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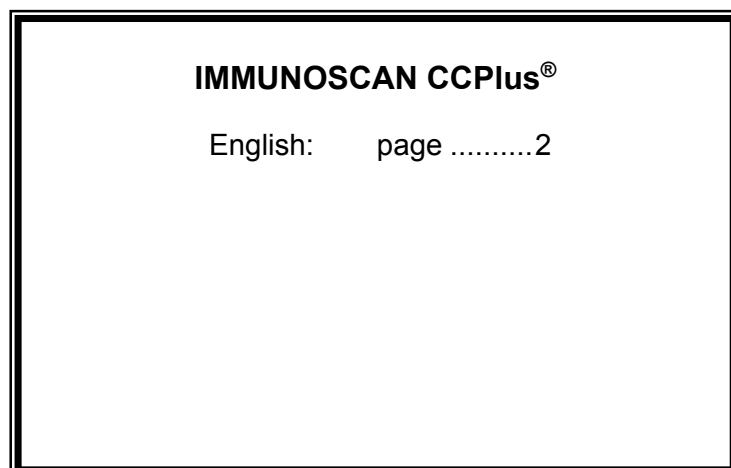
Instruction

IMMUNOSCAN CCPlus®

For professional use only



Document No. LABEL-DOC-0041 3.0



INTENDED USE

The Immunoscan CCPlus[®] test kit is an enzyme-linked immunosorbent assay (ELISA) for qualitative and semi-quantitative determination of IgG antibodies to Cyclic Citrullinated Peptides (CCP) in human sera. The assay is used to detect antibodies in a single serum specimen. The results of the assay are to be used as an aid to the diagnosis of Rheumatoid Arthritis (RA), in conjunction with other laboratory and clinical findings. The analysis should be performed by trained laboratory professionals. "For in vitro diagnostic use".

SUMMARY AND EXPLANATION

Rheumatoid Arthritis (RA) is one of the most common systemic autoimmune diseases. The aetiology of the disease, which affects up to 1-2% of the world population, is unknown. The diagnosis of RA depends primarily on clinical manifestation of the disease. The only serological test routinely used is the determination of the presence of rheumatoid factors (RF) in the serum. RF are antibodies directed to the constant region of immunoglobulins of the IgG class. However, these antibodies are also present in relatively high percentages in other autoimmune diseases, infections and in up to 15% of healthy individuals.

Antibodies of a more specific nature have also been found in sera of RA patients (see (1) for an overview). Anti-perinuclear factor (APF) antibodies are reported to be present in around 50% of RA patients with a specificity of over 70% (2). A number of cyclic synthetic peptides not related to filaggrin or other known proteins were described which are specifically recognized by autoantibodies in sera from RA patients (3). These peptides were subsequently used in an EIA for the detection of RA-specific autoantibodies (3). Clinical evaluation studies showed that the EIA was positive in a significant number of well-defined RA patient sera with an excellent specificity against disease controls (3-8). A diagnostic and prognostic value for the measurement of the anti Cyclic Citrullinated Peptides (anti-CCP) antibodies was found in relation to joint involvement and radiological damage in early RA (7, 9-14). Anti-CCP antibodies can be detected years before the development of clinical symptoms (14). A prospective cohort study showed that 93% of the anti-CCP positive patients with undifferentiated arthritis finally developed rheumatoid arthritis, demonstrating the strong positive predictive value of these antibodies (14). The Immunoscan CCPlus[®] assay offered by Svar Life Science is based on highly purified synthetic peptides containing citrulline residues and is a valuable addition to the diagnosis of RA. This anti-CCP kit contains improved synthetic peptides selected on the basis of superior performance in the detection of RA autoantibodies (8-14).

PRINCIPLE OF THE RA PEPTIDE EIA

The anti-CCP antibody kit is based on an ELISA method. The test utilizes microtitre plate wells coated with citrullinated synthetic peptides (antigen). Diluted patient serum is applied to the wells and incubated. If specific antibodies are present, they will bind to the antigen in the wells. Unbound material is washed away and any bound antibody is detected by adding horse radish peroxidase (HRP) labelled anti-human IgG, followed by a second washing step and an incubation with substrate. The presence of reacting antibodies will result in the development of colour, which is proportional to the quantity of bound antibody, and this is determined photometrically.

PRECAUTIONS

1. The stop solution contains 0.5 M sulphuric acid. Do not allow the reagent to get into contact with the skin.
2. Avoid contact of all biological materials with skin and mucous membranes.
3. Do not pipette by mouth.
4. Controls and calibrators contain serum of human origin. Although tested against and confirmed negative for HIV 1+2, HCV, HbsAg and HIV-1 Ag, this material must be treated as potentially infectious. - The Centers for Disease Control and Prevention and National Institutes of Health recommended that potentially infectious agents be handled at the Biosafety Level 2.
5. TMB (3, 3', 5, 5'-tetramethylbenzidin) is toxic by inhalation, in contact with skin and if swallowed. Observe care when handling the substrate.
6. Do not use components past the expiration date and do not intermix components from different lots.
7. Each well is ultimately used as an optical cuvette. Therefore, do not touch the under-surface of the wells and prevent damage and dirt.
8. Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and washing throughout this procedure are necessary to maintain precision and accuracy.
9. Calibrators, controls and diluent buffer contain 0.09% sodium azide.
10. It has been reported that sodium azide may react with lead and copper in plumbing to form explosive compounds. When disposing, flush drains with water to minimize build-up of metal azide compounds.
11. For in vitro diagnostic use.

Material safety data sheets for all components contained in this kit are available on request from Svar Life Science.

KIT CONTENTS

Contents EIA-kit:

- 1 Sealed (96 wells) CCP peptide-coated microtitre plate. Ready to use.
- 5 Vials containing calibrators (positive human serum pool) (1.2 mL). Ready to use (blue).
- 1 Vial containing reference control human serum (1.2 mL). Ready to use (blue).
- 1 Vial containing positive control human serum (1.2 mL). Ready to use (blue).
- 1 Vial containing negative control human serum (1.2 mL). Ready to use (blue).
- 1 Vial containing conjugate solution (peroxidase conjugated to anti human IgG antibodies) (15 mL) Ready to use (red).
- 1 Vial containing substrate solution TMB (15 mL). Ready to use.
- 2 Vials containing dilution buffer (35 mL). Ready to use (blue).
- 1 Vial containing stop solution (15 mL). Ready to use.
- 2 Vials containing wash buffer (35 mL) 20 x concentrated.

MATERIALS OR EQUIPMENT REQUIRED BUT NOT PROVIDED

- Microplate reader with filter 450 nm.
- Automatic microtitre plate washer.

HANDLING AND STORAGE

- Store the kit at + 2° C to + 8° C in a dark place.
- Do not use reagents beyond their expiration date.
- It is advisable to unpack the sealed microtitre plate immediately before use.
- Any direct action of light on the chromogen solution should be avoided.

If a weak or absent colour reaction of the first calibrator A (3200 U/mL) E450 nm <0.9, is observed, the test result is invalid.

SAMPLE PREPARATION

This test is performed on serum specimens. For serum samples collect venous blood specimens and allow clotting to completion. Store samples for a maximum of 48 hrs at 4-8° C. For prolonged storage freeze at -20° C. Dilute patient sample 1:50. (Mix 10 µL sample in a tube with 490 µL dilution buffer. Use 100 µL in the test. (See assay protocol).

PREPARATION AND HANDLING OF REAGENTS

Before beginning the test, the microtitre plate and reagents should be brought to room temperature. Do not open the plate sealing until the plate has reached room temperature.

Mix reagents thoroughly before use.

The reagents included in the kit are sufficient to carry out 96 analyses (including Calibrator and control analyses).

Calibrators and controls are analysed in duplicate.

Buffer concentrates may contain salt crystals, which should be dissolved at room temperature (18-25° C).

1. Store all reagents immediately after use in the dark at 2-8° C.
2. CCP peptide-coated microtitre plate. Ready to use.
Re-seal surplus wells in foil with desiccant and store at 2-8° C.
3. Wash buffer (35 mL). The wash buffer is delivered 20 times concentrated. Prepare dilutions before use. Add 35 mL wash buffer to 665 mL distilled water and mix thoroughly.
4. Substrate solution TMB (15 mL). Ready to use reagent. Keep in the dark.
5. Dilution buffer (35 mL). Ready to use.
6. Conjugate solution (15 mL). Ready to use.
7. Stop solution (15 mL). Ready to use.
8. Calibrator A-E (1.2 mL). Five diluted positive human serum calibrators, with values expressed in relative units.
Calibrator A contains 3200 U/mL, B 800 U/mL, C 200 U/mL, D 50 U/mL and E 25 U/mL. Calibrators are ready to use.
9. Reference control (1.2 mL). Diluted human serum, 25 U/mL, ready to use.
10. Negative control (1.2 mL). Diluted human serum, ready to use.
11. Positive control (1.2 mL). Diluted human serum, ready to use.

ASSAY PROCEDURE

Rinsing protocol

In EIA's unbound components have to be removed efficiently between each immunological incubation step. This is achieved by appropriate rinsing. It should be clear that each rinsing procedure must be carried out with care to guarantee good results. Rinsing can be carried out manually or with automatic plate washing equipment as follows:

Manual rinsing

1. Empty the contents of each well by turning the microtitre plate upside down followed by a firm short vertical movement.
2. Fill all the wells with 300 μ L wash buffer.
3. This rinsing cycle (1 and 2) should be carried out 3 times.
4. Turn the plate upside down and empty the wells by a firm short vertical movement.
5. Place the inverted plate on absorbent paper towels and tap the plate firmly to remove residual washing solution in the wells.
6. Continue immediately to next reagent addition step.

Rinsing with automatic microtitre plate washing equipment

When using automatic plate washing equipment, check that all wells can be aspirated completely and that the wash buffer is correctly dispensed reaching the rim of each well during each rinsing cycle. The washer should be programmed to execute three rinsing cycles. Continue immediately to next reagent addition step.

Assay Protocol

Prepare samples according to section sample preparation, (i.e. dilute 1:50 in dilution buffer) and reagents according to preparation and handling of reagents. The microtitre plate is ready to use, do not wash! Patient samples can be tested either singular or in duplicate.

Semi-Quantitative protocol

1. Pipette 100 μ L dilution buffer in duplicate (wells A₁, A₂: blank).
2. Pipette 100 μ L of each calibrator in duplicate (wells B₁, B₂ – F₁, F₂).
3. Pipette 100 μ L of negative and positive control in duplicate (wells G₁, G₂- H₁, H₂).
4. Pipette 100 μ L of diluted patient samples into their respective wells of the microtitre plate. The total time for pipetting in steps 1-4 should not exceed 15 minutes.
5. Incubate for 60 min. \pm 5 min. at room temperature (18-25° C).
6. Discard the solution from the microtitre plate and wash according to the rinsing protocol.
7. Pipette 100 μ L conjugate solution into each well.
8. Incubate for 30 min. \pm 5 min. at room temperature (18-25° C).
9. Discard the conjugate solution from the microtitre plate and wash according to the rinsing protocol.
10. Pipette 100 μ L substrate solution into each well.
11. Incubate for 30 min. \pm 5 min. at room temperature (18-25° C).
12. Add 100 μ L stop solution to each well.
13. Read absorbance values within 10 min. at 450 nm.

Qualitative protocol

Run as described in the semi-quantitative protocol with one exception: Replace the calibrator set (A-E) with the reference control.

QUALITY CONTROL

For the semi-quantitative protocol calibrator A (3200 U/mL) should have an OD of ≥ 0.9 . Calculate the mean of duplicate wells for each calibrator and control. The value of the controls should then be calculated as in interpretation of results, see below.

Please refer to positive control label for valid positive control range. Negative control should be < 25 U/mL.

For the qualitative protocol, please refer to positive control label for valid ratio of positive control versus reference control. The ratio of negative control versus reference control should be < 0.95 .

If any of the values are not within their respective ranges, the test should be considered invalid and it should be repeated.

INTERPRETATION OF RESULTS

Semi-Quantitative protocol

Subtract the mean absorbance value of the wells A_1 and A_2 from the individual absorbance of the wells containing the calibrators, controls and samples. The absorbance values of the five calibrators (mean values of the duplicates) can be plotted manually on the linear y-axis versus the units on a logarithmic x-axis. The calibration curve is close to linearity in the range 25-2962 U/mL. The antibody titre is expressed in units determined using the calibrator sera by reading the unit's value corresponding to the net mean absorbance of sample on the calibration curve. Alternatively, a software program using a 4-parameter curve fit can be used for the calculation.

The five calibrators (A - E) have been assigned a value of 3200 U/mL (A), 800 U/mL (B), 200 U/mL (C), 50 U/mL (D) and 25 U/mL (E). These values have been chosen arbitrarily by Svar Life Science, since no generally recognised (inter)national standard exists for expressing the titre of anti-CCP antibodies. Samples reading higher than the calibrator A (3200 U/mL) can be retested at higher sample dilution. At present there is no evidence that the units obtained, can be used as a measure of the severity of the disease. Antibodies from different patients may have different affinities, which means that the autoantibody immunoreactivity rather than the concentration is measured.

The calibration curve cannot be used for absorbance values below calibrator E (25 U/mL). Values should be reported as < 25 U/mL.

Qualitative protocol

Subtract the mean absorbance value of the wells A_1 and A_2 from the individual absorbance of the wells containing the controls and samples.

Calculate the absorbance (optical density) ratio for the control and for each sample.

$$\text{Absorbance ratio} = \frac{\text{Control or Sample OD}}{\text{Reference control OD}}$$

EVALUATION CRITERIA

Semi-Quantitative protocol

Samples with results < 25 U/mL are defined as negative. Samples ≥ 25 U/mL are defined as positive.

Qualitative protocol

Users should calculate a cut-off between positive and negative samples that is specific to their patient populations. Results from the patient populations used in the Svar Life Science clinical trial suggest the following cut-off:

Absorbance ratio

< 0.95
 ≥ 0.95 to ≤ 1.0
 > 1.0

Result Interpretation

Negative
 Borderline - recommend repeat testing
 Positive

Limitations

1. A positive result must be used in conjunction with clinical evaluation and other diagnostic procedures. The values obtained from this assay are intended to be an aid to diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings and other diagnostic procedures.
2. Elevated anti-CCP antibodies may be seen in individuals with no evidence of clinical disease. Also, some individuals with RA may have undetectable antibodies. Anti-CCP antibody levels do not necessarily correlate to disease state.
3. Because anti-CCP antibody levels do not necessarily correlate to disease state treatment should not be initiated or changed based on a positive result. Clinical findings should be taken into account for all treatment decisions.
4. Monitoring CCP antibody levels for progression and or remission of RA has not been established.
5. The performance characteristics for this assay have not been established for paediatric specimens. The diagnostic value of anti-CCP antibodies has not been determined for juvenile arthritis.

Expected Results

The anti-CCP EIA measures antibodies against synthetic peptides with citrulline residues. The anti-CCP EIA is calibrated in the semi-quantitative assay in relative units using a positive patient serum pool. The standard curve ranges from 25-3200 U/mL. These values have been chosen arbitrarily by Svar Life Science since no generally recognised international standard exists for expressing the titre of anti-CCP antibodies. The specificity and sensitivity were evaluated in previous studies with 311 RA patients, 942 diseased non-RA patients (including other autoimmune and wide range of infectious diseases) and 330 healthy controls. The sensitivity was 70%. The specificity was 97% with diseased non-RA patients and 99% with healthy individuals. (15)

PERFORMANCE CHARACTERISTICS

Table 1. Percent Agreement of the Immunoscan CCPlus® kit compared to an alternative CCP ELISA. A total of 628 frozen retrospective sera were assayed. 368 samples were from RA patients and 260 samples were from apparently healthy blood donors. The following table summarises the results.

Alternative ELISA				
Immunoscan CCPlus® Kit		Positive	Negative	Total
	Positive	275	5	280
	Negative	2	346	348
	Total	277	351	628

Positive Percent Agreement: 275/277 = 99.3% 95% CI = 97.4 – 99.9%
 Negative Percent Agreement: 346/351 = 98.6% 95% CI = 96.7 – 99.5%
 Overall Percent Agreement: 621/628 = 98.9% 95% CI = 97.7 – 99.6%

The 95% confidence interval (CI) was calculated using the exact method.

Table 2. Clinical sensitivity and specificity. A total of 1180 frozen retrospective sera with clinical characterisation were assayed. The following table summarises the results

Control and Disease groups	Total number	Negative < 25 U/mL	Positive ≥ 25 U/mL
Blood donors	260	257	3
RA	399	90	309
WG	20	18	2
MP	20	20	0
SLE	66	64	2
Sjögren's syndrome	13	13	0
IBD	98	95	3
Osteoarthritis	21	21	0
Thyroiditis	20	20	0
Epstein Barr Virus	5	5	0
Parvovirus	5	5	0
Mycoplasma	9	9	0
Toxoplasma	6	6	0
Tuberculosis	5	5	0
Yersinia	8	8	0
Salmonella	3	3	0
Chlamydia	5	4	1
Malaria	4	4	0
Borrelia	9	9	0
Syphilis	5	5	0
Infectious endocarditis	3	3	0
Legionella	4	4	0
AST	3	3	0
Schistosomiasis	4	4	0
Rubella	5	5	0
Chaga's syndrome	3	3	0
Scleroderma	17	16	1
Multiple Sclerosis	20	20	0
IDDM	20	20	0
PM/DM	20	20	0
MCTD	20	19	1
Routine samples	80	78	2

RA = rheumatoid arthritis
 WG = Wegener's granulomatosis
 MP = microscopic polyangiitis
 SLE = systemic lupus erythematosus
 PM/DM = Polymyositis/Dermatomyositis
 IBD = inflammatory bowel disease
 AST = anti-Streptolysine test
 IDDM = insulin dependent diabetes mellitus
 MCTD = mixed connective tissue disease

Clinical sensitivity

RA = 309/399 = 77.4 %

95% CI = 73.3 - 81.5%

Clinical specificity

Blood donors	= 257/260 = 98.8%	95% CI = 96.7 - 99.8%
WG	= 18/20 = 90.0%	95% CI = 68.3 - 98.8%
MP	= 20/20 = 100%	95% CI = 83.2 - 100%
SLE	= 64/66 = 97.0 %	95% CI = 89.5 - 99.6%
Sjogren's	= 13/13 = 100 %	95% CI = 75.3 - 100%
IBD	= 95/98 = 96.9%	95% CI = 91.3 - 99.4%
Osteoarthritis	= 21/21 = 100%	95% CI = 83.9 - 100%
Thyroiditis	= 20/20 = 100%	95% CI = 83.2 - 100%
Infectious Disease	= 85/86 = 98.8%	95% CI = 93.7 - 100%
Scleroderma	= 16/17 = 94.1%	95% CI = 71.3 - 99.8%
Multiple Sclerosis	= 20/20 = 100%	95% CI = 83.2 - 100%
IDDM	= 20/20 = 100%	95% CI = 83.2 - 100%
PM/DM	= 20/20 = 100%	95% CI = 83.2 - 100%
MCTD	= 19/20 = 95.0%	95% CI = 75.1 - 99.9%
Routine samples	= 78/80 = 97.5 %	95% CI = 91.3 - 99.7 %

The 95% confidence interval (CI) was calculated using the exact method.

Table 3. Intra-assay precision was determined by testing six different samples eight times each.

	High		High		High	
	U/mL	OD	U/mL	OD	U/mL	OD
Mean.	2672	1.421	2685	1.432	1150	1.664
S.D.	138	0.01	205	0.01	55.3	0.02
% C.V.	5.2	0.4	7.6	0.4	4.8	0.9
	Medium		Low		Low	
	U/mL	OD	U/mL	OD	U/mL	OD
Mean	239	1.014	56	0.421	28	0.232
S.D.	2.3	0.01	2.1	0.01	0.5	0.01
%C.V.	1.0	0.4	3.8	2.8	3.6	1.3

Table 4. Inter-assay precision was determined by testing six different samples eight times each. Results were obtained for three different runs.

	High		High		High	
	U/mL	OD	U/mL	OD	U/mL	OD
Mean.	2696	1.426	2600	1.422	1168	1.706
S.D.	328	0.01	299	0.01	101.7	0.07
% C.V.	12.2	0.7	11.5	0.8	8.7	3.8
	Medium		Low		Low	
	U/mL	OD	U/mL	OD	U/mL	OD
Mean	242	1.031	59	0.428	28	0.232
S.D.	5.0	0.03	3.1	0.02	0.5	0.01
%C.V.	2.1	2.5	5.2	3.8	1.8	0.9

Table 5. Lot to lot variation was determined by testing six different samples eight times each. Results were obtained for three different lots.

	High		High		High	
	U/mL	OD	U/mL	OD	U/mL	OD
Mean.	2896	1.408	2870	1.408	1530	1.807
S.D.	405	0.02	335	0.02	260.4	0.03
% C.V.	14.0	1.4	11.7	1.5	17.0	1.6
	Medium		Low		Low	
	U/mL	OD	U/mL	OD	U/mL	OD
Mean	259	1.100	60	0.462	62	0.471
S.D.	21.8	0.04	4.2	0.02	6.6	0.04
%C.V.	8.4	3.9	6.9	4.4	10.8	8.2

Table 6. Dilution recovery was determined by testing five serial dilutions for three different samples.

Sample	Dilution	Mean Measured Concentration (U/mL)	Calculated Concentration (U/mL)	Dilution Corrected % Recovery
1	1/50	395	395	100
	1/100	195	198	98
	1/200	104	99	105
	1/400	53	50	106
	1/800	26	25	104
Sample	Dilution	Mean Measured Concentration (U/mL)	Calculated Concentration (U/mL)	Dilution Corrected % Recovery
2	1/50	921	921	100
	1/100	486	461	105
	1/200	257	230	112
	1/400	124	115	107
	1/800	63	58	109
Sample	Dilution	Mean Measured Concentration (U/mL)	Calculated Concentration (U/mL)	Dilution Corrected % Recovery
3	1/50	2962	2962	100
	1/100	1496	1481	101
	1/200	771	741	104
	1/400	349	370	94
	1/800	194	185	105

Two additional samples were diluted 1/50-1/1600 in the linear range. The mean concentrations were 164-6.0 U/mL and 321-11 U/mL respectively, with a dilution corrected recovery between 98-105%.

Detection Limit

The detection limit of the assay was determined by running the zero standard 14 times on three different lots. The detection limit of 1.6 U/mL was calculated by finding the mean plus two standard deviations.

Interference Study

Three low positive samples were spiked with bilirubin at 0.2 mg/mL, haemoglobin at 400 mg/dl, lipid at 15 mg/mL and rheumatoid factor at 200 IU/mL. The data indicates that the assayed concentrations do not interfere with the anti-CCP results.

**LITERATURE / BIBLIOGRAPHIE / REFERENCIAS / LITERATUR /
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University of Nijmegen page 24 Table 1 Overview of CCP Sensitivity and Specificity (2004)

APPENDIX / ANNEXE / APÉNDICE / ANHANG / APPENDICE / APÊNDICE / APPENDIKS / TILLEGG / APPENDIX

Symbols used on labels / Symboles utilisés sur les étiquettes / Simbolos usados en las etiquetas / Symbole auf den Etiketten / Simboli utilizzati sulle etichette / Simbolos utilizados nos rótulos / Symboler anvendt på etiketter / Symboler som brukes på etiketter / Symboler på etiketterna

	Batch code. Numéro de lot. Número de lote. Chargen-Nummer. Numero di lotto. Número do lote. Partinummer. Lot nummer. Satsnummer.
	Catalogue number. Numéro de catalogue. Número de catálogo. Katalog-Nr. Numero di catalogo. Número catalogo.. Bestillingsnummer. Katalognummer. Katalognummer.
	Use-by date. Date de péremption. Fecha de caducidad. Verfallsdatum. La data di scadenza. Prazo de validade. Udløbsdato. Utløpsdato. Använd före.
	Temperature limit. Seuils de températures. Rango de temperature. Temperaturbereich. Limitazioni di temperatura. Limite de temperatura. Opbevaringstemperatur. Oppbevares ved. Förvaringstemperatur.
	Biological risk. Risque biologique. Riesgo biológico. Biologische Gefährdung. Rischio biologico. Risco biológico. Biologisk risiko. Biologisk risiko. Biologisk risk.
	Consult instructions for use. Lire le mode d'emploi. Consulte las instrucciones de uso. Gebrauchsanweisung beachten. Leggere le istruzioni per l'uso. Consultar as instruções de utilização. Se brugsanvisning. Se bruksanvisningen. Läs instruktionsmanualen.
	In vitro diagnostic use. Pour le diagnostic in vitro uniquement. Para uso en diagnóstico in vitro. Nur zur in-vitro Diagnostik bestimmt. Uso diagnóstico in vitro. Utilização em diagnóstico <i>in vitro</i> . In vitro diagnostisk brug. Til In vitro diagnostisk bruk. In vitro diagnostika.
	Manufacturer. Fabricant. Fabricante. Hersteller. Produttore. Fabricante. Producent. Tilvirker. Tillverkare.
	Contains sufficient for 96 tests. Contenu suffisant pour 96 tests. Contenido suficiente para 96 pruebas. Inhalt ausreichend für 96. Contenuto sufficiente per 96 test. Número de testes. Indeholder tilstrækkelig for 96 test. Inneholder tilstrekkelig for 96 test. Innehåller tillräckligt för 96 test.
	Conformity to 98/79/EC on In Vitro Diagnostic Medical Device Directive. Conformément à la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro. La conformidad con la Directiva 98/79/CE sobre productos sanitarios para diagnóstico in vitro. Konform mit Richtlinie 98/79/EG zu In-vitro-Diagnostika. Conformità alla direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro. Medicinsk utstyr til in vitro-diagnostik, i overensstemmelse med Europa-Parlamentets og Rådets direktiv 98/79/EF. Medisinsk utstyr i samsvar med EU in vitro diagnostic directive 98/79/EF. Överensstämmer med direktiv 98/79/EG för medicintekniska produkter.

Ag	Antigen (coated plate). Antigène (plaque revêtue). Antigéno (placa recubierta). Antigen (beschichtete Platte). Antigene (pozzetti sensibilizzati). Antigénio (placa revestida). Antigen (belagt plade). Antigen (belagt plate). Antigen (klädd platta).
DIL	Diluent. Diluant. Diluyente. Verdünnungspuffer. Diluente. Diluente. Diluent. Fortynning. Spädningsbuffert.
BUF WASH 20X	Wash buffer 20x concentrate. Tampon de lavage concentré (20x). Tampón de lavado concentrado 20x. Waschpuffer 20fach, Konzentrat. Tampone di lavaggio concentrato 20x. Tampão de lavagem concentrado 20x. Vaskebuffer 20x koncentreret. Vaskebuffer, konsentrert 20 ganger. Tvättbuffert koncentrerad 20 gånger
H₂SO₄ 0.5M	Sulphuric Acid, 0.5 molar (stop solution). Acide sulfurique 0,5 M (solution d'arrêt). Ácido Sulfúrico, 0,5 molar (solución de parada). Schwefelsäure, 0,5 M (Stopplösung). Soluzione di stop (soluzione di acido solforico). Ácido sulfúrico, 0,5 molar (solução de paragem). Svovlsyre 0,5 mol (topopløsning). Svovelsyre, 0,5 molær (stoppløsning). Svavelsyra 0.5 molar (stopplösning).
CONJ	Conjugate. Conjugué. Conjugado. Konjugat. Coniugato. Conjugado. Konjugat. Konjugat. Konjugat.
SUBS TMB	Solution TMB (substrate solution). Solution de TMB (substrat). Solución TMB (solución substrato). TMB (Substratlösung). Cromogeno (TMB) / Substrato. Solução TMB (solução substrato). TMB-opløsning (substratopløsning). Løsning TMB (substratopløsning). Substratlösning, TMB.
CAL	Calibrator. Étalon. Calibrador. Kalibrator. Calibratore. Calibrador. Kalibrator. Kalibrator. Kalibrator.
CONTROL +	Positive control. Contrôle positif. Control positivo. Positivkontrolle. Controllo positivo. Controllo positivo. Positiv kontrol. Positiv kontroll. Positiv kontroll.
CONTROL -	Negative control. Contrôle négatif. Control negativo. Negativkontrolle. Controllo negativo. Controllo negativo. Negativ kontrol. Negativ kontroll. Negativ kontroll.
CONTROL REF	Reference control. Contrôle de référence. Control de referencia. Referenzkontrolle. Controllo di riferimento. Controllo de referência. Referencekontrol. Referansekontroll. Referenskontroll.

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