Prothrombin IgG/IgM, IgA, Screen
- ThromboCombo IgG/IgM

ANCA and Vasculitis Diagnostics

- ANCA-3-Line
- ANCAcombi
- ANCAscreen
- ANCAscreen *hs (high sensitive)*
- Anti-BPI
- Anti-Cathepsin G
- Anti-Elastase
- Anti-GBM
- Anti-Lactoferrin
- Anti-Lysozyme
- Anti-MPO (pANCA)
- Anti-PR3 (cANCA)
- Anti-PR3 *hs (high sensitive)*

Gastroenterology Diagnostics

- AMA-M2
- Anti-DGP IgA, IgG, Screen
- Anti-Gliadin IgA, IgG, Screen
- Anti-gp210
- Anti-Intrinsic Factor
- Anti-LKM-1
- Anti-Parietal Cell
- Anti-SLA
- Anti-Sp100
- Anti-Tissue-Transglutaminase IgA, IgG, Screen
- ASCA IgG/IgA
- Gastro-5-Line
- Liver-9-Line

Thyroid Diagnostics

- Anti-TG
- Anti-TPO
- Thyroglobulin

Diabetes Diagnostics

- Anti-Insulin

Miscellaneous

- Anti-Calprotectin
- 25-OH Vitamin D_3/D_2
- beta-2-Microglobulin
- Ferritin
- Micro-Albumin

Diagnostics of Infectious Diseases

- Anti-B. pertussis Toxin IgA, IgG
- Anti-Borrelia IgG, IgM Abs.
- Anti-Chlamydia pneumoniae IgA, IgG, IgM Abs.
- Anti-Chlamydia trachomatis IgA, IgG, IgM Abs.
- Anti-EBV (EBNA-1) IgG
- Anti-EBV (VCA) IgG, IgM Abs.
- Anti-EBV (ZEBRA) IgM
- Anti-Helicobacter pylori IgA, IgG
- Anti-HSV-1 IgG, IgM Abs.
- Anti-HSV-2 IgG, IgM Abs.
- Anti-HSV-1/2 IgG, IgM Abs.
- Anti-Measles Virus IgG, IgM Abs.
- Anti-Mumps Virus IgG, IgM Abs.
- Anti-Mycoplasma pneumoniae IgA, IgG, IgM Abs.
- Anti-Parovirus B19 IgG, IgM Abs.
- Anti-VZV IgA, IgG, IgM Abs.
- Anti-Yersinia IgA, IgG

Immunofluorescence

- Kits, Slides, Reagents

Please request our folder about our immunofluorescence product line.

Automation

- Alegria®

Over 100 parameters – please request our Alegria® product information!

- iVISION Scanware

For automated analysis of ORGENTEC immunoblot assays!

ORGENTEC Contact Information

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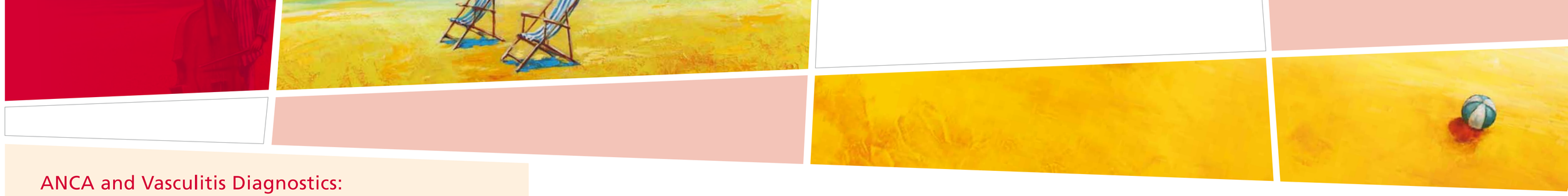

ANCA and Vasculitis Diagnostics:

Innovative ELISA Technology from ORGENTEC

The detection of Anti-Neutrophil Cytoplasmic Antibodies (ANCA) is the foundation of modern diagnosis of ANCA-associated vasculitis. High-quality ELISA test systems for the detection of PR3 and MPO antibodies are essential for the serological evidence and monitoring of granulomatosis with polyangiitis (Wegener's granulomatosis), microscopic polyangiitis, eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome) and rapidly progressing glomerulonephritis.

Goodpasture syndrome can elicit symptoms very similar to those of ANCA-associated vasculitis. Diagnostic indicators of Goodpasture syndrome are antibodies against the glomerular basement membrane (GBM).

Because these life-threatening diseases frequently require immediate and aggressive treatment. Only high-performance ELISA test systems with maximum diagnostic sensitivity and specificity provide certainty in diagnosing the disease and considering treatment options.

In addition, the detection of pANCAs plays a critical role in the differential diagnosis of Crohn's disease and ulcerative colitis.

Uniquely comprehensive product portfolio
With these test systems for modern ANCA diagnostics, ORGENTEC offers an exceptionally comprehensive spectrum of products. This is indicative of our commitment to the patient and our dedication to the continued development of autoimmune diagnostics. To us, service and closeness to customers also includes the desire to be a one-stop shop, even for unusual requirements. High product quality and excellent ability to deliver are important components of our company philosophy.

Standardised test protocols
ORGENTEC ELISAs are carried out under standardised conditions and with a uniform protocol. This provides certainty in carrying out the tests, such as in the parallel differential diagnostic detection of PR3, MPO and GBM antibodies.

In contrast to indirect immunofluorescence, ELISA results can be interpreted objectively and allow for the exact determination of the antibody titre, for example for monitoring disease progression.

The ORGENTEC Immunoblot for rapid ANCA detection in both acute and early diagnosis:

ANCA-3-Line – Immunoblot – ORG 789
Target antigens: PR3, MPO, GBM

Please request our product information about ORGENTEC Immunoblots!

Advantages at a glance:

- uniquely comprehensive product portfolio: routine parameters and specialties
- precise differentiation of PR3- and MPO-negative immunofluorescence patterns
- can be fully automated with Alegria®
- highly pure, conformational antigens
- standardised test protocols: simple execution, reliable readout
- quantitative evaluation, reproducible results

Anti-PR3 *hs (high sensitive)* ORG 618, ORG 318
Anti-PR3 (cANCA) ORG 518, ORG 218

The detection of autoantibodies against proteinase 3 (PR3) is an important component of the diagnosis of granulomatosis with polyangiitis (Wegener's granulomatosis). Because PR3 antibodies bind to conformational epitopes, the correct structural representation of the target antigen is critical to the quality of an ELISA detection system. Innovative coating technology in the Anti-PR3 *hs (high sensitive)* guarantees the presentation of all relevant epitopes and achieves excellent performance characteristics.

- highly pure human proteinase 3 as target antigen
- quantitative determination: the antibody titre correlates with disease activity
- Anti-PR3 *hs (high sensitive):* native conformation of PR3, presence of all relevant epitopes of the target antigen!
- Anti-PR3 *hs (high sensitive):* outstanding diagnostic sensitivity (96 %), excellent specificity (99 %)
- Anti-PR3 *hs (high sensitive):* excellent correlation with indirect immunofluorescence

Anti-PR3 *hs (high sensitive)* is a highly innovative diagnostic test for granulomatosis with polyangiitis (Wegener's granulomatosis), even in the early stages of the disease.

Anti-MPO (pANCA) ORG 519, ORG 219

The enzyme myeloperoxidase from neutrophil granulocytes is one of the target antigens of pANCA. Antibodies against MPO are specific markers for microscopic polyangiitis (MPA), and are also found in cases of eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome) and panarteriitis nodosa. As is the case for PR3 antibodies, antibodies against MPO recognise exclusively native conformational epitopes.

- native target antigen: the protein structure is fully retained
- highly pure myeloperoxidase – no contamination with elastase or lactoferrin
- quantitative ELISA for objective and reproducible results
- high diagnostic specificity results in confidence when making treatment decisions

Anti-GBM ORG 550, ORG 250

Antibodies against glomerular basement membrane are diagnostic markers for Goodpasture syndrome. The symptoms of this life-threatening disease are similar to those of ANCA-associated vasculitis. Untreated, Goodpasture syndrome progresses rapidly, making early diagnosis and sensitive, specific test systems critical.

- high diagnostic specificity by means of an isolated antigen fragment (NC1 domains of the α-3 chain of collagen type IV)
- highly pure preparation guarantees high sensitivity and specificity
- antigen in native conformation
- standardised ORGENTEC test protocol (incubation and rinsing procedures, readout) for accurate parallel detection of GBM, PR3, and MPO antibodies

In cases of rapid deterioration of kidney function, the parallel search for GBM antibodies, cANCA (e.g. Anti-PR3 *hs (high sensitive)* from ORGENTEC) and pANCA (e.g. Anti-MPO by ORGENTEC) is urgently recommended.

ANCAcombi ORG 530

Autoantibodies from the ANCA family are found in a number of inflammatory, primarily rheumatic or gastrointestinal diseases. Some of these antibodies are recognised markers for ANCA-associated vasculitis (PR3 and MPO antibodies). Others are important indicators of rheumatoid arthritis (elastase antibodies), cystic fibrosis (BPI antibodies) or chronic inflammatory bowel diseases (cathepsin G antibodies).

- seven parameters in a single test run
- differentiation and confirmation of immunofluorescence results: also includes rare ANCA subgroups
- native antigen preparation
- economical: one microstrip per patient, twelve tests in one test kit

After differentiation with ANCAcombi, the individual ANCA can be quantitatively detected with the corresponding single tests from ORGENTEC.

Target antigens:

PR3, MPO, BPI (bactericidal permeability-increasing protein), elastase, cathepsin G, lysozyme, lactoferrin

ANCAscreen *hs (high sensitive)* ORG 689, ORG 389
ANCAscreen ORG 589, ORG 289

PR3 and MPO are the primary target antigens of ANCA diagnostics. Antibodies against these two antigens are recognised serological markers for ANCA-associated vasculitis (e.g. granulomatosis with polyangiitis (Wegener's granulomatosis), microscopic polyangiitis, eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome)).

- ANCAscreen *hs (high sensitive):* includes the target antigen PR3 in the innovative high sensitive format for outstanding diagnostic sensitivity and specificity.
- highly pure conformational antigens
- screening test: simultaneous detection of ANCA against PR3 and MPO
- rapid and objective
- both parameters also available in quantitative single tests

For differentiation of the antibody profile after a positive ANCAscreen result, the following ELISAs are available from ORGENTEC: Anti-PR3 *hs (high sensitive)*, Anti-PR3 and Anti-MPO.

Target antigens:

PR3 (Proteinase 3), MPO (Myeloperoxidase)

ANCA ELISA Specialities

ANCA are found in a number of inflammatory, primarily rheumatic or gastrointestinal diseases. Our ELISA test systems allow for the clarification of positive ANCA immunofluorescence patterns and thus support the diagnosis of diseases such as cystic fibrosis (BPI antibodies), rheumatoid arthritis (elastase antibodies), or chronic inflammatory bowel diseases such as Crohn's disease and ulcerative colitis (cathepsin G antibodies).

- uniquely broad spectrum of products allows for the differentiation and quantification of PR3-/MPO-negative immunofluorescence patterns
- quantitative antibody detection following ANCAcombi assay

Anti-BPI . . . . . ORG 523, ORG 223
(BPI = bactericidal permeability-increasing protein)
Anti-Elastase . . . . . ORG 524, ORG 224
Anti-Cathepsin G . . . . . ORG 525, ORG 225
Anti-Lysozyme . . . . . ORG 526, ORG 226
Anti-Lactoferrin . . . . . ORG 527, ORG 227

ORGENTEC literature service:
www.orgentec.com

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 508 Anti-SS-A

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

ORGENTEC Diagnostika GmbH
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CE and ISO-approved
Carl-Zeiss-Str. 49 - 51, 55129 Mainz, GERMANY

Mainz, 2019-04-02

Dr. Christian Löbke
Quality Management Representative

Gültig ab / Valid from 2019-04-02 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-01-12-00
GMDN 55129

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Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 509 Anti-SS-B

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

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Mainz, 2019-04-02

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Quality Management Representative

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EC Declaration of Conformity

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Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 511 Anti-RNP/Sm

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

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Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2020-01-06

Dr. Christian Löbke
Quality Management Representative

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Gültig ab / Valid from 2020-01-06 bis / until 2021-04-01

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GMDN 55160

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Geschäftsführer
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ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

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Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 512 Anti-Scl-70

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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Mainz, 2019-04-02

Dr. Christian Löbke
Quality Management Representative

Gültig ab / Valid from 2019-04-02 bis / until 2021-04-01

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GMDN 55126

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Geschäftsführer
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ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

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Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 515 Anti-Cardiolipin IgG/IgM

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as “Other Devices” (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2019-04-02

Dr. Christian Löbke
Quality Management Representative

ORGENTEC Diagnostika GmbH
ORGENTEC
CE and ISO-approved
Carl-Zeiss-Str. 49 - 51, 55129 Mainz, GERMANY

Gültig ab / Valid from 2019-04-02 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-01-00
GMDN 54870

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USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 516 AMA-M2

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

ORGENTEC Diagnostika GmbH * ORGENTEC CE and ISO-certified * Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-02-00
GMDN 43106

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USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 518 Anti-PR3 (cANCA)

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

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Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-10-00
GMDN 55073

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Geschäftsführer
Ralf Wehen

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
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Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 519 Anti-MPO (pANCA)

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

ORGENTEC Diagnostika GmbH
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CE and ISO-approved
Carl-Zeiss-Str. 49 - 51, 55129 Mainz, GERMANY

Mainz, 2019-04-02

Dr. Christian Löbke
Quality Management Representative

Gültig ab / Valid from 2019-04-02 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-09-00
GMDN 55068

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Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 529 Anti-Phospholipid Screen IgG/IgM

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

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Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2020-01-06

Dr. Christian Löbke
Quality Management Representative

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Gültig ab / Valid from 2020-01-06 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-90-00
GMDN 55085

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Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 538 ANAscreen

zur qualitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in qualitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

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Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

ORGENTEC Diagnostika GmbH * ORGENTEC CE and ISO-approved * Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-01-01-00
GMDN 54809

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USt-IdNr. DE149058799
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Geschäftsführer
Ralf Wehen

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 600 ANA Detect

zur qualitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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ORGENTEC Diagnostika GmbH
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Mainz, 2019-04-02

Dr. Christian Löbke
Quality Management Representative

Gültig ab / Valid from 2019-04-02 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-01-01-00
GMDN 54809

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BIC: COBADEFFXXX

USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 601 Anti-CCP hs (high sensitive)®

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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Mainz, 2019-04-02

Dr. Christian Löbke
Quality Management Representative

Gültig ab / Valid from 2019-04-02 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12 11 01 90 00
GMDN 54896

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USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 604A Anti-dsDNA IgA

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

ORGENTEC Diagnostika GmbH
ORGENTEC
CE and ISO-approved
Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-01-05-00
GMDN 54902

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BIC: COBADEFFXXX

USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 633 Anti-Centromere B

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

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Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2020-01-06

Dr. Christian Löbke
Quality Management Representative

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Gültig ab / Valid from 2020-01-06 bis / until 2021-04-01

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-01-15-00
GMDN 54886

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BIC: MVBMDE55

Commerzbank AG
IBAN: DE13 5504 0022 0200 8670 00
BIC: COBADEFFXXX

USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

AESKU.Systems GmbH & Co. KG
Mikroforum Ring 3-5
Wendelsheim
55234
Germany

Holds Certificate Number: **MD 619746**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, installation, servicing and distribution of in-vitro diagnostic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-10-22
Latest Revision Date: 2018-12-16

Effective Date: 2019-01-04
Expiry Date: 2022-01-03

...making excellence a habit.™

LISTE DER ALLERGENE

LIST OF ALLERGENS

DR FOOKE

Alle Produkte sind CE gekennzeichnet
All products are CE marked

Pollen Pollens

Bäume Trees

Code	Deutsch	English	Latein/Latin
t1	Ahorn	Maple	Acer negundo
t2	Erle	Alder	Alnus glutinosa
t3	Birke	Birch	Betula pendula
t4	Hasel	Hazelnut	Corylus avellana
t5	Buche	Beech	Fagus silvatica
t6	Sadebaum	Sade Tree	Juniperus sabina
t7	Eiche	Oak	Quercus alba
t8	Ulme	Elm	Ulmus spp.
t9	Olive	Olive	Olea europea
t10	Walnuss	Walnut	Juglans regia
t11	Platane	Plane	Platanus acerifolia
t12	Salweide	Willow	Salix alba
t13	Jasmin	Jasmin	Jasminum spp.
t14	Pappel	Poplar	Populus spp.
t15	Esche	Ash	Fraxinus excelsior
t16	Kiefer	White Pine	Pinus silvestris
t17	Kastanie	Chestnut	Aesculus hippocastanum
t18	Eukalyptus	Eucalyptus	Eucalyptus spp.
t19	Mimose	Mimosa	Mimosa spp.
t20	Liguster	Privet	Ligustrum vulgare
t21	Flieder	Lilac	Syringa vulgaris
t22	Weißdorn	Hawthorn	Crataegus spp.
t23	Zypresse	Cypress	Cupressus sempervirens
t24	Zeder	Cedar	Juniperus spp.
t26	Holunder	Elder	Sambucus nigra
t27	Linde	Lime Tree	Tilia cordata
t28	Robinie	Robinia	Robinia pseudoacacia
t29	Kirsche	Cherry	Prunus avium
t30	Mesquite	Mesquite	Prosopis velutina
t31	Melaleuca	Tea Tree	Melaleuca leucadendron (alternifolia)
t32	Orange	Orange	Citrus sinensis
t33	Lombard. Pappel	Lombardy Poplar	Populus nigra italica
t34	Mandel	Almond	Prunus amydalus
t35	Fichte	Fir	Picea abies
t36	Akazie	Acacia	Acacia spp.
t37	Eibe	Yew	Taxus bacchata
t38	Tanne	Fir tree	Abies concolor
t39	Pecan	Pecan	Carya pecan
t40	Pinie	Pine	Pinus pinea
t41	Dattelpalme	Datepalm	Phoenix dactylifera
t43	Thuja	Thuja	Thuja spp.
t50	Magnolie	Magnolia	Magnoliaceae
t70	Maulbeerbaum	Mulberry	Morus alba / rubra
t71	Japanische Zeder	Japanese Cedar	Cryptomeria japonica

Pollen Pollens

Bäume Multi-Allergene Trees Multi-Allergens

Code	Deutsch			Code	English		
Tx1	Bäume frühblühend	t2	Erle	Tx1	Trees early	t2	Alder
		t4	Hasel			t4	Hazelnut
		t8	Ulme			t8	Elm
		t12	Salweide			t12	Willow
		t14	Pappel			t14	Poplar
Tx2	Bäume spätblühend	t1	Ahorn	Tx2	Trees late	t1	Maple
		t3	Birke			t3	Birch
		t5	Buche			t5	Beech
		t7	Eiche			t7	Oak
		t10	Walnuss			t10	Walnut
Tx3	Bäume Mischung 3	t3	Birke	Tx3	Trees Mix 3	t3	Birch
		t7	Eiche			t7	Oak
		t8	Ulme			t8	Elm
		t24	Zeder			t24	Cedar
		t30	Mesquite			t30	Mesquite
Tx4	Bäume Mischung 4	t1	Ahorn	Tx4	Trees Mix 4	t1	Maple
		t3	Birke			t3	Birch
		t5	Buche			t5	Beech
		t7	Eiche			t7	Oak
		t11	Platane			t11	Plane
		t14	Pappel			t14	Poplar
Tx5	Bäume Mischung 5	t1	Ahorn	Tx5	Trees Mix 5	t1	Maple
		t3	Birke			t3	Birch
		t7	Eiche			t7	Oak
		t8	Ulme			t8	Elm
		t28	Robinie			t28	Robinia
		t31	Melaleuca			t31	Tea Tree
Tx6	Bäume Mischung 6	t9	Olive	Tx6	Trees Mix 6	t9	Olive
		t11	Platane			t11	Plane
		t23	Zypresse			t23	Cypress
Tx7	Bäume Mischung 7	t2	Erle	Tx7	Trees Mix 7	t2	Alder
		t3	Birke			t3	Birch
		t9	Olive			t9	Olive
Tx8	Bäume Mischung 8	t2	Erle	Tx8	Trees Mix 8	t2	Alder
		t3	Birke			t3	Birch
		t4	Hasel			t4	Hazelnut
		t7	Eiche			t7	Oak
		t12	Salweide			t12	Willow
Tx9	Bäume Mischung 9	t2	Erle	Tx9	Trees Mix 9	t2	Alder
		t3	Birke			t3	Birch
		t4	Hasel			t4	Hazelnut
		t5	Buche			t5	Beech
		t7	Eiche			t7	Oak
		t8	Ulme			t8	Elm
		t11	Platane			t11	Plane
		t12	Salweide			t12	Willow
Tx10	Bäume Mischung 10	t3	Birke	Tx10	Trees Mix 10	t3	Birch
		t7	Eiche			t7	Oak
		t8	Ulme			t8	Elm
		t9	Olive			t9	Olive
		t11	Platane			t11	Plane
		t12	Salweide			t12	Willow
		t14	Pappel			t14	Poplar

Pollen

Bäume

Multi-Allergene

Code	Deutsch		
Tx13	Bäume Mischung 13	t5	Buche
		t7	Eiche
		t9	Olive
		t12	Salweide
		t36	Akazie
		t40	Pinie
Tx14	Bäume Mischung 14	t2	Erle
		t4	Hasel
		t8	Ulme
		t9	Olive
		t12	Salweide
Tx15	Bäume Mischung 15	t3	Birke
		t5	Buche
		t7	Eiche
		t9	Olive
		t10	Walnuss
Tx16	Bäume Mischung 16	t7	Eiche
		t8	Ulme
		t11	Platane
		t12	Salweide
		t14	Pappel
Tx17	Bäume Mischung 17	t3	Birke
		t7	Eiche
		t8	Ulme
		t11	Platane
		t16	Kiefer
		t18	Eukalyptus
		t19	Mimose
Tx18	Bäume Mischung 18	t3	Birke
		t7	Eiche
		t8	Ulme
		t11	Platane
		t18	Eukalyptus
		t36	Akazie
		t40	Pinie
Tx19	Bäume Mischung 19	t3	Birke
		t6	Sadebaum
		t7	Eiche
		t8	Ulme
		t30	Mesquite
Tx20	Bäume Mischung 20	t2	Erle
		t4	Hasel
		t7	Eiche
		t8	Ulme
		t14	Pappel
Tx21	Bäume Mischung 21	t3	Birke
		t7	Eiche
		t9	Olive
		t12	Salweide
		t14	Pappel
		t16	Kiefer
Tx23	Bäume Mischung 23	t5	Buche
		t7	Eiche
		t11	Platane
		t14	Pappel
		t36	Akazie

Pollens

Trees

Multi-Allergens

Code	English		
Tx13	Trees Mix 13	t5	Beech
		t7	Oak
		t9	Olive
		t12	Willow
		t36	Acacia
		t40	Pine Tree
Tx14	Trees Mix 14	t2	Alder
		t4	Hazelnut
		t8	Elm
		t9	Olive
		t12	Willow
Tx15	Trees Mix 15	t3	Birch
		t5	Beech
		t7	Oak
		t9	Olive
		t10	Walnut
Tx16	Trees Mix 16	t7	Oak
		t8	Elm
		t11	Plane
		t12	Willow
		t14	Poplar
Tx17	Trees Mix 17	t3	Birch
		t7	Oak
		t8	Elm
		t11	Plane
		t16	White Pine
		t18	Eucalyptus
		t19	Mimosa
Tx18	Trees Mix 18	t3	Birch
		t7	Oak
		t8	Elm
		t11	Plane
		t18	Eucalyptus
		t36	Acacia
		t40	Pine Tree
Tx19	Trees Mix 19	t3	Birch
		t6	Sade Tree
		t7	Oak
		t8	Elm
		t30	Mesquite
Tx20	Trees Mix 20	t2	Alder
		t4	Hazelnut
		t7	Oak
		t8	Elm
		t14	Poplar
Tx21	Trees Mix 21	t3	Birch
		t7	Oak
		t9	Olive
		t12	Willow
		t14	Poplar
		t16	White Pine
Tx23	Trees Mix 23	t5	Beech
		t7	Oak
		t11	Plane
		t14	Poplar
		t36	Acacia

Pollen

Bäume

Multi-Allergene

Code	Deutsch		
Tx24	Bäume Mischung 24	t2	Erle
		t4	Hasel
		t7	Eiche
		t8	Ulme
		t11	Platane
		t12	Salweide
		t14	Pappel
Tx25	Bäume Mischung 25	t1	Ahorn
		t3	Birke
		t4	Hasel
		t7	Eiche
		t8	Ulme
		t14	Pappel
		t23	Zypresse
Tx26	Bäume Mischung 26	t1	Ahorn
		t2	Erle
		t3	Birke
		t7	Eiche
		t12	Salweide
		t14	Pappel
Tx27	Bäume Mischung 27	t2	Erle
		t4	Hasel
		t7	Eiche
		t8	Ulme
		t10	Walnuss
		t11	Platane
		t12	Salweide
		t14	Pappel
TTx7	Bäume Mischung T7 *	t9	Olive
		t12	Salweide
		t16	Kiefer
		t18	Eukalyptus
		t19	Mimose
		t31	Melaleuca
TTx8	Bäume Mischung T8 *	t9	Olive
		t12	Salweide
		t16	Kiefer
		t18	Eukalyptus
		t19	Mimose

Pollens

Trees

Multi-Allergens

Code	English		
Tx24	Trees Mix 24	t2	Alder
		t4	Hazelnut
		t7	Oak
		t8	Elm
		t11	Plane
		t12	Willow
		t14	Poplar
Tx25	Trees Mix 25	t1	Maple
		t3	Birch
		t4	Hazelnut
		t7	Oak
		t8	Elm
		t14	Poplar
		t23	Cypress
Tx26	Trees Mix 26	t1	Maple
		t2	Alder
		t3	Birch
		t7	Oak
		t12	Willow
		t14	Poplar
Tx27	Trees Mix 27	t2	Alder
		t4	Hazelnut
		t7	Oak
		t8	Elm
		t10	Walnut
		t11	Plane
		t12	Willow
		t14	Poplar
TTx7	Trees Mix T7 *	t9	Olive
		t12	Willow
		t16	White Pine
		t18	Eucalyptus
		t19	Mimosa
		t31	Tea Tree
TTx8	Trees Mix T8 *	t9	Olive
		t12	Willow
		t16	White Pine
		t18	Eucalyptus
		t19	Mimosa

* nur als biotinyliertes Reagenz verfügbar
* available only as biotinylated reagent

Pollen
Kräuter und Blumen

Pollens
Weeds and Flowers

Code	Deutsch	English	Latein/Latin
w1	beifußbl. Ambrosie	Common Ragweed	Ambrosia arthemisiifolia
w2	ausd. Ambrosie	Western Ragweed	Ambrosia psilotachya
w3	dreil. Ambrosie	Giant Ragweed	Ambrosia trifida
w4	falsche Ambrosie	False Ragweed	Ambrosia acanthicarpa
w5	Wermut	Wormwood	Artemisia absinthium
w6	Beifuß	Mugwort	Artemisia vulgaris
w7	Margerite	Ox Eye Daisy	Leucanthemum vulgare
w8	Löwenzahn	Dandelion	Taraxacum officinale
w9	Spitzwegerich	English plantain	Plantago lanceolata
w10	Weißer Gänsefuß	Lamb's Quaters	Chenopodium album
w11	Salzkraut	Saltwort	Salsola kali
w12	echte Goldrute	Goldenrod	Solidago spp.
w13	Spitzklette	Common Cucklebur	Xanthium strumarium
w14	Fuchsschwanz	Amaranth	Amaranthus retroflexus
w15	Melde	Scale	Artriplex spp.
w16	Weidenröschen	Willow herb	Epilobium spp.
w17	Aster	Aster	Callistephus chinensis
w18	Sauerampfer	Sorrel	Rumex acetosella
w19	Glaskraut 2	Wall pellitory 2	Parietaria judaica
w20	Brennnessel	Nettle	Urtica dioica
w21	Glaskraut 1	Wall pellitory 1	Parietaria officinalis
w22	Chrysantheme	Chrysanthemum	Chrysanthemum segetum
w23	Dahlie	Dahlia	Dahlia cultorum
w24	Besenradmelde	Firebush	Kochia scoparia
w25	Kamille (echte)	Camomile	Matricaria chamomilla
w26	Narzisse	Narcissus	Narcissus spp.
w27	Nelke	Carnation	Dianthus caryophyllus
w28	Rose	Rose	Rosa spp.
w29	Sonnenblume	Sunflower	Helianthus spp.
w30	Tulpe	Tulip	Tulipa spp.
w31	Heidekraut	Heather	Calluna vulgaris
w32	Raps	Rape	Brassica rapa
w33	Malve	Mallow	Malva spp.
w34	Klee	Clover, sweet	Meliotus spp.
w35	Geranie	Geranium	Geranium spp.
w36	Primel	Primerose	Primula spp.
w38	Rispenkraut	Marsh, elder rough	Iva annua
w39	Lupine	Lupine	Lupinus luteus
w40	Hyazinthe, blau	Hyacinth, blue	Hyacinthus spp.
w41	Luzerne	Alfalfa	Medicago sativa
w43	Oleander	Oleander	Nerium oleander
w44	Lilie	Lily	Lilium spp.
w45	Euphorbie	Euphorbia	Euphorbia spp.
w46	Azalee	Acalee	Acalea spp.
w47	Hibiscus	Hibiscus	Hibiscus spp.
w49	Begonie	Begonia	Begonia semperflorens
w50	Forsythie	Golden bell	Forsythia suspensa
w52	Arnika	Arnica	Arnica montana
w53	Johanniskraut	Rose of Sharon	Hypericum perforatum
w54	Lavendel	Lavender	Lavandula
w55	Maiglöckchen	Lily of the valley	Convallaria majalis
w58	Fresie	Fresia	Fresia spp.
w59	Gerbera	Gerbera	Gerbera spp.
w62	Yucca	Yucca	Yucca spp.
w64	Fuchsie	Fuchsia	Fuchsia spp.
w65	Aloevera	Aloevera	Aloe barbadensis
w66	Hartriegel	Cornel	Cornus
w67	Ginseng	Ginseng	Panax ginseng

Weitere Allergene auf Anfrage. Further allergens on request

Pollen
Kräuter und Blumen Multi-Allergene

Pollens
Weeds and Flowers Multi-Allergens

Code	Deutsch			Code	English		
Wx1	Kräuter Mischung 1	w1	beifußbl. Ambrosie	Wx1	Weed Mix 1	w1	Common Ragweed
		w6	Beifuß			w6	Mugwort
		w7	Margerite			w7	Ox Eye Daisy
		w8	Löwenzahn			w8	Dandelion
		w12	echte Goldrute			w12	Goldenrod
Wx2	Kräuter Mischung 2	w9	Spitzwegerich	Wx2	Weed Mix 2	w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w11	Salzkraut			w11	Saltwort
Wx3	Kräuter Mischung 3	w6	Beifuß	Wx3	Weed Mix 3	w6	Mugwort
		w9	Spitzwegerich			w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w20	Brennnessel			w20	Nettle
Wx4	Blumen Mischung 4	w7	Margerite	Wx4	Flower Mix 4	w7	Ox Eye Daisy
		w17	Aster			w17	Aster
		w22	Chrysantheme			w22	Chrysanthemum
		w23	Dahlie			w23	Dahlia
Wx5	Blumen Mischung 5	w30	Tulpe	Wx5	Flower Mix 5	w30	Tulip
		w35	Geranie			w35	Geranium
		w36	Primel			w36	Primerose
		w40	Hyazinthe, blau			w40	Hyacinth, blue
Wx6	Kräuter Mischung 6	w1	beifußbl. Ambrosie	Wx6	Weed Mix 6	w1	Common Ragweed
		w6	Beifuß			w6	Mugwort
		w9	Spitzwegerich			w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w11	Salzkraut			w11	Saltwort
Wx7	Kräuter Mischung 7	w6	Beifuß	Wx7	Weed Mix 7	w6	Mugwort
		w9	Spitzwegerich			w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w12	echte Goldrute			w12	Goldenrod
Wx9	Kräuter Mischung 9	w3	dreilappige Ambrosie	Wx9	Weed Mix 9	w3	Giant Ragweed
		w6	Beifuß			w6	Mugwort
		w9	Spitzwegerich			w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w15	Melde			w15	Scale
		w20	Brennnessel			w20	Nettle
Wx10	Kräuter Mischung 10	w6	Beifuß	Wx10	Weed Mix 10	w6	Mugwort
		w9	Spitzwegerich			w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w11	Salzkraut			w11	Saltwort
Wx11	Kräuter Mischung 11	w1	beifußbl. Ambrosie	Wx11	Weed Mix 11	w1	Common Ragweed
		w6	Beifuß			w6	Mugwort
		w9	Spitzwegerich			w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w19	Glaskraut 2			w19	Wall Pellitory 2
		w20	Brennnessel			w20	Nettle
Wx12	Kräuter Mischung 12	w9	Spitzwegerich	Wx12	Weed Mix 12	w9	English Plantain
		w10	Weißer Gänsefuß			w10	Lamb's Quaters
		w11	Salzkraut			w11	Saltwort
		w19	Glaskraut 2			w19	Wall Pellitory 2
Wx13	Blumen Mischung 13	w7	Margerite	Wx13	Flower Mix 13	w7	Ox Eye Daisy
		w28	Rose			w28	Rose
		w30	Tulpe			w30	Tulip
		w36	Primel			w36	Primerose
Wx14	Blumen Mischung 14	w17	Aster	Wx14	Flower Mix 14	w17	Aster
		w22	Chrysantheme			w22	Chrysanthemum
		w23	Dahlie			w23	Dahlia
		w40	Hyazinthe, blau			w40	Hyacinth, blue

Weitere Allergene auf Anfrage. Further allergens on request

Pollen

Kräuter und Blumen
Multi-Allergene

Pollens

Weeds and Flowers
Multi-Allergens

Code	Deutsch			Code	English		
Wx21	Parietaria Mischung	w19 w21	Glaskraut 2 Glaskraut 1	Wx21	Parietaria Mix	w19 w21	Wall Pellitory 2 Wall Pellitory 1
Wx22	Kräuter Mischung 22	w6 w8 w9	Beifuß Löwenzahn Spitzwegerich	Wx22	Weed Mix 22	w6 w8 w9	Mugwort Dandelion English Plantain
Wx23	Kräuter Mischung 23	w1 w6 w9 w20 w21 w29	beifußbl. Ambrosie Beifuß Spitzwegerich Brennnessel Glaskraut 1 Sonnenblume	Wx23	Weed Mix 23	w1 w6 w9 w20 w21 w29	Common Ragweed Mugwort English Plantain Nettle Wall Pellitory 1 Sunflower
Wx25	Kräuter Mischung 25	w7 w20 w28 w40 w44	Margerite Brennnessel Rose Hyazinthe, blau Lilie	Wx25	Weed Mix 25	w7 w20 w28 w40 w44	Margerite Nettle Rose Hyacinth, blue Lily
Wx26	Kräuter Mischung 26 *	w9 w10 w11 w18	Spitzwegerich weißer Gänsefuß Salzkraut Sauerampfer	Wx26	Weed Mix 26 *	w9 w10 w11 w18	English Plantain Lamb's Quaters Saltwort Sorrel
Wx27	Kräuter Mischung 27 *	w1 w6 w7 w8	beifußbl. Ambrosie Beifuß Margerite Löwenzahn	Wx27	Weed Mix 27 *	w1 w6 w7 w8	Common Ragweed Mugwort Ox Eye Daisy Dandelion
Wx28	Kräuter Mischung 28 *	w6 w9 w10 w21	Beifuß Spitzwegerich Weißer Gänsefuß Glaskraut 1	Wx28	Weed Mix 28 *	w6 w9 w10 w21	Mugwort English Plantain Lamb's Quaters Wall Pellitory 1
Wx29	Kräuter Mischung 29 *	w6 w8 w12 w13 w18	Beifuß Löwenzahn echte Goldrute Spitzklette Sauerampfer	Wx29	Weed Mix 29 *	w6 w8 w12 w13 w18	Mugwort Dandelion Goldenrod Common Cucklebur Sorrel
Wx30	Kräuter Mischung 30 *	w6 w9 w13 w18 w20 w21	Beifuß Spitzwegerich Spitzklette Sauerampfer Brennnessel Glaskraut 1	Wx30	Weed Mix 30 *	w6 w9 w13 w18 w20 w21	Mugwort English Plantain Common Cucklebur Sorrel Nettle Wall Pellitory 1
TWx1	Kräuter Mischung T1 *	w1 w5 w12 w29 w38	beifußbl. Ambrosie Wermut echte Goldrute Sonnenblume Rispenkraut	TWx1	Weed Mix T1 *	w1 w5 w12 w29 w38	Common Ragweed Wormwood Goldenrod Sunflower Marsh, elder rough
TWx3	Kräuter Mischung T3	w6 w9 w10 w12 w20	Beifuß Spitzwegerich Weißer Gänsefuß echte Goldrute Brennnessel	TWx3	Weed Mix T3	w6 w9 w10 w12 w20	Mugwort English Plantain Lamb's Quaters Goldenrod Nettle

* nur als biotinyliertes Reagenz verfügbar
* available only as biotinylated reagent

Pollen

Gräser und Getreide

Pollens

Grasses and Corn

Code	Deutsch	English	Latein/Latin
g1	Ruchgras	Sweet Vernal Grass	Anthoxanthum odoratum
g2	Hundszahngras	Bermuda Grass	Cynodon dactylon
g3	Knäuelgras	Orchard Grass	Dactylis glomerata
g4	Wiesenschwingel	Meadow fescue	Festuca elatior
g5	Lolch	Perennial Rye Grass	Lolium perenne
g6	Lieschgras	Timothy Grass	Phleum pratense
g7	Riedgras	Common Reed	Phragmites communis
g8	Wiesenrispengras	June Grass	Poa pratensis
g9	Weißes Straußgras	Creeping Bentgrass	Agrostis stolonifera
g10	Sudangras (Sorgho)	Sudan Grass	Sorghum halepense
g11	Trespe	Brome Grass	Bromus inermis
g12	Roggen	Cultivated Rye	Secale cereale
g13	Wolliges Honiggras	Velvet Grass	Holcus lanatus
g14	Hafer	Cultivated Oat	Avena sativa
g15	Weizen	Wheat	Triticum sativum
g16	Wiesenfuchsschwanz	Meadow foxtail	Alopecurus pratensis
g17	Bahiagras	Bahia Grass	Paspalum notatum
g18	Gerste	Barley	Hordeum vulgare
g19	Kammgras	Dog's Tail Grass	Cynosurus cristatus
g20	Mais	Corn	Zea mays
g21	Quecke	Couch Grass	Elymus repens
g71	Glatthafer	Oat Grass Tall	Arrenatherum elatius
g74	Rohrglanzgras	Canary Grass red	Phalaris arundinacea

Gräser und Getreide
Multi-Allergene

Grasses and Corn
Multi-Allergens

Code	Deutsch			Code	English		
Gx1	Gräser frühblühend	g3 g4 g5 g6 g8	Knäuelgras Wiesenschwingel Lolch Lieschgras Wiesenrispengras	Gx1	Grasses early	g3 g4 g5 g6 g8	Orchard Grass Meadow Fescue Perennial Rye Grass Timothy Grass June Grass
Gx2	Gräser spätblühend	g1 g5 g7 g12 g13	Ruchgras Lolch Riedgras Roggen Wolliges Honiggras	Gx2	Grasses late	g1 g5 g7 g12 g13	Sweet Vernal Grass Perennial Rye Grass Common Reed Cultivated Rye Velvet Grass
Gx3	Gräser Mischung 3	g3 g4 g5 g8	Knäuelgras Wiesenschwingel Lolch Wiesenrispengras	Gx3	Grass Mix 3	g3 g4 g5 g8	Orchard Grass Meadow Fescue Perennial Rye Grass June Grass
Gx4	Getreide Mischung 4	g12 g14 g15 g18 g20	Roggen Hafer Weizen Gerste Mais	Gx4	Corn Mix 4	g12 g14 g15 g18 g20	Cultivated Rye Cultivated Oat Wheat Barley Corn

Pollen
Gräser und Getreide
Multi-Allergene

Pollens
Grasses and Corn
Multi-Allergens

Code	Deutsch			Code	English		
Gx5	Gräser Mischung 5	g1	Ruchgras	Gx5	Grass Mix 5	g1	Sweet Vernal Grass
		g2	Hundszahngras			g2	Bermuda Grass
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g10	Sudangras			g10	Sudan Grass
Gx6	Gräser Mischung 6	g2	Hundszahngras	Gx6	Grass Mix 6	g2	Bermuda Grass
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g8	Wiesenrispengras			g8	June Grass
		g10	Sudangras			g10	Sudan Grass
Gx10	Gräser Mischung 10	g2	Hundszahngras	Gx10	Grass Mix 10	g2	Bermuda Grass
		g4	Wiesenschwingel			g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g8	Wiesenrispengras			g8	June Grass
		g14	Hafer			g14	Cultivated Oat
Gx11	Gräser Mischung 11	g3	Knäuelgras	Gx11	Grass Mix 11	g3	Orchard Grass
		g4	Wiesenschwingel			g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g8	Wiesenrispengras			g8	June Grass
		g20	Mais			g20	Corn
Gx12	Gräser Mischung 12	g1	Ruchgras	Gx12	Grass Mix 12	g1	Sweet Vernal Grass
		g2	Hundszahngras			g2	Bermuda Grass
		g9	Weißes Straußgras			g9	Creeping Bentgrass
		g10	Sudangras			g10	Sudan Grass
		g15	Weizen			g15	Wheat
Gx13	Gräser Mischung 13	g3	Knäuelgras	Gx13	Grass Mix 13	g3	Orchard Grass
		g4	Wiesenschwingel			g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g13	Wolliges Honiggras			g13	Velvet Grass
Gx15	Gräser Mischung 15	g2	Hundszahngras	Gx15	Grass Mix 15	g2	Bermuda Grass
		g3	Knäuelgras			g3	Orchard Grass
		g4	Wiesenschwingel			g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g8	Wiesenrispengras			g8	June Grass
Gx17	Gräser Mischung 17	g2	Hundszahngras	Gx17	Grass Mix 17	g2	Bermuda Grass
		g4	Wiesenschwingel			g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g10	Sudangras			g10	Sudan Grass
		g17	Bahiagras			g17	Bahia Grass
Gx18	Gräser Mischung 18	g4	Wiesenschwingel	Gx18	Grass Mix 18	g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g21	Quecke			g21	Couch Grass

Pollen
Gräser und Getreide
Multi-Allergene

Pollens
Grasses and Corn
Multi-Allergens

Code	Deutsch			Code	English		
Gx19	Gräser Mischung 19	g6	Lieschgras	Gx19	Grass Mix 19	g6	Timothy Grass
		g12	Roggen			g12	Cultivated Rye
		g14	Hafer			g14	Cultivated Oat
		g15	Weizen			g15	Wheat
		g18	Gerste			g18	Barley
		g21	Quecke			g21	Couch Grass
Gx20	Gräser Mischung 20	g1	Ruchgras	Gx20	Grass Mix 20	g1	Sweet Vernal Grass
		g3	Knäuelgras			g3	Orchard Grass
		g4	Wiesenschwingel			g4	Meadow Fescue
		g5	Lolch			g5	Perennial Rye Grass
		g8	Wiesenrispengras			g8	June Grass
TGx3	Gräser Mischung T3	g1	Ruchgras	TGx3	Grass Mix T3	g1	Sweet Vernal Grass
		g5	Lolch			g5	Perennial Rye Grass
		g6	Lieschgras			g6	Timothy Grass
		g12	Roggen			g12	Cultivated Rye
		g13	Wolliges Honiggras			g13	Velvet Grass
		w6	Beifuß			w6	Mugwort

Tierallergene
(Epithelien, Haare, Federn, Urin, Kot)

Animal Allergens
(Dander, Hair, Feathers, Urine, Droppings)

Code	Deutsch	English
e1	Katze (Epithel)	Cat (Dander)
e2	Hund (Haare)	Dog (Hair)
e3	Pferd (Epithel)	Horse (Dander)
e4	Rind (Epithel)	Cow (Dander)
e5	Hund (Epithel)	Dog (Dander)
e6	Meerschweinchen (Haare)	Guinea Pig (Hair)
e7	Taube (Kot)	Pigeon (Droppings)
e9	Kanarienvogel (Federn)	Canary (Feathers)
e10	Papagei (Federn)	Parrot (Feathers)
e11	Taube (Federn)	Pigeon (Feathers)
e12	Taube (Eiweiß)	Pigeon (Egg White)
e13	Taube (Serum)	Pigeon (Serum)
e14	Kanarienvogel (Serum)	Canary (Serum)
e15	Huhn (Serum)	Chicken (Serum)
e16	Papagei (Serum)	Parrot (Serum)
e17	Kamelhaar (Wolle)	Camel hair (Wool)
e18	Kanarienvogel (Kot)	Canary (Droppings)
e19	Gans (Kot)	Goose (Droppings)
e20	Huhn (Kot)	Chicken (Droppings)
e32	Katze (Serum)	Cat (Serum)
e33	Kaninchen (Serum)	Rabbit (Serum)
e50	Zierfink (Federn)	Finch (Feathers)
e51	Zierfink (Kot)	Finch (Droppings)
e52	Hase (Epithel)	Hare (Dander)
e70	Gans (Federn)	Goose (Feathers)
e71	Maus (Epithel)	Mouse (Dander)
e72	Maus (Urin)	Mouse (Urine)
e73	Ratte (Epithel)	Rat (Dander)
e74	Ratte (Urin)	Rat (Urine)
e75	Ratte (Serum)	Rat (Serum)
e76	Maus (Serum)	Mouse (Serum)
e77	Wellensittich (Kot)	Budgerigar (Droppings)
e78	Wellensittich (Federn)	Budgerigar (Feathers)

Tierallergene
(Epithelien, Haare, Federn, Urin, Kot)

Animal Allergens
(Dander, Hair, Feathers, Urine, Droppings)

Code	Deutsch	English
e79	Wellensittich (Serum)	Budgerigar (Serum)
e80	Ziege (Epithel)	Goat (Dander)
e81	Schaf (Epithel)	Sheep (Dander)
e82	Kaninchen (Haare)	Rabbit (Hair)
e83	Schwein (Epithel)	Pig (Dander)
e84	Goldhamster (Haare)	Gold Hamster (Hair)
e85	Huhn (Federn)	Chicken (Feathers)
e86	Ente (Federn)	Duck (Feathers)
e87	Ratte (Epithel + Protein)	Rat (Dander + Protein)
e88	Maus (Epithel + Protein)	Mouse (Dander + Protein)
e89	Maus (Kot)	Mouse (Droppings)
e90	Ratte (Kot)	Rat (Droppings)
e91	Truthahn (Federn)	Turkey (Feathers)
e97	Papagei (Kot)	Parrot (Droppings)
e98	Chinchilla (Haare)	Chinchilla (Hair)
e99	Gans (Eiweiß)	Goose (Egg White)
e100	Ente (Kot)	Duck (Droppings)
e101	BSA Rinderserum	BSA Bovine Serum albumine (Cow)
e102	Schwein (Serum)	Pig (Serum)
e103	Wildschwein (Epithel)	Wild Boar (Dander)

Tierallergene
Multi-Allergene

Animal Allergens
Multi-Allergens

Code	Deutsch			Code	English		
Ex1	Tierepithelien 1	e1	Katze (Epithel)	Ex1	Epithelia 1	e1	Cat (Dander)
		e3	Pferd (Epithel)			e3	Horse (Dander)
		e4	Rind (Epithel)			e4	Cow (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
Ex2	Tierepithelien 2	e1	Katze (Epithel)	Ex2	Epithelia 2	e1	Cat (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
		e6	Meerschweinchen (Haare)			e6	Guinea Pig (Hair)
		e84	Goldhamster (Haare)			e84	Goldhamster (Hair)
Ex3	Tierepithelien 3	e3	Pferd (Epithel)	Ex3	Epithelia 3	e3	Horse (Dander)
		e4	Rind (Epithel)			e4	Cow (Dander)
		e81	Schaf (Epithel)			e81	Sheep (Dander)
		e82	Kaninchen (Haare)			e82	Rabbit (Hair)
Ex4	Bettfedern	e70	Gans (Federn)	Ex4	Bed Feathers	e70	Goose (Feathers)
		e85	Huhn (Federn)			e85	Chicken (Feathers)
		e86	Ente (Federn)			e86	Duck (Feathers)
Ex5	Nagetiere	e6	Meerschweinchen (Haare)	Ex5	Rodents	e6	Guinea Pig (Hair)
		e71	Maus (Epithel)			e71	Mouse (Dander)
		e73	Ratte (Epithel)			e73	Rat (Dander)
		e82	Kaninchen (Haare)			e82	Rabbit (Hair)
		e84	Goldhamster (Haare)			e84	Gold Hamster (Hair)
Ex6	Federn Mischung 6	e11	Taube (Federn)	Ex6	Feathers 6	e11	Pigeon (Feathers)
		e70	Gans (Federn)			e70	Goose (Feathers)
		e85	Huhn (Federn)			e85	Chicken (Feathers)
		e86	Ente (Federn)			e86	Duck (Feathers)
Ex7	Käfigvögel Mischung 7	e14	Kanarienvogel (Serum)	Ex7	Cagebirds 7	e14	Canary (Serum)
		e16	Papagei (Serum)			e16	Parrot (Serum)
		e51	Zierfink (Kot)			e51	Finch (Droppings)
		e79	Wellensittich (Serum)			e79	Budgerigar (Serum)

Tierallergene
Multi-Allergene

Animal Allergens
Multi-Allergens

Code	Deutsch			Code	English		
Ex11	Käfigvögel Mischung 11	e9	Kanarienvogel (Federn)	Ex11	Cagebirds 11	e9	Canary (Feathers)
		e10	Papagei (Federn)			e10	Parrot (Feathers)
		e50	Zierfink (Federn)			e50	Finch (Feathers)
		e78	Wellensittich (Federn)			e78	Budgerigar (Feathers)
Ex13	Tier Mischung 13	e1	Katze (Epithel)	Ex13	Animal Mix 13	e1	Cat (Dander)
		e11	Taube (Federn)			e11	Pigeon (Feathers)
		e80	Ziege (Epithel)			e80	Goat (Dander)
		e81	Schaf (Epithel)			e81	Sheep (Dander)
Ex14	Tier Mischung 14	e1	Katze (Epithel)	Ex14	Animal Mix 14	e1	Cat (Dander)
		e3	Pferd (Epithel)			e3	Horse (Dander)
		e4	Rind (Epithel)			e4	Cow (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
		e6	Meerschweinchen (Haare)			e6	Guinea Pig (Hair)
Ex16	Tierepithelien/ Federn *	e3	Pferd (Epithel)	Ex16	Epithelia/ Feathers *	e3	Horse (Dander)
		e4	Rind (Epithel)			e4	Cow (Dander)
		e70	Gans (Federn)			e70	Goose (Feathers)
		e85	Huhn (Federn)			e85	Chicken (Feathers)
Ex17	Tierepithelien 17*	e1	Katze (Epithel)	Ex17	Epithelia 17*	e1	Cat (Dander)
		e3	Pferd (Epithel)			e3	Horse (Dander)
		e4	Rind (Epithel)			e4	Cow (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
		e70	Gans (Federn)			e70	Goose (Feathers)
		e81	Schaf (Epithel)			e81	Sheep (Dander)
		e85	Huhn (Federn)			e85	Chicken (Feathers)
Ex18	Tier Mischung 18*	e1	Katze (Epithel)	Ex18	Epithelia 18*	e1	Cat (Dander)
		e3	Pferd (Epithel)			e3	Horse (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
		e6	Meerschweinchen (Haare)			e6	Guinea Pig (Hair)
		e82	Kaninchen (Haare)			e82	Rabbit (Hair)
Ex19	Tier Mischung 19*	e1	Katze (Epithel)	Ex19	Animal Mix19*	e1	Cat (Dander)
		e4	Rind (Epithel)			e4	Cow (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
		e70	Gans (Federn)			e70	Goose (Feathers)
		e81	Schaf (Epithel)			e81	Sheep (Dander)
		e88	Maus (Epithel + Protein)			e88	Mouse (Dander + Protein)
TEx2	Tierepithelien*	e1	Katze (Epithel)	TEx2	Animal Epithelia*	e1	Cat (Dander)
		e5	Hund (Epithel)			e5	Dog (Dander)
		e6	Meerschweinchen (Haare)			e6	Guinea Pig (Hair)
		e87	Ratte (Epithel + Protein)			e87	Rat (Dander + Protein)
		e88	Maus (Epithel + Protein)			e88	Mouse (Dander + Protein)

* nur als biotinyliertes Reagenz verfügbar
* available only as biotinylated reagent

Insekten Gifte — Insects Venoms

Code	Deutsch	English	Latein/Latin
i1	Bienengift	Honey Bee Venom	Apis mellifera
i3	Wespengift	Wasp Venom	Vespula germanica
i4	Bremse	Gadfly	Tabanus spp.
i5	Gelbwespe	Yellow Hornet	Dolichovespula arenaria
i6	Küchenschabe (deutsch)	German Cockroach	Blatella germanica
i7	Hornissengift	Hornet Venom	Vespa crabro
i8	Hummelgift	Bumble Bee Venom	Bombus terrestris
i9	Reismehlkäfer	Tribolium confusum	Tribolium confusum
i10	Papierwespe	Paper Wasp	Polystes apachus
i11	Phospholipase A	Phospholipase A/Honey Bee	Phospholipase A/Apis mellifera
i12	Melittin	Melittin	
i13	Dolichovespula maculata	White (bald) faced Hornet	Dolichovespula maculata
i14	Küchenschabe (amerikanisch)	American Cockroach	Periplaneta americana
i15	Hausfliege	Housefly	Musca domestica
i70	Feuerameise	Fire Ant	Solenopsis invicta
i71	Stechmücke	Mosquito	Culex pipiens
i73	Rote Mückenlarve	Red Midge Larva	Chironomus spp.
i74	Wasserfloh	Waterflea	Daphnia spp.

Milben — Mites

Code	Latein/Latin
d1	D. pteronyssinus
d2	D. farinae
d3	Euroglyphus maynei
d4	D. microceras
d5	Blomia tropicalis
d70	Acarus siro
d71	Lepidoglyphus destructor
d72	Tyrophagus putreus
d73	Glycophagus domesticus

Multi-Allergene — Multi-Allergens

Code	Deutsch		Latein/Latin	Code	English	
Dx1	Hausstaub-/ Mehlmilbe	d1 d2	D. pteronyssinus D. farinae	Dx1	House Dust-Mites	d1 d2
Dx3	Milben-Mischung 3	d70 d71 d72 d73	Acarus siro Lepidoglyphus destructor Tyrophagus putreus Glycophagus domesticus	Dx3	Mites - Mix 3	d70 d71 d72 d73
Dx4	Milben-Mischung 4	d1 d2 d3 d4 d70 d71 d72 d73	D. pteronyssinus D. farinae Euroglyphus maynei D. microceras Acarus siro Lepidoglyphus destructor Tyrophagus putreus Glycophagus domesticus	Dx4	Mites - Mix 4	d1 d2 d3 d4 d70 d71 d72 d73

Hausstaub Mischungen — House Dust Mixes

Code	Deutsch		Code	English	
H2	Hausstaub-Mischung T/S (Hollister Stier)	e1 Katze (Epithel) e5 Hund (Epithel) d1 D. pteronyssinus d2 D. farinae m2 Cladosporium herbarum m3 Aspergillus fumigatus	H2	House Dust T/S (Hollister Stier)	e1 Cat (Dander) e5 Dog (Dander) d1 D. pteronyssinus d2 D. farinae m2 Cladosporium herbarum m3 Aspergillus fumigatus
H3	Hausstaub-Mischung M (Bencard)	e1 Katze (Epithel) e5 Hund (Epithel) d1 D. pteronyssinus d2 D. farinae m2 Cladosporium herbarum m3 Aspergillus fumigatus	H3	House Dust M (Bencard)	e1 Cat (Dander) e5 Dog (Dander) d1 D. pteronyssinus d2 D. farinae m2 Cladosporium herbarum m3 Aspergillus fumigatus
Hx1	Haus-Mischung 1	d1 D. pteronyssinus d2 D. farinae i6 Küchenschabe	Hx1	House Dust Mix 1	d1 D. pteronyssinus d2 D. farinae i6 German Cockroach
Hx2	Haus-Mischung 2	d1 D. pteronyssinus d2 D. farinae e1 Katze (Epithel) e5 Hund (Epithel)	Hx2	House Dust Mix 2	d1 D. pteronyssinus d2 D. farinae e1 Cat (Dander) e5 Dog (Dander)
HMx1	Haus-Mischung	d1 D. pteronyssinus d2 D. farinae e1 Katze (Epithel) e5 Hund (Epithel) m2 Cladosporium herbarum m3 Aspergillus fumigatus	HMx1	House Mix	d1 D. pteronyssinus d2 D. farinae e1 Cat (Dander) e5 Dog (Dander) m2 Cladosporium herbarum m3 Aspergillus fumigatus
HMx2	Hausmischung 2	d1 D. pteronyssinus e1 Katze (Epithel) e5 Hund (Epithel) m3 Aspergillus fumigatus m6 Alternaria tenuis (alternata)	HMx2	House Mix 2	d1 D. pteronyssinus e1 Cat (Dander) e5 Dog (Dander) m3 Aspergillus fumigatus m6 Alternaria tenuis (alternata)
HMx3	Hausmischung 3	d1 D. pteronyssinus d2 D. farinae i6 Küchenschabe m1 Penicillium chrysogenum (notatum) m3 Aspergillus fumigatus m5 Candida albicans m6 Alternaria tenuis (alternata)	HMx3	House Mix 3	d1 D. pteronyssinus d2 D. farinae i6 German Cockroach m1 Penicillium chrysogenum (notatum) m3 Aspergillus fumigatus m5 Candida albicans m6 Alternaria tenuis (alternata)

Parasiten — Parasites

Code	Deutsch	Code	English
p1	Ascaris	p1	Ascaris

Medikamente Drugs

Code	Deutsch	English
c1	Penicilloyl G	Penicilloyl G
c2	Penicilloyl V	Penicilloyl V
c50	Ampicillin	Ampicillin
c51*	Acetylsalicylsäure (ASS)	Acetylsalicylic Acid (ASS)
c52*	Pyrazolon (4-Amino-Antipyrin)	Pyrazolone (4-Amino-Antipyrine)
c53*	Alcuronium	Alcuronium
c54*	Cefalotin	Cefalotin
c55*	Cephalosporin	Cephalosporin
c56	Amoxycillin	Amoxycillin
c57*	TMP (Trimethoprim)	TMP (Trimethoprime)
c58*	SMZ (Sulfamethoxazol)	SMZ (Sulfamethoxazole)
c59*	Tetracyclin	Tetracycline
c60*	Gentamycin	Gentamycin
c61*	Erythromycin	Erythromycin
c62*	Doxycyclin	Doxycyclin
c64*	Piperacillin	Piperacillin
c65*	Phenylbutazon	Phenylbutazone
c66*	Streptomycin	Streptomycin
c67*	Cloxacillin	Cloxacillin
c68*	Articain	Articaine
c70*	Insulin human (Protaphane Penfill)	Insulin human (Protaphane Penfill)
c71*	Insulin human (Insuman Rapid)	Insulin human (Insuman Rapid)
c73*	Insulin human (Humalog)	Insulin human (Humalog)
c77*	Piroxicam	Piroxicam
c78*	Ibuprofen	Ibuprofen
c79*	Diclofenac	Diclofenac
c80*	Tetanus - Toxoid	Tetanus - Toxoide
c81*	Theophyllin / Aminophyllin	Theophylline / Aminophylline
c82*	Lidocain / Xylocain	Lidocaine / Xylocain
c83*	Procain	Procaine
c85*	Paracetamol	Paracetamol
c86*	Benzocain	Benzocaine
c87*	Carbocain	Carbocain
c88*	Mepivacain	Mepivacain
c89*	Bupivacain	Bupivacain
c90*	Propyphenazon	Propyphenazone
c91*	Dipyron/Metamizol	Dipyron/Metamizole
c93*	Indometacin	Indomethacine
c94*	Tobramycin	Tobramycin
c95*	Neomycin	Neomycin
c96*	Ambroxol	Ambroxole
c97*	Bromhexin	Bromhexine
c99*	L-Thyroxin	L-Thyroxine
c100*	Prilocain	Prilocaine
c103*	Isoprenalin / Orciprenalin	Isoprenalin / Orciprenalin
c104*	Clindamycin	Clindamycin
c106*	Vitamin B1 (Thiamin)	Vitamin B1 (Thiamine)
c107*	Captopril	Captoprile
c108*	Ciprofloxacin	Ciprofloxacin
c109*	Vitamin B6	Vitamin B6
c110*	Naproxen	Naproxene
c111*	Phenacetin	Phenacetine
c112*	Tartrazin	Tartrazin
c113*	Tyramin	Tyramine
c114*	Tryptophan	Tryptophan
c115*	Lincomycin	Lincomycin
c116*	Oxacillin	Oxacillin
c118*	Ofloxacin	Ofloxacin

*Zu Forschungszwecken. *For research use

Medikamente Drugs

Code	Deutsch	English
c119	Bacampicillin	Bacampicillin
c120*	Carbenicillin	Carbenicillin
c122*	Nystatin	Nystatin
c126*	Penicillamin	Penicillamin
c127*	5-Aminosalicylsäure	5-Aminosalicylicacid
c128*	Minocyclin	Minocyclin
c129*	Erythrosin-B	Erythrosin-B
c130*	Azlocillin	Azlocillin
c133*	Cyanocobalamin Vitamin B12	Cyanocobalamin Vitamin B12
c138*	Ginkgo	Ginkgo
c145*	Echinacea	Echinacea
c151*	Acetylcystein	Acetylcysteine
c152*	Chloramphenicol	Chloramphenicol
c153*	Metronidazol	Metronidazole
c154*	Prednisolon	Prednisolone
c156*	Maleinsäureanhydrid	Maleinacidanhydrid
c157*	Hexahydrophthalsäure	Hexahydrophthalicacid
c158*	Methyltetrahydrophthalsäure	Methyltetrahydrophthalicacid
c161*	Roxithromycin	Roxithromycin
c162*	Vancomycin	Vancomycin
c165*	Cefaclor	Cefaclor
c169*	Heparin	Heparin
c170*	Clarithromycin	Clarithromycin
c172*	Ketoprofen	Ketoprofen
c175*	Norfloxacin	Norfloxacin
c179*	Chymotrypsin	Chymotrypsin
c181*	Ascorbinsäure	Ascorbic acid
c186*	Hydrochlorothiazid	Hydrochlorothiazid
c194*	Azithromycin	Azithromycin
c196*	Epinephrin	Epinephrine
c200*	Clavulansäure	Clavulanic acid
c210*	Tetracain	Tetracaine
c308*	Cefuroxim	Cefuroxime
c425	Simvastatin	Simvastatin

*Zu Forschungszwecken. *For research use

Berufs-allergene

Occupational Allergens

Code	Deutsch	English	E-Nr.
k70	Grüne Kaffeebohne	Green Coffee Bean	
k71	Rhizinusbohne	Castor Bean	
k72	Isphagula	Isphagula	
k74	Rohseide (Bombyx mori)	Silk (Bombyx mori)	
k75	Isocyanat TDI	Toluene diisocyanate TDI	
k76	Isocyanat MDI	Diphenyl methane MDI	
k77	Isocyanat HDI	Hexamethylene diisocyanate HDI	
k78	Ethylenoxid	Ethyleneoxide	
k79	Phthalsäureanhydrid	Phthalic anhydride	
k80	Formaldehyd	Formaldehyde	
k81	Birkenfeige	Ficus benjamina	
k82	Latex (Hevea brasiliensis)	Latex (Hevea brasiliensis)	
k83	Guarkernmehl	Guarflour	E 412
k84	Sonnenblumensamen	Sunflower Seed	
k85	Chloramin T	Chloramine T	
k86	Trimellitsäureanhydrid	Trimellitic anhydride	
k87	Phenylendiamin	Phenylendiamine	
k88	Amyloglucosidase	Amyloglucosidase	
k89	Hemizellulase	Hemicellulase	
k90	Lipoxigenase	Lipoxigenase	
k92	Abietinsäure (Kollophonium)	Collophonium (Abietic acid)	
k93	Ammoniumpersulfat	Ammoniumpersulphate	
k94	Kollagen (tierisch, pflanzlich)	Collagen (animal, herbal)	
k95	Tragant (Astragalus spp.)	Tragacanth (Astragalus spp.)	E 413
k96	Chinolingelb	Chinolin yellow	E 104
k97	Gelborange S	Yelloworange S	E 110
k99	Amaranth	Amaranth	E 123
k102	Alkalase	Alcalase	
k104	Savinase	Savinase	
k105	Gummi Arabicum	Gum arabic	E 414
k106	Karminrot	Carmine red	
k107	Azorubin	Azorubin	E 122

Beruf und Hobby

Occupational Allergens

Code	Deutsch	English
b2	Baumwolle (bearbeitet)	Cotton (treated)
b3	Baumwollflocken (unbearbeitet)	Cotton flock (untreated)
b4	Dreschstaub	Threshing Dust
b5	Flachs	Flax
b7	Heustaub	Hay Dust
b8	Hopfen	Hop
b13	Jute	Jute
b14	Kapok	Kapok
b16	Leinen	Linen
b20	Schafwolle (bearbeitet)	Sheep Wool (treated)
b21	Schafwolle (unbearbeitet)	Sheep Wool (untreated)
b22	Seide (Bombyx mori)	Silk (Bombyx mori)

Beruf und Hobby

Occupational Allergens

Code	Deutsch	English
b23	Strohstaub	Straw Dust
b24	Tabakstaub	Tobacco Dust
b26	Weizendrusch	Wheat Threshing

Holz-/Sägespäne

Smuts

b31	Ahorn	Maple
b32	Buche	Beech
b33	Eiche	Oak
b34	Esche	Ash
b35	Fichte	Fir
b36	Kiefer	White Pine
b40	Nussbaum	Walnut Tree
b41	Obechi (Abachi)	Obechi (Abachi)
b43	Rote Zeder	Red Cedar
b44	Tanne	Silver Fir
b50	Pappel	Poplar
b52	Erle	Alder
b53	Kirschbaum	Cherry Tree
b55	Lärche	Larch

Beruf und Hobby

Multi-Allergene

Occupational Allergens

Multi-Allergens

Code	Deutsch			Code	English		
Bx2	Naturstoffe/ Fasern	b2	Baumwolle (bearb.)	Bx2	Natural Fibres	b2	Cotton (treated)
		b13	Jute			b13	Jute
		b20	Schafwolle (bearb.)			b20	Sheep´s Wool (treated)
		b22	Seide			b22	Silk
Bx3	Weichhölzer	b32	Buche	Bx3	Wood I	b32	Beech
		b36	Kiefer			b36	White Pine
		b43	Rote Zeder			b43	Red Cedar
		b44	Tanne			b44	Fir
Bx5	Stäube	b4	Dreschstaub	Bx5	Dusts	b4	Threshing Dust
		b7	Heustaub			b7	Hay Dust
		b23	Strohstaub			b23	Straw Dust
		b26	Weizendrusch			b26	Wheat Threshing
Bx7	Staub-mischung 7	b7	Heustaub	Bx7	Dust Mix 7	b7	Hay Dust
		b23	Strohstaub			b23	Straw Dust
		b24	Tabakstaub			b24	Tobacco Dust
		b26	Weizendrusch			b26	Wheat Threshing

Konservierungsstoffe Preservatives

Code	Deutsch	English	E-Nr.
Ko1*	p-Hydroxybenzoesäureethylester	p-Hydroxybenzoicacidethylester	E 214
Ko2*	p-Hydroxybenzoesäurebutylester	p-Hydroxybenzoicacidbutylester	
Ko3*	p-Hydroxybenzoesäurepropylester	p-Hydroxybenzoicacidpropylester	E 216
Ko4*	Sorbinsäure	Sorbic Acid	E 200
Ko5*	Benzoesäure	Benzoic Acid	E 210
Ko7*	p-Hydroxybenzoesäuremethylester	p-Hydroxybenzoicacidmethylester	E 218

Suchtests

Multi-Allergene

Code	Deutsch		
STx0	Suchtest multi	g6	Lieschgras
		g12	Roggen
		t3	Birke
		w6	Beifuß
		d1	D. pteronyssinus
		e1	Katze (Epithel)
		e5	Hund (Epithel)
		m2	Cladosporium herbarum
STx1	Suchtest saisonal	g6	Lieschgras
		t3	Birke
		w6	Beifuß
		m6	Alternaria tenuis (alternata)
STx2	Suchtest perennial	d1	D. pteronyssinus
		e1	Katze (Epithel)
		e5	Hund (Epithel)
		m3	Aspergillus fumigatus
STx3	Inhalations-Panel	t1	Ahorn
		t8	Ulme
		t17	Kastanie
		t28	Robinie
		w20	Brennessel
		b14	Kapok
		b23	Strohstaub
		m22	Mucor spinosus
		m36	Aspergillus terreus
STx4	Nahrungs-mittel-Panel	f7	Hafermehl
		f18	Paranuss
		f29	Banane
		f38	Spinat
		f48	Zwiebel
		f51	Sojaschrot
		f65	Linse
		f70	Schweizer Käse
		f88	Hammel/Lamm
STx5	Regionalmix	g6	Lieschgras
		w6	Beifuß
		w9	Spitzwegerich
		w21	Glaskraut 1
		t3	Birke

Screening Tests

Multi-Allergens

Code	English		
STx0	Screen multi	g6	Timothy Grass
		g12	Barley
		t3	Birch
		w6	Mugwort
		d1	D. pteronyssinus
		e1	Cat (Dander)
		e5	Dog (Dander)
		m2	Cladosporium herbarum
STx1	Screen saisonal	g6	Timothy Grass
		t3	Birch
		w6	Mugwort
		m6	Alternaria tenuis (alternata)
STx2	Screen perennial	d1	D. pteronyssinus
		e1	Cat (Dander)
		e5	Dog (Dander)
		m3	Aspergillus fumigatus
STx3	Inhalation-Panel	t1	Maple
		t8	Elm
		t17	Chestnut
		t28	Robinia
		w20	Nettle
		b14	Kapok
		b23	Straw Dust
		m22	Mucor spinosus
		m36	Aspergillus terreus
STx4	Food-Panel	f7	Oat Flour
		f18	Brazil Nut
		f29	Banana
		f38	Spinach
		f48	Onion
		f51	Soy bean (bruised grain)
		f65	Lentil
		f70	Swiss Cheese
		f88	Mutton/Lamb
STx5	Regionalmix	g6	Timothy Gras
		w6	Mugwort
		w9	English Plantain
		w21	Wall Pellitory 1
		t3	Birch

*Zu Forschungszwecken. *For research use

Suchtests

Multi-Allergene

Code	Deutsch		
STx6	Inhalations-Panel 6	d2	D. farinae
		e1	Katze (Epithel)
		e5	Hund (Epithel)
		e3	Pferd (Epithel)
		m6	Alternaria tenuis (alternata)
STx7	Inhalations-Mix	g2	Hundszahngras
		g4	Wiesenschwingel
		g5	Lolch
		t11	Platane
		t14	Pappel
		t15	Esche
		t36	Akazie
		w9	Spitzwegerich
		w18	Sauerampfer
STx8	Inhalations-Mix	d1	D. pteronyssinus
		d2	D. farinae
		ex6	Federn Mischung 6
		e1	Katze (Epithel)
		e5	Hund (Epithel)
		m2	Cladosporium herbarum
		m3	Aspergillus fumigatus
		m6	Alternaria tenuis (alternata)
STx9	Pollen/ Schimmel-Pilze*	m3	Aspergillus fumigatus
		m6	Alternaria tenuis (alternata)
		g12	Roggen
		g15	Weizen
STx10	Suchtest Multi 10	e1	Katze (Epithel)
		e5	Hund (Epithel)
		d1	D. pteronyssinus
		d3	Euroglyphus maynei
		m2	Cladosporium herbarum
		m3	Aspergillus fumigatus
STx32	Suchtest Multi 32*	d1	D. pteronyssinus
		d2	D. farinae
		e1	Katze (Epithel)
		e5	Hund (Epithel)
		g6	Lieschgras
		t3	Birke
		t14	Pappel
		w6	Beifuß
		w15	Melde
		m6	Alternaria tenuis (alternata)

Screening Tests

Multi-Allergens

Code	English		
STx6	Inhalation-Panel 6	d2	D. farinae
		e1	Cat (Dander)
		e5	Dog (Dander)
		e3	Horse (Dander)
		m6	Alternaria tenuis (alternata)
STx7	Inhalation-Mix	g2	Bermuda Grass
		g4	Meadow fescue
		g5	Perennial Rye Grass
		t11	Plane
		t14	Poplar
		t15	Ash
		t36	Acacia
		w9	English Plantain
		w18	Sorrel
STx8	Inhalation-Mix	d1	D. pteronyssinus
		d2	D. farinae
		ex6	Feathers 6
		e1	Cat (Dander)
		e5	Dog (Dander)
		m2	Cladosporium herbarum
		m3	Aspergillus fumigatus
		m6	Alternaria tenuis (alternata)
STx9	Pollen/ Molds *	m3	Aspergillus fumigatus
		m6	Alternaria tenuis (alternata)
		g12	Cultivated Rye
		g15	Wheat
STx10	Screen Multi 10	e1	Cat (Dander)
		e5	Dog (Dander)
		d1	D. pteronyssinus
		d3	Euroglyphus maynei
		m2	Cladosporium herbarum
		m3	Aspergillus fumigatus
STx32	Screen Multi 32*	d1	D. pteronyssinus
		d2	D. farinae
		e1	Cat (Dander)
		e5	Dog (Dander)
		g6	Timothy Grass
		t3	Birch
		t14	Poplar
		w6	Mugwort
		w15	Scale
		m6	Alternaria tenuis (alternata)

* nur als biotinyliertes Reagenz verfügbar
* available only as biotinylated reagent

Nahrungsmittel Foods

Code	Deutsch	English	Latein/Latin
f1	Eiklar	Egg White	
f2	Kuhmilch (roh)	Cow's milk (raw)	
f3	Dorsch (Kabeljau)	Codfish	Gadus morhua
f4	Weizenmehl	Wheat flour	Triticum aestivum
f5	Roggenmehl	Rye flour	Secale cereale
f6	Gerstenmehl	Barley flour	Hordeum vulgare
f7	Hafermehl	Oat flour	Avena sativa
f8	Maismehl	Corn flour	Zea mays
f9	Reis	Rice	Oryza sativa
f10	Sesamschrot	Sesame (bruised grain)	Sesamum indicum
f11	Buchweizenmehl	Buckwheat flour	Fagopyrum esculentum
f12	Erbse	Pea	Pisum sativum
f13	Erdnuss	Peanut	Arachis hypogaea
f14	Sojabohne	Soybean	Glycine max.
f15	Bohne (weiß)	White Bean	Phaseolus vulgaris
f16	Walnuss	Walnut	Juglans regia
f17	Haselnuss	Hazelnut	Corylus avellana
f18	Paranuss	Brazil Nut	Bertholletia excelsa
f19	Esskastanie	Sweet Chestnut	Castanea sativa
f20	Mandel	Almond	Amygdalus communis
f21	Hering	Herring	Clupea harengus
f22	Forelle	Trout	Oncorhynchus mykiss (Salmo gairdnieri)
f23	Krabbe	Crab	Cancer pagurus
f24	Garnele	Shrimp	Pandalus borealis
f25	Tomate	Tomato	Solanum lycopersicum
f26	Schweinefleisch	Pork	Sus spp.
f27	Rindfleisch	Beef	Bos spp.
f29	Banane	Banana	Musa spp.
f30	Birne	Pear	Pyrus communis
f31	Karotte	Carrot	Daucus carota
f32	Zitrone	Lemon	Citrus limon
f33	Orange	Orange	Citrus sinensis
f34	Mandarine	Tangerine	Citrus reticulata
f35	Kartoffel	Potato	Solanum tuberosum
f36	Kokosnuss	Coconut	Cocos nucifera
f37	Miesmuschel	Blue mussel	Mytilus edulis
f38	Spinat	Spinach	Spinachia oleracea
f39	Kohl	Cabbage	Brassica oleracea var. capitata
f40	Thunfisch	Tuna	Thunnus albacares
f41	Lachs	Salmon	Salmo salar
f42	Sauerampfer	Sorrel	Rumex acetosella
f43	Brauereihefe	Saccharomyces carlsbergensis	Saccharomyces carlsbergensis
f44	Erdbeere	Strawberry	Fragaria ananassa
f45	Bäckerhefe	Yeast	Saccharomyces cerevisiae
f46	Paprika	Paprika	Capsicum spp.
f47	Knoblauch	Garlic	Allium sativum
f48	Zwiebel	Onion	Allium cepa
f49	Apfel	Apple	Malus sylvestris
f50	Weintraube	Grape	Vitis vinifera
f51	Sojaschrot	Soy (bruised grain)	Glycine max.
f52	Schokolade	Chocolate	Theobroma cacao
f53	Pfirsich	Peach	Prunus persica
f54	Stutenmilch	Maremilk	
f55	Aal	Eel	Anguilla anguilla
f56	Rotbarsch	Rosefish	Sebastus marinus
f57	Entenfleisch	Duck meat	Anas spp.
f58	Gänsefleisch	Goose meat	Anser spp.
f61	Blumenkohl roh	Cauliflower raw	Brassica oleracea

Nahrungsmittel Foods

Code	Deutsch	English	Latein/Latin
f62	Blumenkohl gekocht	Cauliflower boiled	Brassica oleracea
f63	Rindfleisch gekocht	Beef boiled	Bos spp.
f64	Kresse	Cress	Lepidium sativum
f65	Linse	Lentil	Lens esculenta
f66	Porree	Leek	Melium porrum
f67	Ovalbumin	Ovalbumin	Ovalbumina
f68	Ovomucoid	Ovomucoid	Ovomucoida
f70	Schweizer Käse	Swiss Cheese	
f71	Languste	Spiny Lobster	Palinurus spp.
f72	Ananas	Pineapple	Ananas comosus
f73	Kirsche	Cherry	Prunus spp.
f74	Maiskorn	Corn (grain)	Zea mays
f75	Eigelb	Egg Yolk	
f76	Alpha - Lactalbumin	Alpha - Lactalbumin	Alpha - Lactalbumina
f77	Beta - Lactoglobulin	Beta - Lactoglobulin	Beta - Lactoglobulina
f78	Casein	Casein	Caseina
f79	Gluten	Gluten	Gluten
f80	Hummer	Lobster	Homarus spp.
f81	Cheddarkäse	Cheddar Cheese	
f82	Schimmelkäse	Mould Cheese	
f83	Hühnerfleisch	Chicken meat	Gallus spp.
f84	Kiwi	Kiwi	Actinidia deliciosa
f85	Sellerie	Celeriac	Apium graveolens
f86	Petersilie	Parsley	Petroselinum crispum
f87	Melone	Melon	Citrullus lanatus
f88	Hammel/Lamm	Mutton/Lamb	Ovis spp.
f89	Senf	Mustard	Sinapis spp.
f90	Malz	Malt	
f91	Mango	Mango fruit	Mangifera indica
f92	Grapefruit	Grapefruit	Citrus paradisi
f93	Roquefort	Roquefort Cheese	
f94	Camembert	Camembert Cheese	
f95	Kaffee	Coffee	Coffea spp.
f96	Kamillentee	Camomile Tea	Chamomilla
f97	Kakao	Cacao	Theobroma cacao
f98	Leinsamenschrot	Flax Seed (bruised grain)	
f99	Schwarzer Tee	Black Tea	
f100	Kopfsalat	Lettuce	Lactuca sativa
f101	Venusmuschel	Clam Shell	Ruditapes spp.
f102	Kohlrabi	Kohlrabi	Brassica oleracea var. gongylodes
f103	Pecannuss	Pecan Nut	Carya illinoensis
f108	Rosenkohl	Brussels sprout	Brassica oleracea var. gemmifera
f114	Sonnenblumenkerne	Sunflowergrain	Helianthus spp.
f122	Olive grün	Olive green	Olea europea
f124	Feldsalat	Lamb's lettuce	Valerianella
f126	Pfefferminze	Peppermint	Mentha piperita
f127	Champignon	Mushroom	Agaricus hortensis
f128	Mohn	Poppy	Papaver somniferum
f129	Makadamianuss	Macadamia Nut	
f130	Truthahn	Turkey	
f131	Avocado	Avocado	Persea americana
f132	Grüne Bohne	Green bean	Phaseolus vulgaris
f133	Gurke	Cucumber	Cucumis sativus
f134	Broccoli	Broccoli	Brassica oleracea var. italica
f136	Rote Beete	Beet Root	Beta vulgaris
f137	Spargel	Asparagus	Asparagus officinalis
f138	Emmentalerkäse	Emmentaler Cheese	
f140	Hirse	Millet	Panicum miliaceum

Nahrungsmittel Foods

Code	Deutsch	English	Latein/Latin
f142	Schwarzwurzel	Black Salsify	Scorzonera hispanica
f144	Pistazienkerne	Pistachio Nut	Pistacia vera
f145	Feige	Fig	Ficus carica
f146	Hartweizengries	Semolina	
f147	Hibiscustee	Hibiscus Tea	Hibiscus
f148	Pflaume	Plum	Prunus domestica
f149	Papaya	Papaya	Carica papaya
f150	Edamer Käse	Edam Cheese	
f151	Zucchini	Zucchini	Cucurbita pepo subsp. pepo convar. giromontiina
f152	Aprikose	Apricot	Prunus armeniaca
f153	Weizenkleie	Wheat Clay	Triticum clia
f154	Johannisbrot	Carob	Ceratonia siliqua
f155	Vanille	Vanilla	Vanilla planifolia
f156	Himbeere	Raspberry	Rubus idaeus
f157	Kabeljau	Codfish	Gadus morhua
f158	Cashew - Kerne	Cashew Nut	Anacardium occidentale
f159	Kichererbse	Chick-pea	Cicer arietinum
f160	Sardine	Anchovy	Sardinops melanosticta
f161	Tintenfisch	Squid	Loligo spp.
f162	Seezunge	Sole	Solea solea
f163	Hecht	Pike	Merluccius merluccius
f164	Schwertfisch	Swordfish	Xiphias gladius
f165	Kalbfleisch	Veal	
f166	Fenchel	Fennel	Foeniculum vulgare
f167	Kaninchen	Rabbit	Oryctolagus cuniculus
f168	Milchpulver	Milk powder	
f169	Milch, gekocht	Milk, cooked	
f170	Nektarine	Nectarine	
f171	Johannisbeere, rot	Redcurrant	Ribes spicatum
f172	Artischocke	Artichoke	Cynara scolymus
f173	Knurrhahn	Gurnard	Trigla spp.
f174	Makrele	Mackerel	Scomber scombrus
f175	Brombeere	Blackberry	Rubus fruticosus
f176	Aubergine	Aubergine	Solanum melongena
f177	Auster	Oyster	Ostrea edulis
f178	Schellfisch	Haddock / White Fish	Gadus aeglefinus
f179	Steingarnele	Prawn	Palaemon squilla
f180	Karpfen	Carp	Cyprinus carpio
f182	Preiselbeere	Cranberry	Vaccinicum vitis-idaea
f183	Dinkel	Dinkel	Triticum spelta
f184	Pferdefleisch	Horsemeat	Cavallus spp.
f185	Rotkohl	Red cabbage	Brassica gemmifera
f186	Scholle	Plaice	Pleuronectes platessa
f187	Schafskäse	Sheep´s milk cheese	
f188	Sojamehl	Soy flour	
f191	Kürbis	Pumpkin	Cucurbita pepo
f192	Wachtelfleisch	Quail Meat	Coturnix coturnix
f193	Grünkern	Green rye	
f194	Peperoni	Chili	Capiscum annuum
f195	Sojamilch	Soymilk	
f196	Heilbutt	Halibut	Hippoglossus hippoglossus
f197	Pinienkerne	Pine nut, pignoles	Pinus edulis
f198	Goudakäse	Gouda Cheese	
f199	Rosinen	Raisin	
f200	Steinpilz	Boletus	Boletus edulis
f201	Pfifferling	Chanterelle	Cantharellus cibarius
f202	Gelatine (Schwein)	Gelatin (Pork)	
f203	Granatapfel	Grenadine	Punica granatum

Nahrungsmittel Foods

Code	Deutsch	English	Latein/Latin
f205	Ziegenkäse	Goat‘s milk cheese	Capra hircus
f206	Rote Kidney Bohnen	Red Kidney Bean	Phaseolus vulgaris
f207	Fencheltee	Fennel Tea	Foeniculum vulgare
f208	Chinakohl	Chinese Cabbage	Brassica chinensis
f209	Salbeitee	Sage Tea	Salvia officinale
f210	Weizenschrot	Wheat (bruised grain)	Triticum sativum
f211	Maracuja	Maracuja	
f212	Johannisbeere schwarz	Black Currant	Ribes nigrum
f213	Rhabarber	Rhubarb	Rheum officinale
f214	Radieschen	Red radish	Raphanus vadicula
f215	Maisstärke	Corn Starch	Zea mays
f217	Sojaeiweiß	Soy white	
f219	Ziegenmilch	Goat´s milk	Capra hircus
f220	Sardelle	Anchovis	Engraulidae
f221	Bambussprossen	Bamboo‘s sprouts	
f222	Kürbiskerne	Pumpkin seed	Cucurbita pepo
f223	Alpha-Amylase	Alpha-Amylase	
f224	Runkelrübe	Beet (Root)	Beta vulgaris
f226	Flugente	Muscovy duck	Cairina moschata
f227	Reh	Deer	Capreolus capreolus
f228	Wildschwein	Wild Boar	Sus scrofa
f229	Heidelbeere	Blueberry	Vaccinium myrtilleus
f230	Kaviar (schwarz)	Caviare (black)	
f231	Lychee	Lychee	Litchi chinensis
f232	Seeteufel	Monk Fish	Lophius piscatorius
f233	Grünkohl	Green cabbage	Brassia spp.
f234	Chicorée	Chicory	Cichorium intybus
f235	Stachelbeere	Gooseberry	Ribes grossularia
f236	Mangold	Mangel	Beta cicla
f237	Quitte	Quince	Cydonia oblonga
f238	Kartoffelmehl	Potato flour	Solanum tuberosum
f239	Rettich	White radish	Raphanus sativus
f240	Aspartam	Aspartam	
f241	Rinderleber	Beefliver	Bos primijenius taurus
f242	Wels	Cat fish	Silurus glanis
f243	Hopfen	Hop	Humulus lupulus
f244	Gartenbohne	Garden bean	Phaseolus vulgaris
f245	Guave	Guava	Psidium guajava
f246	Schafsmilch	Sheep´s milk	
f247	Zander	Pike perch	Sander lucioperca
f248	Dattel	Date	
f249	Seelachs	Pollack	Pollachius virens
f250	Joghurt	Yoghurt	
f251	Parmesan	Parmesan	
f252	Vollei	Egg (White & Yolk)	
f253 *	Meerrettich	Horseradish	Armoracia rusticana
f254	Roggenkorn	Rye corn	Secale cereale
f255	Weizenkorn	Wheat corn	Triticum aestivum
f256	Kokosmilch	Coconut milk	
f257	Eisbergsalat	Iceberg lettuce	
f258	Kapern	Caper	Capparis spinosa
f259	Limette	Limette	
f260	Tofu	Tofu	
f264	Leerdamerkäse	Leerdam Cheese	
f265	Appenzellerkäse	Appenzell Cheese	
f266	Grüner Tee	Green Tea	
f267	Tilsiterkäse	Tilsit Cheese	
f268	Wirsingkohl	Savoy cabbage	Brassica oleracea var. sabauda

Nahrungsmittel Foods

Code	Deutsch	English	Latein/Latin
f269	Rucola	Rocket	Eruca vesicaria
f281	Hagebutte	Rose hip	Rosa canina
f283	Römischer Salat	Roman lettuce	
f284	Radicchio	Radicchio	
f285	Zitronenmelisse	Lemon balm	Melissa officinalis
f286	Kaki	Kaki	Diospyros kaki
f287	Hase	Hare	Leporidae
f288	Hirsch	Deer	Cervidae
f289	Fasan	Pheasant	Phasianus colchicus
f291	Chesterkäse	Chester Cheese	
f292	Krebsfleisch	Crab meat	
f293	Alpha - Lactalbumin (gekocht)	Alpha - Lactalbumin (boiled)	
f294	Beta - Lactoglobulin (gekocht)	Beta - Lactoglobulin (boiled)	
f295	Casein (gekocht)	Casein (boiled)	
f298	Petersilienwurzel	Parsley root	Petroselium crispum subsp. tuberosum
f300	Honigmelone	Honeydew melon	Cucumis melo
f301	Weintraube (blau)	Grape (blue)	
f302	Austernpilz	Chinese mushroom	Pleurotus ostreatus
f315	Amaranth	Amaranth	
f320	Gerstenkorn	Barley (bruised grain)	Hordeum vulgare
f321	Haferkorn	Oat (bruised grain)	Avena sativa
f323	Kaviar (rot)	Caviare (red)	
f326	Bärlauch	Wild Garlic	Allium ursinum
f328	Rooibos Tee	Rooibos Tea	
f341	Steinbutt	Turbot	Scophthalmus maximus
f342	Mirabelle	Mirabelle	Prunus domestica subsp. syriaca
f344	Süßlupinen (Mehl)	Sweet Lupines (Flour)	
f348	Olive schwarz	Olive black	
f352	Zackenbarsch	Goliath Grouper	Epinephelus itajara
f353	Seebarsch	Bass	Atractoscion nobilis
f354	Seehecht	Hake	Merluccius merluccius
f355	Dorade	Gilthead	Sparus auratus
f357	Zitronengras	Lemon Grass	Cymbopogon citratus
f358	Sauerkirsche	Sour cherry	Prunus cerasus
f359	Physalis	Cape gooseberry	Physalis peruviana
f360	Pangasius	Thai catfish	Pangasianodon hypophthalmus

Nahrungsmittel Foods

Multi-Allergene Multi-Allergens

Code	Deutsch			Code	English		
Fx1	Nüsse 1	f13	Erdnuss	Fx1	Nuts 1	f13	Peanut
		f16	Walnuss			f16	Walnut
		f17	Haselnuss			f17	Hazelnut
		f20	Mandel			f20	Almond
Fx2	Mehle 2	f4	Weizenmehl	Fx2	Flours 2	f4	Wheat Flour
		f5	Roggenmehl			f5	Rye Flour
		f7	Hafermehl			f7	Oat Flour
		f79	Gluten			f79	Gluten
Fx3	Schalentiere/ Fische	f3	Dorsch / Kabeljau	Fx3	Crustaceae/ Fish	f3	Codfish
		f24	Garnele			f24	Shrimp
		f37	Miesmuschel			f37	Blue Mussel
		f40	Thunfish			f40	Tuna
		f41	Lachs			f41	Salmon
Fx4	Nahrungs- mittel 4	f1	Eiklar	Fx4	Foods 4	f1	Egg White
		f2	Kuhmilch (roh)			f2	Cow´s milk (raw)
		f4	Weizenmehl			f4	Wheat Flour
		f13	Erdnuss			f13	Peanut
		f14	Sojabohne			f14	Soybean
Fx5	Gemüse 5	f12	Erbse	Fx5	Vegetable 5	f12	Pea
		f15	Weiße Bohne			f15	White Bean
		f31	Karotte			f31	Carrot
		f35	Kartoffel			f35	Potato
Fx6	Gemüse 6	f25	Tomate	Fx6	Vegetable 6	f25	Tomato
		f38	Spinat			f38	Spinach
		f39	Kohl			f39	Cabbage
		f46	Paprika			f46	Paprika
Fx7	Gemüse 7	f14	Sojabohne	Fx7	Vegatable 7	f14	Soybean
		f48	Zwiebel			f48	Onion
		f85	Sellerie			f85	Celeriac
		f127	Champignon			f127	Mushroom
Fx8	Fleisch Mischung 8	f26	Schweinefleisch	Fx8	Meat 8	f26	Pork
		f27	Rindfleisch			f27	Beef
		f88	Hammel/Lamm			f88	Mutton / Lamb
Fx9	Früchte 9	f29	Banane	Fx9	Fruit 9	f29	Banana
		f33	Orange			f33	Orange
		f49	Apfel			f49	Apple
		f53	Pfirsich			f53	Peach
Fx10	Früchte 10	f30	Birne	Fx10	Fruits 10	f30	Pear
		f32	Zitrone			f32	Lemon
		f44	Erdbeere			f44	Strawberry
		f72	Ananas			f72	Pineapple
Fx11	Käse 11	f70	Schweizer Käse	Fx11	Cheese 11	f70	Swiss Cheese
		f81	Cheddarkäse			f81	Cheddar Cheese
		f82	Schimmelkäse			f82	Mold Cheese
		f150	Edamer Käse			f150	Edam Cheese
Fx12	Geflügelfleisch	f57	Ente	Fx12	Poultry	f57	Duck
		f58	Gans			f58	Goose
		f83	Huhn			f83	Chicken
		f130	Truthahn			f130	Turkey
Fx13	Nahrungs- mittel 13	f1	Eiklar	Fx13	Foods 13	f1	Egg White
		f2	Kuhmilch (roh)			f2	Cow´s milk (raw)
		f13	Erdnuss			f13	Peanut
		f85	Sellerie			f85	Celeriac

Nahrungsmittel

Multi-Allergene

Foods

Multi-Allergens

Code	Deutsch			Code	English		
Fx14	Mehle 14	f4	Weizenmehl	Fx14	Flours 14	f4	Wheat Flour
		f7	Hafermehl			f7	Oat Flour
		f8	Maismehl			f8	Corn Flour
		f10	Sesamschrot			f10	Sesame (bruised grain)
		f11	Buchweizenmehl			f11	Buckwheat Flour
Fx15	Nüsse 15	f13	Erdnuss	Fx15	Nuts 15	f13	Peanut
		f17	Haselnuss			f17	Hazelnut
		f18	Paranuss			f18	Brazil Nut
		f20	Mandel			f20	Almond
		f36	Kokosnuss			f36	Coconut
Fx16	Fleisch Mischung 16	f26	Schweinefleisch	Fx16	Meat Mix 16	f26	Pork
		f27	Rindfleisch			f27	Beef
		f83	Hühnerfleisch			f83	Chicken
		f88	Hammel/ Lamm			f88	Mutton / Lamb
Fx17	Fische 17	f3	Dorsch	Fx17	Fish 17	f3	Codfish
		f21	Hering			f21	Herring
		f174	Makrele			f174	Mackerel
		f186	Scholle			f186	Plaice
Fx19	Früchte 19	f32	Zitrone	Fx19	Fruit 19	f32	Lemon
		f33	Orange			f33	Orange
		f34	Mandarine			f34	Tangerine
		f92	Grapefruit			f92	Grapefruit
Fx20	Nahrungsmittel Screen	f1	Eiklar	Fx20	Food Screen	f1	Egg White
		f2	Kuhmilch (roh)			f2	Cow's milk (raw)
		f3	Dorsch			f3	Codfish
		f4	Weizenmehl			f4	Wheat Flour
		f13	Erdnuss			f13	Peanut
		f14	Sojabohne			f14	Soybean
		f44	Erdbeere			f44	Strawberry
		f85	Sellerie			f85	Celeriac
Fx23	Nüsse 23	f16	Walnuss	Fx23	Nuts 23	f16	Walnut
		f17	Haselnuss			f17	Hazelnut
		f20	Mandel			f20	Almond
		f52	Schokolade			f52	Chocolate
Fx25	Milch-komponenten	f76	Alpha-Lactalbumin	Fx25	Milk-components	f76	Alpha-Lactalbumin
		f77	Beta-Lactoglobulin			f77	Beta-Lactoglobulin
		f78	Casein			f78	Casein
Fx26	Mehle 26	f4	Weizenmehl	Fx26	Flours 26	f4	Wheat Flour
		f7	Hafermehl			f7	Oat Flour
		f8	Maismehl			f8	Corn Flour
		f9	Reis			f9	Rice
		f11	Buchweizenmehl			f11	Buckwheat Flour
Fx27	Fische 27	f3	Dorsch (Kabeljau)	Fx27	Fish 27	f3	Codfish
		f40	Thunfisch			f40	Tuna
		f41	Lachs			f41	Salmon
Fx28	Nüsse 28	f16	Walnuss	Fx28	Nuts 28	f16	Walnut
		f17	Haselnuss			f17	Hazelnut
		f18	Paranuss			f18	Brazil Nut
		f20	Mandel			f20	Almond
		f36	Kokosnuss			f36	Coconut
Fx29	Gemüse 29	f12	Erbse	Fx29	Vegetable 29	f12	Pea
		f25	Tomate			f25	Tomato
		f31	Karotte			f31	Carrot
		f35	Kartoffel			f35	Potato
		f85	Sellerie			f85	Celeriac

Nahrungsmittel

Multi-Allergene

Foods

Multi-Allergens

Code	Deutsch			Code	English		
Fx30	Früchte 30	f29	Banane	Fx30	Fruits 30	f29	Banana
		f30	Birne			f30	Pear
		f33	Orange			f33	Orange
		f44	Erdbeere			f44	Strawberry
		f49	Apfel			f49	Apple
		f53	Pfirsich			f53	Peach
		f131	Avocado			f131	Avocado
Fx34	Nüsse 34	f13	Erdnuss	Fx34	Nuts 34	f13	Peanut
		f16	Walnuss			f16	Walnut
		f17	Haselnuss			f17	Hazelnut
		f20	Mandel			f20	Almond
		f36	Kokosnuss			f36	Coconut
Fx35	Schalentiere Mischung	f24	Garnele	Fx35	Crustaceae	f24	Shrimp
		f80	Hummer			f80	Lobster
Fx36	Fisch-mischung 36	f40	Thunfisch	Fx36	Fish Mix 36	f40	Tuna
		f41	Lachs			f41	Salmon
		f163	Hecht			f163	Hake
Fx37	Fisch-mischung 37	f24	Garnele	Fx37	Fish Mix 37	f24	Shrimp
		f40	Thunfisch			f40	Tuna
		f41	Lachs			f41	Salmon
		f80	Hummer			f80	Lobster
Fx38	Obst- und Gemüse 38	f14	Sojabohne	Fx38	Fruits & Vegetables 38	f14	Soybean
		f25	Tomate			f25	Tomato
		f29	Banane			f29	Banana
		f31	Karotte			f31	Carrot
		f33	Orange			f33	Orange
		f49	Apfel			f49	Apple
		f74	Maiskorn			f74	Corn
Fx40	Zitrusfrüchte*	f32	Zitrone	Fx40	Fruits*	f32	Lemon
		f33	Orange			f33	Orange
		f92	Grapefruit			f92	Grapefruit
Fx50	Obst-Birkenpollen Ass.*	f17	Haselnuss	Fx50	Fruit-Birch Pollen Ass.*	f17	Hazelnut
		f49	Apfel			f49	Apple
		f53	Pfirsich			f53	Peach
		f73	Kirsche			f73	Cherry
		f148	Pflaume			f148	Plum
Fx51	Obst Latex Ass.*	f29	Banane	Fx51	Fruit Latex Ass.*	f29	Banana
		f84	Kiwi			f84	Kiwi
		f91	Mango			f91	Mango
		f131	Avocado			f131	Avocado
		f149	Papaya			f149	Papaya
Fx52	Nahrungsmittel (Fleisch) *	f26	Schwein	Fx52	Meat Mix*	f26	Pork
		f27	Rind			f27	Beef
		f75	Eigelb			f75	Egg Yolk
		f83	Huhn			f83	Chicken
		f130	Truthahn			f130	Turkey
Fx54	Nahrungs-mittel 54	f1	Eiklar	Fx54	Food 54	f1	Egg White
		f2	Kuhmilch (roh)			f2	Cow's milk (raw)
		f4	Weizenmehl			f4	Wheat Flour
		f52	Schokolade			f52	Chocolate
		f144	Pistazie			f144	Pistachio Nut
Fx55	Nahrungs-mittel 55	f1	Eiklar	Fx55	Food 55	f1	Egg White
		f27	Rindfleisch			f27	Beef
		f44	Erdbeere			f44	Strawberry
		f83	Huhn			f83	Chicken
		f144	Pistazienkerne			f144	Pistachio Nut

Nahrungsmittel

Multi-Allergene

Code	Deutsch		
Fx56	Nahrungs-mittel 56	f1	Eiklar
		f25	Tomate
		f29	Banane
		f48	Zwiebel
		s26	Grüner Pfeffer
Fx57	Nahrungs-mittel 57	f25	Tomate
		f31	Karotte
		f45	Bäckerhefe
		f47	Knoblauch
		f48	Zwiebel
		f85	Sellerie
Fx58	Nahrungs-mittel 58	f29	Banane
		f53	Pfirsich
		f72	Ananas
		f84	Kiwi
		f87	Melone
Fx90	Früchte 90*	f30	Birne
		f49	Apfel
		f53	Pfirsich
		f73	Kirsche
		f148	Pflaume
Fx114	Käse 114*	f70	Schweizer Käse
		f81	Cheddarkäse
		f82	Schimmelkäse
		f150	Edamer Käse
		f198	Gouda
Fx128	Mehle 128*	f4	Weizenmehl
		f6	Gerstenmehl
		f7	Hafermehl
		f8	Maismehl
		f9	Reis
		f14	Sojabohne
Fx129	Mehle 129*	f4	Weizenmehl
		f5	Roggenmehl
		f6	Gerstenmehl
		f7	Hafermehl
		f8	Maismehl
		f14	Sojabohne
		f79	Gluten

Foods

Multi-Allergens

Code	English		
Fx56	Food 56	f1	Egg White
		f25	Tomato
		f29	Banana
		f48	Onion
		s26	Green Pepper
Fx57	Food 57	f25	Tomato
		f31	Carrot
		f45	Yeast
		f47	Garlic
		f48	Onion
		f85	Celeriac
Fx58	Food 58	f29	Banana
		f53	Peach
		f72	Pineapple
		f84	Kiwi
		f87	Melon
Fx90	Fruits 90 *	f30	Pear
		f49	Apple
		f53	Peach
		f73	Cherry
		f148	Plum
Fx114	Cheese 114*	f70	Swiss Cheese
		f81	Cheddar Cheese
		f82	Mold Cheese
		f150	Edam Cheese
		f198	Gouda Cheese
Fx128	Flours 128*	f4	Wheat Flour
		f6	Barley Flour
		f7	Oat Flour
		f8	Corn Flour
		f9	Rice
		f14	Soybean
Fx129	Flours 129*	f4	Wheat Flour
		f5	Rye Flour
		f6	Barley Flour
		f7	Oat Flour
		f8	Corn Flour
		f14	Soybean
		f79	Gluten

* nur als biotinyliertes Reagenz verfügbar
* available only as biotinylated reagent

Gewürze

Spices

Code	Deutsch	English	Latein/Latin
s1	Anis	Aniseed	Pimpinella anisum
s2	Curry	Curry	
s3	Kümmel	Caraway	Lavum carvi
s4	Lorbeerblatt	Laurel	Laurus nobilis
s5	Muskatnuss	Nutmeg	Myristica fragrans
s6	Paprika	Paprika	Capsicum spp.
s7	Schwarzer Pfeffer	Black Pepper	Piper nigrum
s8	Zimt	Cinnamon	Cinnamomum spp.
s9	Oregano	Origan	Origanum vulgare
s10	Basilikum	Basil	Ocimum basilicum
s11	Dill	Dill	Anethum graveolens
s12	Schnittlauch	Chives	Allium shoenoprasum
s13	Thymian	Thyme	Thymus vulgaris
s14	Majoran	Marjoram	Origanum majorana
s15	Chili	Chili	Capsicum frutescens
s16	Gewürznelke	Clove	Syzygium aromaticum
s17	Koriander	Coriander	Coriandrum sativum
s18	Salbei	Sage	Salvia officinalis
s19	Melisse	Balm	Melissa officinalis
s20	Liebstöckel	Lovage	Levisticum officinale
s21	Wacholderbeeren	Juniper berry	Juniperus communis
s22	Bohnenkraut	Beanstalk	Satureja hortensis
s23	Kerbel	Chervil	Anthriscus cerefolium
s24	Rosmarin	Rosemary	Rosmarinus spp.
s25	Ingwer	Ginger	Zingiber officinale
s26	Grüner Pfeffer	Green Pepper	Piper spp.
s27	Estragon	Tarragon	Artemisia dracunculus
s28	Kardamom	Cardamom	Elettaria cardamomum
s29	Roter Pfeffer	Red Pepper	Piper nigrum
s30	Curcuma	Curcuma	Curcuma
s31	Muskatblüte	Mace	Myristica fragrans
s32	Piment	Piment	Pimentum
s33	Weißer Pfeffer	White Pepper	Piper spp.

Multi-Allergene

Multi-Allergens

Code	Deutsch			Code	English		
Sx1	Gewürze 1	s1	Anis	Sx1	Spices 1	s1	Aniseed
		s2	Curry			s2	Curry
		s3	Kümmel			s3	Caraway
		f47	Knoblauch			f47	Garlic
Sx2	Gewürze 2	s4	Lorbeerblatt	Sx2	Spices 2	s4	Laurel
		s6	Paprika			s6	Paprika
		s7	Schwarzer Pfeffer			s7	Black Pepper
		f89	Senf			f89	Mustard
Sx3	Gewürze 3	s5	Muskatnuss	Sx3	Spices 3	s5	Nutmeg
		s6	Paprika			s6	Paprika
		s7	Schwarzer Pfeffer			s7	Black Pepper
		f79	Gluten			f79	Gluten
Sx4	Gewürze 4	s1	Anis	Sx4	Spices 4	s1	Aniseed
		s2	Curry			s2	Curry
		s3	Kümmel			s3	Caraway
Sx5	Gewürze 5	s5	Muskatnuss	Sx5	Spices 5	s5	Nutmeg
		s6	Paprika			s6	Paprika
		s7	Schwarzer Pfeffer			s7	Black Pepper
Sx16	Gewürze 16*	s1	Anis	Sx16	Spices 16*	s1	Aniseed
		s2	Curry			s2	Curry
		s3	Kümmel			s3	Caraway
		s6	Paprika			s6	Paprika
		f47	Knoblauch			f47	Garlic
Sx71	Gewürze 71*	s3	Kümmel	Sx71	Spices 71*	s3	Caraway
		s5	Muskat			s5	Nutmeg
		s16	Nelke			s16	Clove
		s28	Kardamom			s28	Cardamom

* nur als biotinyliertes Reagenz verfügbar * available only as biotinylated reagent

Schimmelpilze Molds

Code	Latein/Latin
m1	Penicillium chrysogenum (notatum)
m2	Cladosporium herbarum
m3	Aspergillus fumigatus
m4	Mucor racemosus
m5	Candida albicans
m6	Alternaria tenuis (alternata)
m7	Botrytis cinerea
m8	Helminthosporium halodes
m9	Gibberella fujikuroi (Syn. Fusarium moniliforme)
m10	Stemphylium botryosum
m11	Rhizopus nigricans
m12	Aureobasidium pullulans
m13	Phoma betae
m14	Epicoccum purpurascens
m15	Trichoderma viride
m16	Curvularia lunata
m19	Aspergillus versicolor
m20	Mucor mucedo
m22	Mucor spinosus
m23	Neurospora sitophila
m24	Paecilomyces spp.
m25	Penicillium brevicompactum
m28	Penicillium expansum
m30	Penicillium roqueforti
m32	Cladosporium spp.
m33	Aspergillus niger
m34	Serpula lacrymans (Syn. Merulius lacrymans)
m37	Trichophyton mentagrophytes (Var. interdigitale)
m40	Aspergillus amstelodami
m41	Cephalosporium acremonium
m43	Saccharomyces carlsbergensis (Brauereihefe)
m44	Saccharomyces cerevisiae (Bäckerhefe)
m45	Chaetomium globosum
m46	Saccharomyces ellipsoideus (Weinhefe)
m47	Aspergillus flavus
m48	Aspergillus oryzae
m49	Aspergillus nidulans
m52	Thermoactinomyces vulgaris
m55	Penicillium digitatum
m56	Microsporum canis
m57	Epidermophyton floccosum
m58	Thermoactinomyces candidus

Schimmelpilze Molds

Multi-Allergene Multi-Allergens

Code	Deutsch		Latein/Latin	Code	English	
Mx1	Schimmelpilz-Mischung 1	m1	Penicillium chrysogenum (notatum)	Mx1	Mold Mix 1	m1
		m2	Cladosporium herbarum			m2
		m3	Aspergillus fumigatus			m3
		m6	Alternaria tenuis (alternata)			m6
Mx2	Schimmelpilz-Mischung 2	m11	Rhizopus nigricans	Mx2	Mold Mix 2	m11
		m12	Aureobasidium pullulans			m12
		m22	Mucor spinosus			m22
		m23	Neurospora sitophila			m23
Mx3	Schimmelpilz-Mischung 3	m14	Epicoccum purpurascens	Mx3	Mold Mix 3	m14
		m20	Mucor mucedo			m20
		m45	Chaetomium globosum			m45
Mx4	Schimmelpilz-Mischung 4	m13	Phoma betae	Mx4	Mold Mix 4	m13
		m24	Paecilomyces spp.			m24
Mx5	Schimmelpilz-Mischung 5	m4	Mucor racemosus	Mx5	Mold Mix 5	m4
		m11	Rhizopus nigricans			m11
		m20	Mucor mucedo			m20
		m22	Mucor spinosus			m22
Mx6	Schimmelpilz-Mischung 6	m3	Aspergillus fumigatus	Mx6	Mold Mix 6	m3
		m40	Aspergillus amstelodami			m40
		m49	Aspergillus nidulans			m49
Mx8	Schimmelpilz-Mischung 8	m1	Penicillium chrysogenum (notatum)	Mx8	Mold Mix 8	m1
		m25	Penicillium brevicompactum			m25
		m28	Penicillium expansum			m28
		m30	Penicillium roqueforti			m30
Mx11	Schimmelpilz-Mischung 11	m1	Penicillium chrysogenum (notatum)	Mx11	Mold Mix 11	m1
		m3	Aspergillus fumigatus			m3
		m5	Candida albicans			m5
Mx12	Schimmelpilz-Mischung 12	m1	Penicillium chrysogenum (notatum)	Mx12	Mold Mix 12	m1
		m2	Cladosporium herbarum			m2
		m3	Aspergillus fumigatus			m3
		m5	Candida albicans			m5
		m6	Alternaria tenuis (alternata)			m6
Mx14	Schimmelpilz-Mischung 14	m1	Penicillium chrysogenum (notatum)	Mx14	Mold Mix 14	m1
		m2	Cladosporium herbarum			m2
		m3	Aspergillus fumigatus			m3
		m4	Mucor racemosus			m4
		m5	Candida albicans			m5
Mx15	Schimmelpilz-Mischung 15	m6	Alternaria tenuis (alternata)	Mx15	Mold Mix 15	m6
		m7	Botrytis cinerea			m7
		m8	Helminthosporium halodes			m8
		m9	Fusarium moniliforme			m9
		m16	Curvularia lunata			m16
Mx17	Schimmelpilz-Mischung 17	m1	Penicillium chrysogenum (notatum)	Mx17	Mold Mix 17	m1
		m3	Aspergillus fumigatus			m3
		m5	Candida albicans			m5
		m47	Aspergillus flavus			m47
		m56	Microsporium canis			m56
TMx9	Schimmel-pilze TM9	m1	Penicillium chrysogenum (notatum)	TMx9	Mold TM9	m1
		m2	Cladosporium herbarum			m2
		m3	Aspergillus fumigatus			m3
		m5	Candida albicans			m5
		m6	Alternaria tenuis (alternata)			m6
		m8	Helminthosporium halodes			m8

Rekombinante (R) und native (N) Allergene

Recombinant (R) and native (N) allergens

Code	Deutsch	English
ND11	D. pteronyssinus (Der p 1)*	D. pteronyssinus (Der p 1)*
ND12	D. pteronyssinus (Der p 2)*	D. pteronyssinus (Der p 2)*
RD 110	D. pteronyssinus (Der p 10)*	D. pteronyssinus (Der p 10)*
RD 123	D. pteronyssinus (Der p 23)*	D. pteronyssinus (Der p 23)*
ND21	D. farinae (Der f 1)*	D. farinae (Der f 1)*
ND22	D. farinae (Der f 2)*	D. farinae (Der f 2)*
RE11	Katze (Fel d 1)*	Cat (Fel d 1)*
NF24	Tropomyosin Garnele*	Tropomyosin Shrimp*
F67	Hühnerei (Gal d 2)*	Hen's egg (Gal d 2)*
F68	Hühnerei (Gal d 1)*	Hen's egg (Gal d 1)*
NF103	Hühnerei (Gal d 3)*	Hen's egg (Gal d 3)*
F76	Kuhmilch (Bos d4)*	Cow's milk (Bos d 4)*
F77	Kuhmilch (Bos d 5)*	Cow's milk (Bos d 5)*
F78	Kuhmilch (Bos d 8/9/10)*	Cow's milk (Bos d 8/9/10)*
NF131	Erdnuss (Ara h 1)*	Peanut (Ara h 1)*
NF132	Erdnuss (Ara h 2)*	Peanut (Ara h 2)*
NF133	Erdnuss (Ara h 3)*	Peanut (Ara h 3)*
NF136	Erdnuss (Ara h 6)*	Peanut (Ara h 6)*
RF138	Erdnuss (Ara h 8)*	Peanut (Ara h 8)*
RF139	Erdnuss (Ara h 9)*	Peanut (Ara h 9)*
RF171	Haselnuss (Cor a 1)*	Hazelnut (Cor a 1)*
RF178	Haselnuss (Cor a 8)*	Hazelnut (Cor a 8)*
RF179	Haselnuss (Cor a 9)*	Hazelnut (Cor a 9)*
RF1714	Haselnuss (Cor a 14)*	Haselnut (Cor a 14)*
RF180	Parvalbumin Karpfen (Cyp c 1)*	Parvalbumin Carp (Cyp c 1)*
RF311	Karotte (Dau c 1)*	Carrot (Dau c 1)*
RF491	Apfel (Mal d 1)*	Apple (Mal d 1)*
RF493	Apfel (Mal d 3)*	Apple (Mal d 3)*
RF441	Erdbeere (Fra a 1)*	Strawberry (Fra a 1)*
RF443	Erdbeere (Fra a 3)*	Strawberry (Fra a 3)*
RF531	Pfirsich (Pru p 1)*	Peach (Pru p 1)*
RF533	Pfirsich (Pru p 3)*	Peach (Pru p 3)*
RF534	Pfirsich (Pru p 4)*	Peach (Pru p 4)*
NFgal	α-Gal*	α-Gal*
NF253	CCD Meerrettich*	CCD Horseradish*
RG601	Lieschgras (Phl p 1)*	Timothy Grass (Phl p 1)*
RG605	Lieschgras (Phl p 5)*	Timothy Grass (Phl p 5)*
RG607	Lieschgras (Phl p 7)*	Timothy Grass (Phl p 7)*
RG612	Lieschgras (Phl p 12)*	Timothy Grass (Phl p 12)*
RG620	Lieschgras (Phl p 1/Phl p 5)*	Timothy Grass (Phl p 1/Phl p 5)*
RG621	Lieschgras (Phl p 7/Phl p 12)*	Timothy Grass (Phl p 7/Phl p 12)*
RI101	Bienengift (Api m 1)*	Honey Bee Venom (Api m 1)*
RI102	Bienengift (Api m 2)*	Honey Bee Venom (Api m 2)*
RI110	Bienengift (Api m 10)*	Honey Bee Venom (Api m 10)*
RI305	Wespengift (Ves v 5)*	Wasp Venom (Ves v 5)*
RK825	Latex (Hev b 5)*	Latex (Hev b 5)*
RK826	Latex (Hev b 6)*	Latex (Hev b 6)*
RK827	Latex (Hev b 7)*	Latex (Hev b 7)*
RK828	Latex (Hev b 8)*	Latex (Hev b 8)*
NW101	Ambrosia (Amb a 1)*	Common ragweed (Amb a 1)*
RW601	Beifuß (Art v 1)*	Mugwort (Art v 1)*
RM601	Alternaria alternata (Alt a 1)*	Alternaria alternata (Alt a 1)*
RT201	Hasel (Cor a 1)*	Hazel (Cor a 1)*
RT301	Birke (Bet v 1a)*	Birch (Bet v 1a)*
RT302	Birke (Bet v 2)*	Birch (Bet v 2)*
RT304	Birke (Bet v 4)*	Birch (Bet v 4)*

* nur als biotinyliertes Reagenz verfügbar
* available only as biotinylated reagent

Weitere Allergene auf Anfrage. Further allergens on request

Pollenflugkalender für Deutschland*

Allergen	Code	Jan.	Feb.	Mär.	Apr.	Mai	Jun.	Jul.	Aug.	Sep.	Okt.	Nov.	Dez.
Bäume													
Ahorn	t1			■	■	■	■						
Birke	t3			■	■	■							
Buche	t5				■	■	■	■					
Eibe	t37			■	■	■	■						
Eiche	t7			■	■	■	■						
Erle	t2	■	■	■	■								
Esche	t15			■	■	■	■	■					
Fichte	t35				■	■	■						
Flieder	t21				■	■							
Hainbuche	t46			■	■	■							
Hasel	t4		■	■	■								
Holunder	t26					■	■	■	■				
Rosskastanie	t17				■	■	■						
Kiefer	t16				■	■	■	■	■	■			
Kirsche	t29			■	■								
Liguster	t20					■	■	■					
Linde	t27						■	■	■				
Pappel	t14			■	■	■							
Platane	t11			■	■	■							
Robinie	t28					■	■						
Tanne	t38					■	■						
Thuja (Koniferen)	t43			■	■	■	■	■	■				
Ulme	t8			■	■								
Walnuss	t10				■	■	■						
Weide	t12		■	■	■	■							
Kräuter													
Ambrosie	w1								■	■	■		
Beifuß	w6						■	■	■	■	■		
Berennnessel	w20					■	■	■	■	■	■		
Gänsefuß	w10						■	■	■	■	■		
Goldrute	w12						■	■	■	■			
Löwenzahn	w8				■	■	■	■	■	■			
Raps	w32				■	■	■	■	■				
Sauerampfer	w18					■	■	■	■				
Spitzwegerich	w9				■	■	■	■	■				
Gräser													
Gerste	g18					■	■	■					
Glatthafer	g71					■	■	■	■	■			
Hafer	g14					■	■	■	■				
Honiggras	g13					■	■	■	■	■			
Kammgras	g19					■	■	■	■				
Knäuelgras	g3					■	■	■	■				
Lieschgras	g6					■	■	■	■	■			
Lolch	g5					■	■	■	■	■			
Mais	g20						■	■	■				
Roggen	g12					■	■	■					
Rohrglanzgras	g74					■	■	■	■				
Ruchgras	g1				■	■	■	■	■	■			
Straußgras	g9						■	■	■				
Weizen	g15					■	■	■					
Wiesenfuchsschwanzgras	g16				■	■	■	■					
Wiesenrispengras	g8					■	■	■	■				
Wiesenschwingel	g4					■	■	■	■	■			
		Jan.	Feb.	Mär.	Apr.	Mai	Jun.	Jul.	Aug.	Sep.	Okt.	Nov.	Dez.

* aufgrund der regionalen Unterschiede im Pollenflugverhalten wurde auf die Angabe von Vor,- Haupt- und Nachblütezeit verzichtet.

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Rev: 05-2019

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.

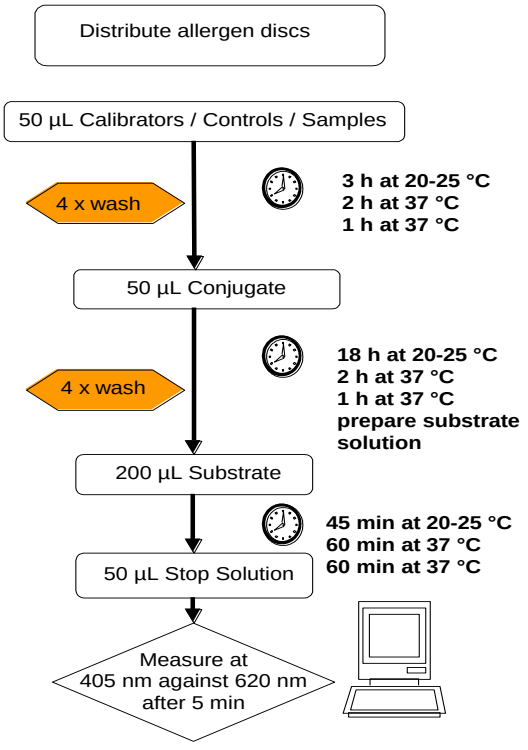
ASSAY PROCEDURE

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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508_3

ORG 508 Anti-SS-A

INTENDED PURPOSE

Anti-SS-A is an ELISA test system for the quantitative measurement of IgG class autoantibodies against SS-A (52 and 60 kDa) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

This test is useful for the differential diagnosis and monitoring of systemic rheumatic inflammatory autoimmune diseases. Autoantibodies against the two antigens SS-A 52 and SS-A 60 are predominantly found in cases of Sjoegren's syndrome. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
508_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified SS-A (52 and 60 kDa) is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 508	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Color code on module
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 U/ml, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 U/ml, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 U/ml, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 U/ml, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing SS-A antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognized reference sera from CDC, Atlanta USA.

Measuring range

The calculation range of this ELISA assay is 0 - 200 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 25 U/ml

Interpretation of results

Negative:	< 15 U/ml
Borderline:	15 - 25 U/ml
Positive:	> 25 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	139.0	139.0	100
	1:200	67.9	69.5	98
	1:400	33.0	34.8	95
	1:800	17.2	17.4	99
2	1:100	161.6	161.6	100
	1:200	70.6	80.8	87
	1:400	39.2	40.4	97
	1:800	20.0	20.2	99

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	32.2	2.7
2	73.2	2.6
3	134.0	3.6

Inter-Assay		
Sample	Mean U/ml	CV %
1	33.8	6.4
2	71.3	6.2
3	133.1	1.1

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Sjoegren´s syndrome	70	51	72.9
Normal human sera	100	7	7.0

		Clinical Diagnosis POS	NEG	
ORG 508	POS	51	7	
	NEG	19	93	
		70	100	170

Sensitivity: 72.9 %
Specificity: 93.0 %
Overall agreement: 84.7 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire

clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 508_IFU_EN_QM113135_2013-12-16_1.2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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509_3

ORG 509 Anti-SS-B

INTENDED PURPOSE

Anti-SS-B is an ELISA test system for the quantitative measurement of IgG class autoantibodies against SS-B (La) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Antibodies against SS-B are used for the differential diagnosis of systemic inflammatory autoimmune diseases. Autoantibodies against the SS-B protein are usually found together with anti-SS-A in cases of Sjoegren's syndrome. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
509_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified SS-B is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 509	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Color code on module
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 U/ml, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 U/ml, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 U/ml, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 U/ml, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing SS-B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognized reference sera from CDC, Atlanta USA.

Measuring range

The calculation range of this ELISA assay is 0 - 200 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 25 U/ml

Interpretation of results

Negative:	< 15 U/ml
Borderline:	15 - 25 U/ml
Positive:	> 25 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	124.2	127.1	98
	1:200	62.4	34.8	98
	1:400	33.2	17.4	104
	1:800	16.1	8.7	101
2	1:100	104.4	104.4	100
	1:200	53.1	52.2	102
	1:400	27.6	26.1	106
	1:800	13.9	13.1	107

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	28.8	5.6
2	67.1	5.8
3	143.2	5.2

Inter-Assay		
Sample	Mean U/ml	CV %
1	24.5	11.0
2	70.5	6.9
3	157.6	4.1

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Sjoegren´s syndrome	70	43	61.4
Rheumatoid arthritis	20	1	5.0
Normal human sera	100	4	4.0

		Clinical Diagnosis POS	NEG	
ORG 509	POS	43	5	
	NEG	27	115	
		70	120	190

Sensitivity: 61.4 %
Specificity: 95.8 %
Overall agreement: 83.2 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but

should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 509_IFU_EN_QM113136_2013-12-16_1.2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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511_3

ORG 511 Anti-RNP/Sm

INTENDED PURPOSE

Anti-RNP/Sm is an ELISA test system for the quantitative measurement of IgG class autoantibodies against RNP/Sm in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Antibodies against the RNP/Sm complex are useful in the diagnosis of mixed connective tissue disorder (MCTD, Sharp syndrome) and related autoimmune diseases. Antibodies against the 70 kDa protein of this complex are a very specific marker for Sharp syndrome. The Sm proteins are recognised by antibodies that may occur in cases of mixed connective tissue disorder and systemic lupus erythematosus. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
511_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified RNP/Sm is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 511	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Color code on module
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 U/ml, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 U/ml, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 U/ml, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 U/ml, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing RNP/Sm antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognized reference sera from CDC, Atlanta USA.

Measuring range

The calculation range of this ELISA assay is 0 - 200 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 25 U/ml

Interpretation of results

Negative:	< 15 U/ml
Borderline:	15 - 25 U/ml
Positive:	> 25 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	161.4	161.4	100
.	1:200	78.0	80.7	97
.	1:400	39.7	40.4	98
.	1:800	20.1	20.2	100
2	1:100	167.2	167.2	100
.	1:200	83.7	83.6	100
.	1:400	41.5	41.8	99
.	1:800	20.8	20.9	100

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	65.6	4.1
2	101.9	5.9
3	182.0	1.8

Inter-Assay		
Sample	Mean U/ml	CV %
1	33.3	4.2
2	109.0	3.1
3	176.8	2.9

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
SLE	70	37	52.9
MCTD	30	29	96.7
Rheumatoid arthritis	20	3	15.0
Normal human sera	100	2	2.0

		Clinical Diagnosis POS	NEG	
ORG 511	POS	66	5	
	NEG	34	115	
		100	120	220

Sensitivity: 66.0 %
Specificity: 95.8 %
Overall agreement: 82.3 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.

The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: *ORG 511_IFU_EN_QM113138_2013-12-16_1.2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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512_3

ORG 512 Anti-Scl-70

INTENDED PURPOSE

Anti-Scl-70 is an ELISA test system for the quantitative measurement of IgG class autoantibodies against Scl-70 in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Antibodies against Scl-70 (DNA topoisomerase I) are an accepted marker for progressive systemic scleroderma. They contribute to the differential diagnosis of scleroderma. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
512_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified Scl-70 is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 512	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Color code on module
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 U/ml, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 U/ml, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 U/ml, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 U/ml, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing Scl-70 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognized reference sera from CDC, Atlanta USA.

Measuring range

The calculation range of this ELISA assay is 0 - 200 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 25 U/ml

Interpretation of results

Negative:	< 15 U/ml
Borderline:	15 - 25 U/ml
Positive:	> 25 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	146.9	146.9	100
	1:200	76.3	73.5	104
	1:400	38.1	36.7	104
	1:800	18.8	18.4	102
2	1:100	122.3	122.3	100
	1:200	60.4	61.2	99
	1:400	29.6	30.6	97
	1:800	14.8	15.3	97

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	45.7	4.0
2	90.4	3.2
3	184.1	3.4

Inter-Assay		
Sample	Mean U/ml	CV %
1	41.1	2.8
2	89.9	2.8
3	157.4	2.3

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Scleroderma	25	19	76.0
Rheumatoid arthritis	20	0	0.0
Normal human sera	80	1	1.3

		Clinical Diagnosis POS	NEG	
ORG 512	POS	19	1	
	NEG	6	99	
		25	100	125

Sensitivity: 76.0 %
Specificity: 99.0 %
Overall agreement: 94.4 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but

should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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19. Tozzoli R, Bizzaro N, Tonutti E, Villalta D, Bassetti D, Manoni F et al. Guidelines for the laboratory use of autoantibody tests in the diagnosis and monitoring of autoimmune rheumatic diseases. Am J Clin Pathol 2002; 117(2):316-324.
20. Maidhof W., Hilias O. Lupus: an pverview of the disease and management options. P T 2012; 37(4):240-9.
21. Hahn BH, McMahon MA, Wilkinson A, Wallace WD, Daikh DI, Fitzgerald JD et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care Res (Hoboken) 2012; 64(6):797-808.

Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 512_IFU_EN_QM113139_2013-12-16_1.2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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515_3

ORG 515 Anti-Cardiolipin IgG/IgM

INTENDED PURPOSE

Anti-Cardiolipin IgG/IgM is an ELISA test system for the quantitative measurement of IgG and IgM class autoantibodies against cardiolipin in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Antiphospholipid syndrome (APS, Hughes Syndrome) is a systemic autoimmune disease that causes thromboses, recurrent miscarriage or stillbirths, and stroke. Clinical symptoms are accompanied by specific autoantibodies in the blood, which bind to phospholipids like cardiolipin, or phospholipid-binding proteins like beta-2-glycoprotein I. Autoantibodies against proteins of the coagulation cascade, e.g. prothrombin or annexin V may also be found in patients with APS with otherwise negative phospholipid antibody results. In primary APS autoantibodies against phospholipids appear independently, while in secondary APS phospholipid antibodies are detected in conjunction with other autoimmune diseases, such as lupus erythematosus, rheumatoid arthritis, or Sjögren's syndrome.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
515_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE G	Enzyme Conjugate
CONJUGATE M	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified cardiolipin is coated on microwells saturated with beta-2-glycoprotein I.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 515	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***CLP***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 GPL-U/ml / 0 MPL-U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 7.5 GPL-U/ml / 5 MPL-U/ml, containing Cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent,NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 15 GPL-U/ml / 10 MPL-U/ml, containing Cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 30 GPL-U/ml / 20 MPL-U/ml, containing Cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 60 GPL-U/ml / 40 MPL-U/ml, containing Cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 120 GPL-U/ml / 80 MPL-U/ml, containing Cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing cardiolipin antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P; containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate 5x.
CONJUGATE G	15 ml	Enzyme Conjugate IgG; containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
CONJUGATE M	15 ml	Enzyme Conjugate IgM; containing anti-human IgM antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate, containing 3,3', 5,5'- Tetramethylbenzidin. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
i	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production.
  Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C.
  We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µl** of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µl** of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1	A	P1								
B	B	P2	B	P2								
C	C	P3	C	P3								
D	D	P4	D	P4								
E	E	P5	E	P5								
F	F	P6	F	P6								
G	C+	P7	C+	P7								
H	C-	P8	C-	P8								
	IgG	IgG	IgM	IgM								

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognised reference sera from E.N. Harris, Louisville and the specific reference material IRP 97/656 (IgG) and HCAL (IgG) / EY2C9 (IgM).

Measuring range

The calculation range of this ELISA assay is IgG: 0 - 120 GPL-U/ml IgM: 0 - 80 MPL-U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off IgG: 10 GPL-U/ml IgM: 7 MPL-U/ml

Interpretation of results

Negative:	IgG < 10 GPL-U/ml	IgM < 7 MPL-U/ml
Positive:	≥ 10 GPL-U/ml	≥ 7 MPL-U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution Factor	Observed GPL/MPL-U/ml	Expected GPL/MPL-U/ml	O/E [%]
IgG 1	1	73.0	73.0	100
	2	37.1	36.5	102
	4	19.6	18.3	107
	8	10.9	9.1	120
IgG 2	1	80.5	80.5	100
	2	42.0	40.3	104
	4	22.2	20.1	111
	8	12.1	10.1	120
IgG 3	1	66.2	64.4	103
	2	34.5	32.2	107
	4	16.2	16.1	101
	8	8.1	8.1	101
IgM 1	1	70.9	70.9	100
	2	34.1	35.5	96
	4	18.2	17.7	103
	8	10.1	8.9	114
IgM 2	1	114.0	114.0	100
	2	50.6	57.0	89
	4	27.3	28.5	96
	8	14.8	14.3	104
IgM 3	1	48.2	48.2	100
	2	24.7	24.1	102
	4	12.7	12.1	105
	8	7.1	6.0	118

Limit of detection

Functional sensitivity was determined to be: IgG: 1 GPL-U/ml IgM: 0.5 MPL-U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay IgG		
Sample	Mean GPL-U/ml	CV %
1	10.9	5.5
2	20.5	5.4
3	73.0	5.4

Inter-Assay IgG		
Sample	Mean GPL-U/ml	CV %
1	11.8	5.3
2	21.1	3.7
3	70.5	6.3

Intra-Assay IgM		
Sample	Mean MPL-U/ml	CV %
1	12.8	3.7
2	30.7	4.1
3	65.2	3.8

Inter-Assay IgM		
Sample	Mean MPL-U/ml	CV %
1	12.2	3.5
2	31.4	3.5
3	64.9	4.2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	Pos IgG	%	Pos IgM	%
Primary APS	8	6	75.0	4	50.0
Secondary APS	65	57	87.7	26	40.0
Normal human serum	150	6	4.0	3	2.0

		Clinical Diagnosis POS	NEG	
ORG 515 IgG	POS	63	6	
	NEG	10	144	
		73	150	223
Sensitivity:	86.3 %			
Specificity:	96.0 %			
Overall agreement:	92.8 %			

		Clinical Diagnosis Pos	Neg	
ORG 515 IgM	Pos	30	3	
	Neg	43	147	
		73	150	223
Sensitivity:	41.1 %			
Specificity:	98.0 %			
Overall agreement:	79.4 %			

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 515_IFU_EN_QM113142_2016-04-18_2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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516_4

ORG 516 AMA-M2

INTENDED PURPOSE

AMA-M2 is an ELISA test system for the quantitative measurement of IgG class autoantibodies against mitochondrial M2 subtype antigen in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

The test is used as an aid in the differential diagnosis of primary biliary cirrhosis (PBC). In patients with other autoimmune diseases occurrence of AMA antibodies may be related to the development or association of PBC. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
516_4	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified mitochondrial M2 subtype (PDC-E2, BCOADC-E2, OGDC-E2) antigen is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 516	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***AMA***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 IU/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the international reference preparation WHO 67/183 for AMA-M2 as 100 IU/ml.

Measuring range

The calculation range of this ELISA assay is 0 - 200 IU/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 10 IU/ml

Interpretation of results

Negative: < 10 IU/ml
Positive: ≥ 10 IU/ml

Linearity

Samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed IU/ml	Expected IU/ml	O/E [%]
WHO	1:100	108.5	100.0	109
.	1:200	51.2	50.0	102
.	1:400	25.2	25.0	101
.	1:800	12.8	12.5	102
.	1:1600	6.1	6.3	98
.	1:3200	3.1	3.1	99
1	1:100	49.5	49.5	100
.	1:200	25.0	24.8	101
.	1:400	12.2	12.4	99
.	1:800	5.9	6.2	95

Limit of detection

Functional sensitivity was determined to be: 1 IU/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean IU/ml	CV %
1	39.8	7.0
2	81.3	3.8
3	177.3	3.6

Inter-Assay		
Sample	Mean IU/ml	CV %
1	40.1	6.2
2	84.6	11.8
3	180.4	3.8

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Primary biliary cirrhosis (PBC)	143	139	97.2
Rheumatoid Arthritis	60	1	1.7
Normal human sera	267	18	6.7

		Clinical Diagnosis POS	NEG	
ORG 516	POS	139	19	
	NEG	4	308	
		143	327	470

Sensitivity: 97.2 %
Specificity: 94.2 %
Overall agreement: 95.1 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: *ORG 516_IFU_EN_QM113145_2013-12-16_2.1* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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518_3

ORG 518 Anti-PR3 (cANCA)

INTENDED PURPOSE

Anti-PR3 is an ELISA test system for the quantitative measurement of IgG class autoantibodies against proteinase 3 (PR3) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Anti-neutrophil cytoplasmic antibodies (ANCA) are diagnostic markers for ANCA-associated vasculitides. Anti-PR3 characterises granulomatosis with polyangiitis (GPA, formerly: Wegener's granulomatosis). The test supports the differential diagnosis of vasculitis when used in combination with other laboratory and clinical findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
518_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified Proteinase 3 (PR3) is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 518	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***PR3***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 5 U/ml, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 10 U/ml, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 20 U/ml, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 40 U/ml, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 100 U/ml, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing PR3 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production.
  Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C.
  We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

This assay system is calibrated in relative arbitrary units, since no international reference preparation is available for this assay.

Measuring range

The calculation range of this ELISA assay is 0 - 100 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 5 U/ml

Interpretation of results

Negative: < 5 U/ml
Positive: ≥ 5 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	78.9	78.9	100
.	1:200	39.8	39.5	101
.	1:400	20.6	19.7	105
.	1:800	10.6	9.9	107
.	1:1600	5.3	4.9	108
2	1:100	77.5	77.5	100
.	1:200	37.4	38.8	96
.	1:400	19.1	19.4	98
.	1:800	9.7	9.7	100
.	1:1600	5.0	4.8	104

Limit of detection

Functional sensitivity was determined to be: 0.5 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	10.9	4.7
2	24.6	2.8
3	58.5	2.8

Inter-Assay		
Sample	Mean U/ml	CV %
1	10.4	6.2
2	23.4	8.8
3	60.7	3.9

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Morbus Wegener (c-ANCA pos,	61	52	85.2
vasculitis (pANCA-positive)	20	0	0.0
infammatory/Non-inflammatory	150	3	2.0
Normal human sera	80	0	0.0

		Immunological Diagnosis POS	NEG	
ORG 518	POS	52	3	
	NEG	9	247	
		61	250	311

Sensitivity: 85.2 %
Specificity: 98.8 %
Overall agreement: 96.1 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 518_IFU_EN_QM113147_2013-12-16_1.2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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519_3

ORG 519 Anti-MPO (pANCA)

INTENDED PURPOSE

Anti-MPO is an ELISA test system for the quantitative measurement of IgG class autoantibodies against myeloperoxidase (MPO) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Anti-neutrophil cytoplasmic antibodies (ANCA) are diagnostic markers for ANCA-associated vasculitides. Anti-MPO differentiates microscopic polyangiitis (MPA) and eosinophilic granulomatosis with polyangiitis (EGPA) The test supports differential diagnosis of vasculitis, when used in conjunction with other clinical and laboratory findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
Σ 96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
519_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified myeloperoxidase (MPO) is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 519	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***MPO***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 5 U/ml, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 10 U/ml, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 20 U/ml, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 40 U/ml, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 100 U/ml, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing MPO antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

This assay system is calibrated in relative arbitrary units, since no international reference preparation is available for this assay.

Measuring range

The calculation range of this ELISA assay is 0 - 100 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 5 U/ml

Interpretation of results

Negative: < 5 U/ml
Positive: ≥ 5 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	87.3	87.3	100
.	1:200	44.1	43.7	101
.	1:400	21.5	21.8	99
.	1:800	9.7	10.9	89
.	1:1600	5.0	5.5	91
2	1:100	79.9	79.9	100
.	1:200	39.3	40.0	98
.	1:400	19.0	20.0	95
.	1:800	8.5	10.0	85
.	1:1600	4.3	5.0	86

Limit of detection

Functional sensitivity was determined to be: 0.5 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	7.5	6.4
2	30.2	4.1
3	59.9	3.1

Inter-Assay		
Sample	Mean U/ml	CV %
1	7.0	5.0
2	33.8	4.9
3	78.3	6.3

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Crescendic glomerulonephritis	55	53	96.4
Morbus Wegener (cANCA pos)	20	1	5.0
Non-ANCA kidney disease	10	1	10.0
Normal human sera	120	3	2.5

		Immunological Diagnosis		
		POS	NEG	
ORG 519	POS	54	5	
	NEG	1	145	
		55	150	205

Sensitivity: 98.2 %
Specificity: 96.7 %
Overall agreement: 97.1 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 519_IFU_EN_QM113148_2016-05-03_1.3* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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529_4

ORG 529 Anti-Phospholipid Screen IgG/IgM

INTENDED PURPOSE

Anti-Phospholipid Screen IgG/IgM is an ELISA test system to screen for the presence of IgG and IgM class autoantibodies against cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and beta-2-glycoprotein I in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Antiphospholipid syndrome (APS, Hughes Syndrome) is a systemic autoimmune disease that causes thromboses, recurrent miscarriage or stillbirths, and stroke. Clinical symptoms are accompanied by specific autoantibodies in the blood, which bind to phospholipids like cardiolipin, or phospholipid-binding proteins like beta-2-glycoprotein I. Autoantibodies against proteins of the coagulation cascade, e.g. prothrombin or annexin V may also be found in patients with APS with otherwise negative phospholipid antibody results. In primary APS autoantibodies against phospholipids appear independently, while in secondary APS phospholipid antibodies are detected in conjunction with other autoimmune diseases, such as lupus erythematosus, rheumatoid arthritis, or Sjögren's syndrome.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
529_4	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE G	Enzyme Conjugate
CONJUGATE M	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

A mixture of highly purified cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and human beta -2-Glycoprotein I is bound to microwells.

The determination is based on an indirect enzyme linked immune reaction with the following steps:

Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 529	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***PSC***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 GPL-U/ml / 0 MPL-U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 6.3 GPL-U/ml / 6.3 MPL-U/ml, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 12.5 GPL-U/ml / 12.5 MPL-U/ml, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 25 GPL-U/ml / 25 MPL-U/ml, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 50 GPL-U/ml / 50 MPL-U/ml, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 100 GPL-U/ml / 100 MPL-U/ml, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing phospholipid antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE G	15 ml	Enzyme Conjugate; containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
CONJUGATE M	15 ml	Enzyme Conjugate; containing anti-human IgM antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1	A	P1								
B	B	P2	B	P2								
C	C	P3	C	P3								
D	D	P4	D	P4								
E	E	P5	E	P5								
F	F	P6	F	P6								
G	C+	P7	C+	P7								
H	C-	P8	C-	P8								
	IgG	IgG	IgM	IgM								

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

Calibration is related to the internationally recognised reference sera from E.N. Harris, Louisville and to IRP 97/656 (IgG) and HCAL (IgG) / EY2C9 (IgM).

Measuring range

The calculation range of this ELISA assay is IgG: 0 - 100 GPL-U/ml IgM: 0 - 100 MPL-U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off IgG: 10 GPL-U/ml IgM: 10 MPL-U/ml

Interpretation of results

Negative:	IgG < 10 GPL-U/ml	IgM < 10 MPL-U/ml
Positive:	≥ 10 GPL-U/ml	≥ 10 MPL-U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed GPL/MPL-U/ml	Expected GPL/MPL-U/ml	O/E [%]
IgG 1	1:100	98.0	98.4	100
	1:200	49.6	49.2	101
	1:400	24.3	24.6	99
	1:800	12.0	12.3	98
	1:1600	5.8	6.2	94
IgG 2	1:100	92.4	92.4	100
	1:200	45.9	46.2	99
	1:400	22.7	23.1	98
	1:800	11.4	11.6	99
	1:1600	5.4	5.8	94
IgM 1	1:100	92.7	92.7	100
	1:200	45.7	46.4	99
	1:400	22.8	23.2	98
	1:800	11.2	11.6	97
	1:1600	5.4	5.8	93
IgM 2	1:100	72.4	74.2	100
	1:200	36.5	37.1	98
	1:400	18.7	18.6	101
	1:800	8.9	9.3	96
	1:1600	4.4	4.6	95

Limit of detection

Functional sensitivity was determined to be: IgG: 0.5 GPL-U/ml IgM: 0.5 MPL-U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay IgG		
Sample	Mean GPL-U/ml	CV %
1	10.4	5.1
2	18.7	3.4
3	59.9	5.2

Inter-Assay IgG		
Sample	Mean GPL-U/ml	CV %
1	10.0	3.6
2	17.7	5.4
3	57.9	4.9

Intra-Assay IgM		
Sample	Mean MPL-U/ml	CV %
1	12.8	4.1
2	30.8	3.5
3	63.8	3.7

Inter-Assay IgM		
Sample	Mean MPL-U/ml	CV %
1	12.6	5.3
2	31.9	4.1
3	62.1	4.2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	Pos IgG	%	Pos IgM	%
Primary APS	8	7	87.5	6	75.0
Secondary APS	65	60	92.3	33	50.8
Normal human sera	150	4	2.7	5	3.3

		Clinical Diagnosis POS	NEG	
ORG 529	POS	67	4	
IgG	NEG	6	146	
		73	150	223

Sensitivity: 91.8 %
Specificity: 97.3 %
Overall agreement: 95.5 %

		Clinical Diagnosis Pos	Neg	
ORG 529	Pos	39	5	
IgM	Neg	34	145	
		73	150	223

Sensitivity: 53.4 %
Specificity: 96.7 %
Overall agreement: 82.5 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 529_IFU_EN_QM113163_2016-04-18_3* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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601_3

ORG 601 Anti-CCP hs® (high sensitive)

INTENDED PURPOSE

Anti-CCP hs® (high sensitive) is an ELISA test system for the quantitative measurement of IgG class autoantibodies against cyclic citrullinated peptides (CCP) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Measurement of anti-CCP antibodies may aid in the diagnosis of rheumatoid arthritis (RA), where anti-CCP antibody levels represent one parameter of a multi-criterion diagnostic process, encompassing both clinical and laboratory-based assessments.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
601_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified cyclic citrullinated vimentin peptides (CCP) is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 601	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***CCP***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 20 U/ml, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 40 U/ml, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 100 U/ml, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 300 U/ml, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 1000 U/ml, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing CCP antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

This assay system is calibrated in relative arbitrary units. It is calibrated against an external anti-CCP Assay, since no international reference sera for RA diagnostic are available so far.

Measuring range

The calculation range of this ELISA assay is 0 - 1000 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 20 U/ml

Interpretation of results

Negative: < 20 U/ml
Positive: ≥ 20 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	950.2	950.2	100
	1:200	467.3	475.1	98
	1:400	245.4	237.6	103
	1:800	115.6	118.8	97
2	1:100	120.0	120.0	100
	1:200	60.5	60.0	101
	1:400	31.4	30.0	105
	1:800	14.2	15.0	95
	1:1600	7.3	7.5	97
3	1:100	321.3	321.3	100
	1:200	157.9	160.7	98
	1:400	96.4	80.3	120
	1:800	48.2	40.2	120

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	13.0	7.8
2	144.5	9.9
3	250.6	13.6

Inter-Assay		
Sample	Mean U/ml	CV %
1	12.3	6.1
2	134.9	7.1
3	262.2	9.3

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Rheumatoid arthritis	259	237	91.5
Other arthritis	22	6	27.3
Other rheumatic disease	37	1	2.7
Healthy controls	118	1	0.8

		Clinical Diagnosis		
		POS	NEG	
ORG 601	POS	237	8	
	NEG	22	169	
		259	177	436

Sensitivity: 91.5 %
Specificity: 95.5 %
Overall agreement: 93.1 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 601_IFU_EN_QM113201_2016-04-18_2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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604_4

ORG 604 Anti-dsDNA

INTENDED PURPOSE

Anti-dsDNA is an ELISA test system for the quantitative measurement of IgG class autoantibodies against double-stranded DNA in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

The test is used as an aid in the differential diagnosis of inflammatory autoimmune diseases, especially systemic lupus erythematosus (SLE). Autoantibodies to dsDNA are diagnostic markers for SLE and levels may be elevated during active disease. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
604_4	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Highly purified double-stranded DNA (dsDNA) is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 604	▽96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***dsD***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 IU/ml, containing no serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 IU/ml, containing dsDNAantibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 IU/ml, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing dsDNA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer PD, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer PD Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the international reference preparation WHO Wo/80 for human anti-dsDNA IgG antibodies as 200 IU/ml.

Measuring range

The calculation range of this ELISA assay is 0 - 200 IU/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 20 IU/ml

Interpretation of results

Negative: < 20 IU/ml
Positive: ≥ 20 IU/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed IU/ml	Expected IU/ml	O/E [%]
1	1:100	104.2	104.2	100
.	1:200	50.6	52.1	97
.	1:400	24.9	26.1	95
.	1:800	11.2	13.0	86
2	1:100	135.3	135.3	100
.	1:200	68.9	67.7	102
.	1:400	35.2	33.8	104
.	1:800	18.2	16.9	108

Limit of detection

Functional sensitivity was determined to be: 1 IU/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean IU/ml	CV %
1	26.0	4.5
2	61.0	3.1
3	114.0	6.4

Inter-Assay		
Sample	Mean IU/ml	CV %
1	29.0	12.4
2	68.0	7.3
3	138.0	5.2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n pos	%
SLE	202	164	81.2
Other autoimmune diseases	33	1	3.0
Normal human sera	115	1	0.9

Clinical Diagnosis

		POS	NEG	
ORG 604	POS	164	2	
	NEG	38	146	
		202	148	350

Sensitivity: 81.2 %
Specificity: 98.6 %
Overall agreement: 88.6 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 604_IFU_DE_QM112991_2018-01-02_3* Reason for revision: *updated description of coating material.*

1. **100 µl** Standards, Kontrollen und verdünnte Patientenproben pipettieren
   → **30 Minuten** bei Raumtemperatur inkubieren
   → Inhalt der Platte verwerfen und
   3 mal mit **300 µl** Waschpuffer waschen
2. **100 µl** Enzymkonjugatlösung pipettieren
   → **15 Minuten** bei Raumtemperatur inkubieren
   → Inhalt der Platte verwerfen und
   3 mal mit **300 µl** Waschpuffer waschen
3. **100 µl** Substratlösung pipettieren
   → **15 Minuten** bei Raumtemperatur inkubieren
4. **100 µl** Stopplösung zugeben
   → Platte **5 Minuten** stehenlassen
   → Bei **450 nm** messen

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633_3

ORG 633 Anti-Centromere B

INTENDED PURPOSE

Anti-Centromere B is an ELISA test system for the quantitative measurement of IgG class autoantibodies against centromere B in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

The test is used as an aid in the differential diagnosis of inflammatory autoimmune diseases, e.g. CREST syndrome. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
633_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Recombinant centromere protein B is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 633	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***CEN***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 10 U/ml, containing centromere B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 30 U/ml, containing centromere B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 100 U/ml, containing centromere B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 300 U/ml, containing centromere B antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing centromere B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing centromere B antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.

- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P2										
B	B	P3										
C	C											
D	D											
E	E											
F	C+											
G	C-											
H	P1											

P1, ... patient sample A-E calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation. Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

This assay system is calibrated in relative arbitrary units, since no international reference preparation is available for this assay.

Measuring range

The calculation range of this ELISA assay is 0 - 300 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 10 U/ml

Interpretation of results

Negative: < 10 U/ml
Positive: ≥ 10 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	136.8	136.8	100
.	1:200	67.1	68.4	98
.	1:400	35.2	34.2	103
.	1:800	16.9	17.1	99
2	1:100	285.0	285.0	100
.	1:200	139.2	142.5	98
.	1:400	73.5	71.3	103
.	1:800	37.0	35.6	104

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	15.2	5.4
2	122.0	4.4
3	220.0	4.7

Inter-Assay		
Sample	Mean U/ml	CV %
1	16.4	5.4
2	125.6	5.0
3	225.4	4 2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
CREST syndrome	32	31	96.9
Rheumatoid arthritis	20	1	5.0
Normal human sera	100	6	6.0

		Clinical Diagnosis POS	NEG	
ORG 633	POS	31	7	
	NEG	1	113	
		32	120	152

Sensitivity: 96.9 %
Specificity: 94.2 %
Overall agreement: 94.7 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.

The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Change Control

Former version: *ORG 633_IFU_EN_QM113209_2016-08-16_1.3* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

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600_3

ORG 600 ANA Detect

INTENDED PURPOSE

ANA Detect is an ELISA test system for the qualitative measurement of IgG class autoantibodies against SS-A-52 (Ro-52), SS-A-60 (Ro-60), SS-B (La), RNP/Sm, RNP-70, RNP-A, RNP-C, Sm-BB, Sm-D, Sm-E, Sm-F, Sm-G, Scl -70, Jo-1, dsDNA, ssDNA, ssDNA, polynucleosomes, mononucleosomes, histone complex, histone H1, histone H2A, histone H2B, histone 3, histone H4, Pm-Scl-100 and centromere B in human serum or plasma samples. This product is intended for professional in vitro diagnostic use only.

The test is used for screening of patients with suspected autoimmune connective tissue diseases, e.g. systemic lupus erythematosus, mixed connective tissue disease, Sjoegren's syndrome, scleroderma, and polymyositis/dermatomyositis. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
600_3	Electronic Instruction For Use: version

MICROPLATE	Microplate
CONTROL A	Control
CONTROL B	Control
CONTROL C	Control
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

A mixture of purified antigens SS-A-52 (Ro-52), SS-A-60 (Ro-60), SS-B (La), RNP/Sm, RNP-70, RNP-A, RNP-C, Sm-BB, Sm-D, Sm-E, Sm-F, Sm-G, Scl-70, Jo-1, dsDNA, ssDNA, polynucleosomes, mononucleosomes, histone complex, histone H1, histone H2A, histone H2B, histone 3, histone H4, Pm-Scl-100 and centromere B is coated on to microwells.

The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 600	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***ANA***
CONTROL A	1x 1.5 ml	Control A (negative), containing ANA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL B	1x 1.5 ml	Control B (cut-off), containing ANA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL C	1x 1.5 ml	Control C (positive), containing ANA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.

- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A											
B	B											
C	C											
D	P1											
E	P2											
F	P3											
G												
H												

P1, ... patient sample A-C controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For qualitative results the optical density (OD) of a sample is compared to the optical density of Control B:

Negative: OD sample < OD Control B
Positive: OD sample ≥ OD Control B

For detailed results the optical density of a sample is expressed as Index value:

Index = OD sample / OD Control B

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognised reference sera from CDC, Atlanta, USA and furthermore against the reference preparation WHO Wo/80 for human anti-dsDNA.

Measuring range

not applicable

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off Index 1.0

Interpretation of results

Negative:	Index < 1.0
Borderline:	Index 1.0 - 1.2
Positive:	Index > 1.2

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer. Activity for each dilution step was calculated as Index-Value.

Sample	Dilution	Observed Index	Expected Index	O/E [%]
1	1:100	4.8	4.8	100
	1:200	2.2	2.4	92
	1:400	1.3	1.2	108
	1:800	0.6	0.6	100
2	1:100	2.8	2.8	100
	1:200	1.5	1.4	107
	1:400	0.8	0.7	114
	1:800	0.4	0.4	111
3	1:100	3.5	3.5	100
	1:200	1.7	1.8	94
	1:400	0.8	0.9	89
	1:800	0.5	0.5	96

Limit of detection (not applicable)

n.a.

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean Index	CV %
1	1.8	6.9
2	2.4	9.1
3	2.8	10.4

Inter-Assay		
Sample	Mean Index	CV %
1	1.6	9.9
2	3.7	10.4
3	4.1	11.2

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
SLE	63	62	98.4
Sjogren's syndrome	2	2	100.0
MCTD	9	9	100.0
Poly-/dermatomyositis	8	8	100.0
Scleroderma	3	3	100.0
CREST syndrome	9	9	100.0
Normal human sera	148	3	2.0

		Clinical Diagnosis		
		POS	NEG	
ORG 600	POS	93	3	
	NEG	1	145	
		94	148	242

Sensitivity: 98.9 %
Specificity: 98.0 %
Overall agreement: 98.3 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
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   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**