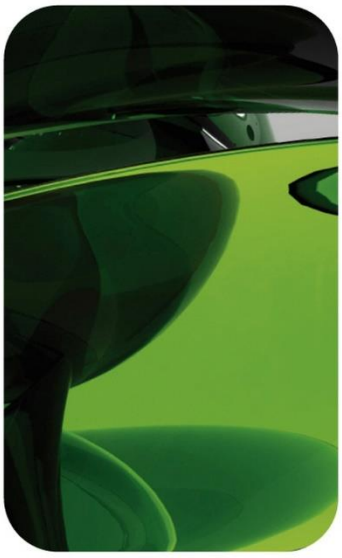
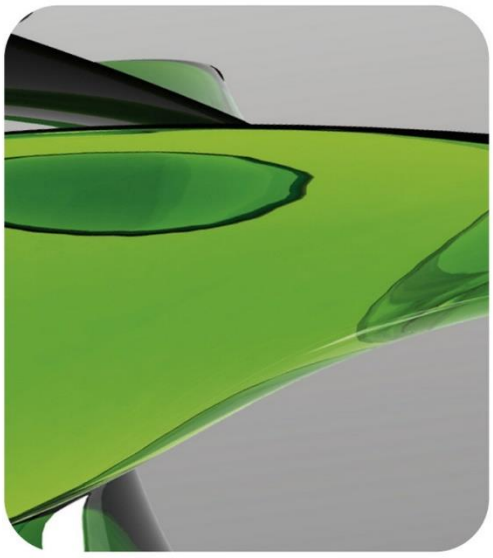
AESKU.DIAGNOSTICS
THE DIAGNOSTIC TOOL THAT WORKS

AESKULISA®

THE DIAGNOSTIC TOOL THAT WORKS

INSTRUCTION MANUAL

AESKULISA® SpA detect

Ref 3190

DIN EN ISO 13485

Instruction Manual

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AESKU.DIAGNOSTICS GmbH & Co. KG
Mikroforum Ring 2
55234 Wendelsheim, Germany
Tel: +49-6734-9622-0
Fax: +49-6734-9622-2222
Info@aesku.com
www.aesku.com

1 Intended Use

AESKULISA® SpA detect is a solid phase enzyme immunoassay with recombinant human CD74 for the semi-quantitative determination of IgA antibodies against human CD74 in the serum.

The test is used for diagnosing SpA (spondyloarthritis) and accordingly for clarifying the origin of inflammatory or chronic back pain. It is not a screening assay and is not used for the differential diagnosis of rheumatoid arthritis and systemic lupus erythematosus (SLE).

2 Clinical Application and Principle of the Assay

Spondyloarthritis (SpA) is an umbrella term for a group of related rheumatic-inflammatory diseases that are classified into the following subgroups: ankylosing spondylitis (AS), psoriatic arthritis, reactive SpA (following previous infections), SpA associated with chronic inflammatory bowel diseases, and a form of juvenile idiopathic arthritis. The various clinical manifestations include inflammation of the axial skeleton (axial SpA), which manifests in the cardinal symptoms of back pain and sacroiliitis, and other manifestations, such as peripheral arthritis, enthesopathies, uveitis, psoriasis, and inflammatory bowel diseases. Spondyloarthritis occurs in the population at a prevalence of 0.5 to 2%. Most patients develop the disease at an age of 20 to 45 years, whereas men are more affected than women (ratio 3:1) and often have more severe courses. NSAIDs (non-steroidal anti-inflammatory drugs) and physical therapy are used to improve the long-term prognosis of SpA patients. In more severe cases, anti-TNF alpha therapy can positively influence disease activity and delay progression of the inflammatory processes in the skeletal system. The pathogenesis of SpA is unexplained for the most part, but there is a strong genetic association: 95% of SpA patients are HLA-B27 positive. The presence of HLA-B27 increases the probability of the occurrence of SpA by a factor of 10, which is why the detection of HLA-B27 has been included in the ASAS criteria for the diagnosis of SpA. Evidence of sacroiliitis using x-ray and/or MRI is another main criterion for the diagnosis of SpA. The diagnosis of SpA is often made with a delay of several years as the symptoms can be very non-specific at the beginning of the disease and there has not been a specific serological marker so far. Recent papers have shown that CD74 antibodies are associated with the presence of SpA, especially with axial SpA (Baerlecken et al. 2014; Baraliakos et al. 2014). CD74 antibodies are, therefore, a new serological marker for the presence of SpA. CD74 antibodies can be detected in HLA-B27 positive as well as negative patients. Likewise, CD74 antibodies are detectable in the early phases of the disease, making them an important tool especially for the early diagnosis of spondyloarthritis.

Test principle

The serum samples diluted 1:101 are incubated in the cavities that are coated with the specific antigen. In this process, specific antibodies from the patient serum bind, if present, to the antigen on the plate; unbound serum components are washed away in the subsequent washing step. An anti-human immunoglobulin, which is marked with horseradish peroxidase (conjugate), is then added. During incubation, this immunoglobulin binds to the previously formed antigen-antibody complex; unbound immunoglobulins are removed in the subsequent washing step. Bound antibodies are detected by an enzymatic color reaction (blue) of the substrate, which is stopped using diluted acid (sudden color change to yellow). The intensity of the color development of the chromogen depends on the amount of conjugate bound to the antibody-antigen complex and is, therefore, directly proportional to the antibody concentration in the serum.

3 Kit Contents

TO BE RECONSTITUTED				
Item	Quantity	Cap color	Solution color	Description / Contents
Sample Buffer (5x)	1 x 20ml	White	Yellow	5 x concentrated Tris, sodium chloride (NaCl), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Wash Buffer (50x)	1 x 20ml	White	Green	50 x concentrated Tris, NaCl, Tween 20, sodium azide < 0.1% (preservative)
READY TO USE				
Item	Quantity	Cap color	Solution color	Description / Contents
Negative Control	1 x 1.5ml	Green	Colorless	Control material (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Positive Control	1 x 1.5ml	Red	Yellow	Control material (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Calibrators	6 x 1.5ml	White	Yellow *	Concentration of each calibrator: 0, 3, 10, 30, 100, 300 U/ml. calibrator material (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Conjugate, IgA	1 x 15ml	Red	Red	Containing: immunoglobulins conjugated to horseradish peroxidase, bovine serum albumin (BSA)
TMB Substrate	1 x 15ml	Black	Colorless	Stabilized tetramethylbenzidine and hydrogen peroxide (TMB/H_2O_2)
Stop Solution	1 x 15ml	White	Colorless	1M Hydrochloric Acid
Microtiter plate	12 x 8 well strips	N/A	N/A	With breakaway microwells. Refer to paragraph 1 for coating.
* Color increasing with concentration				
MATERIALS REQUIRED, BUT NOT PROVIDED				
Microtiter plate reader 450 nm reading filter and recommended 620 nm reference filter (600-690 nm). Glass ware (cylinder 100-1000ml), test tubes for dilutions. Vortex mixer, precision pipettes (10, 100, 200, 500, 1000 µl) or adjustable multipipette (100-1000µl). Microplate washing device (300 µl repeating or multichannel pipette or automated system), adsorbent paper. Our tests are designed to be used with purified water according to the definition of the United States Pharmacopeia (USP 26 - NF 21) and the European Pharmacopeia (Eur.Ph. 4th ed.).				

4 Storage and Shelf Life

Store all reagents and the micro plate at 2-8°C/35-46°F, in their original containers. Once prepared, reconstituted solutions are stable at 2-8°C/35-46°F for 1 month. Reagents and the microplate shall be used within the expiry date indicated on each component, only. Avoid intense exposure of TMB solution to light. Store micro plates in designated foil, including the desiccant, and seal tightly.

5 Precautions of Use

5.1 Health hazard data

THIS PRODUCT IS FOR IN VITRO DIAGNOSTIC USE ONLY. Thus, only staff trained and specially advised in methods of in vitro diagnostics may perform the kit. Although this product is not considered particularly toxic or dangerous in conditions of the intended use, refer to the following for maximum safety:

Recommendations and precautions

This kit contains potentially hazardous components. Though kit reagents are not classified being irritant to eyes and skin we recommend to avoid contact with eyes and skin and wear disposable gloves.

WARNING ! Calibrators, Controls and Buffers contain sodium azide (NaN_3) as a preservative. NaN_3 may be toxic if ingested or adsorbed by skin or eyes. NaN_3 may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. Please refer to decontamination procedures as outlined by CDC or other local/national guidelines.

Do not smoke, eat or drink when manipulating the kit. Do not pipette by mouth.

All biological source material used for some reagents of this kit has been tested by approved methods and found negative for HbsAg, Hepatitis C and HIV 1. However, no test can guarantee the absence of viral agents in such material completely. Thus handle kit controls, standards and patient samples as if capable of transmitting infectious diseases and according to national requirements.

The kit contains material of animal origin as stated in the table of contents, handle according to national requirements.

5.2 General directions for use

In case that the product information, including the labeling, is defective or incorrect please contact the manufacturer or the supplier of the test kit.

Do not mix or substitute Controls, Calibrators, Conjugates or micro plates from different lot numbers. This may lead to variations in the results.

Allow all components to reach room temperature (20-32°C/68-89.6°F) before use, mix well and follow the recommended incubation scheme for an optimum performance of the test.

Incubation: We recommend test performance at 30°C/86°F for automated systems.

Never expose components to higher temperature than 37°C/ 98.6°F.

Always pipette substrate solution with brand new tips only. Protect this reagent from light. Never pipette conjugate with tips used with other reagents prior.

A definite clinical diagnosis should not be based on the results of the performed test only, but should be made by the physician after all clinical and laboratory findings have been evaluated. The diagnosis is to be verified using different diagnostic methods.

6 Sample Collection, Handling and Storage

Use preferentially freshly collected serum samples. Blood withdrawal must follow national requirements. Do not use icteric, lipemic, hemolysed or bacterially contaminated samples. Sera with particles should be cleared by low speed centrifugation (<1000 x g). Blood samples should be collected in clean, dry and empty tubes.

After separation, the serum samples should be used during the first 8h, respectively stored tightly closed at 2-8°C/35-46°F up to 48h, or frozen at -20°C/-4°F for longer periods. (Thomas: Labor und Diagnose; CLSI Guideline GP 44-A4).

7 Assay Procedure

7.1 Preparations prior to starting

Dilute concentrated reagents:

Dilute the concentrated sample buffer 1:5 with distilled water (e.g. 20 ml plus 80 ml).

Dilute the concentrated wash buffer 1:50 with distilled water (e.g. 20 ml plus 980 ml).

To avoid mistakes we suggest to mark the cap of the different calibrators.

Samples:

Dilute serum samples 1:101 with sample buffer (1x)

e.g. 1000 µl sample buffer (1x) + 10 µl serum. Mix well !

Washing:

Prepare 20 ml of diluted wash buffer (1x) per 8 wells or 200 ml for 96 wells

e.g. 4 ml concentrate plus 196 ml distilled water.

Automated washing:

Consider excess volumes required for setting up the instrument and dead volume of robot pipette.

Manual washing:

Discard liquid from wells by inverting the plate. Knock the microwell frame with wells downside vigorously on clean adsorbent paper. Pipette 300 µl of diluted wash buffer into each well, wait for 20 seconds. Repeat the whole procedure twice again.

Microplates:

Calculate the number of wells required for the test. Remove unused wells from the frame, replace and store in the provided plastic bag, together with desiccant, seal tightly (2-8°C/35-46°F).

7.2 Pipetting Scheme

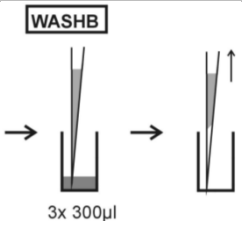
We suggest pipetting calibrators, controls and samples as follows:

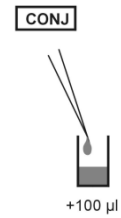
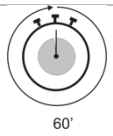
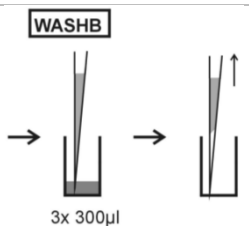
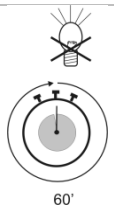
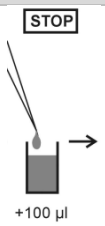
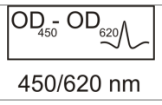
For *SEMI-QUANTITATIVE* interpretation

	1	2	3	4...
A	Cal A	Cal E	P1	
B	Cal A	Cal E	P1	
C	Cal B	Cal F	P2	
D	Cal B	Cal F	P2	
E	Cal C	PC	P3	
F	Cal C	PC	P3	
G	Cal D	NC	…	
H	Cal D	NC	…	

CalA: calibrator A
CalB: calibrator B
CalC: calibrator C
CalD: calibrator D
CalE: calibrator E
CalF: calibrator F
PC: positive control
NC: negative control
P1: patient 1
P2: patient 2
P3: patient 3

7.3 Test Steps

Step	*Description*
1.	Ensure preparations from step 7.1 above have been carried out prior to pipetting.
2.	Use the following steps in accordance with quantitative / qualitative interpretation results desired:
	CONTROLS & SAMPLES
3.	 Pipette into the designated wells as described in chapter 7.2 above, 100 µl of either: a. Calibrators (CAL.A to CAL.F) for *SEMI-QUANTITATIVE* or b. Cut-off Calibrator (CC) for *QUALITATIVE* interp. and 100 µl of each of the following: • Negative control (NC) and Positive control (PC), and • Patients diluted serum (P1, P2...)
4.	 Incubate for 60 minutes at 20-32°C/68-89.6°F.
5.	 Wash 3x with 300 µl washing buffer (diluted 1:50).

	CONJUGATE	
6.		Pipette 100 µl conjugate into each well.
7.		Incubate for 60 minutes at 20-32°C/68-89.6°F.
8.		Wash 3x with 300 µl washing buffer (diluted 1:50).
	SUBSTRATE	
9.		Pipette 100 µl TMB substrate into each well.
10.		Incubate for 60 minutes at 20-32°C/68-89.6°F, protected from intense light.
	STOP	
11.		Pipette 100 µl stop solution into each well, using the same order as pipetting the substrate.
12.		Incubate 5 minutes minimum.
13.		Agitate plate carefully for 5 sec.
14.		Read absorbance at 450 nm (recommended 450/620 nm) within 30 minutes.

8 Semi-Quantitative Interpretation

For semi-**quantitative interpretation** establish the standard curve by plotting the **optical density** (**OD) of each calibrator (y-axis)** with respect to the corresponding concentration values in U/ml (x-axis). For best results we recommend log/lin coordinates and 4-Parameter Fit. From the OD of each sample, read the corresponding antibody concentrations expressed in U/ml.

Normal Range	Positive Results
≤ 20 U/ml	>20 U/ml

Example of a standard curve

Do NOT use this example for interpreting patient´s result

Calibrators IgA	OD 450/620 nm	CV % (Variation)
0 U/ml	0.08	2.9
3 U/ml	0.166	3.0
10 U/ml	0.297	1.9
30 U/ml	0.619	2.6
100 U/ml	1.358	2.2
300 U/ml	2.250	0.2

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (APL/ml)
P 01	0.968/1.016	0.993	62.1
P 02	0.634/0.654	0.642	31.8

Samples above the highest calibrator range should be reported as >Max. They should be diluted as appropriate and re-assayed. Samples below calibrator range should be reported as < Min. For lot specific data, see enclosed quality control leaflet. Medical laboratories might perform an in-house quality control by using own controls and/or internal pooled sera, as foreseen by national regulations.

Each laboratory should establish its own normal range based upon its own techniques, controls, equipment and patient population according to their own established procedures.

In case that the values of the controls do not meet the criteria the test is invalid and has to be repeated.

The following technical issues should be verified: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, photometer, incubation conditions and washing methods.

If the items tested show aberrant values or any kind of deviation or that the validation criteria are not met without explicable cause please contact the manufacturer or the supplier of the test kit.

9 Technical Data

Sample material:	serum
Sample volume:	10 µl of sample diluted 1:101 with 1x sample buffer
Total incubation time:	180 minutes at 20-32°C/68-89.6°F
Calibration range:	3-300 U/ml
Analytical sensitivity:	2.7 U/ml
Storage:	at 2-8°C/35-46°F use original vials only.
Number of determinations:	96 tests

10 Performance Data

10.1 Analytical sensitivity

80 tests with the sample buffer in the AESKULISA SpA detect gave a Limit of Blank of 1.26 U/ml, and testing 10 sera at low CD74 concentration with 8 repetitions gave a Limit of Detection of 2.7 U/ml.

10.2 Clinical Evaluation

The microtiter plates are coated with recombinant human HLA class II histocompatibility antigen, gamma chain (Cluster of Differentiation 74, CD74).

The diagnostic sensitivity of 91% and specificity of 95% were calculated from 320 samples: 120 spondylarthritis serum samples were used with defined axSpA, along with 80 samples of other autoimmune diseases (celiac disease, vasculitis, collagenosis,scleroderma, polymyositis, collagenosis), as well as 120 healthy control samples (see table below). Elevated cross-reactivity with RA and SLE can occur (*see table below). The results for the RA sera were not included in the calculation for specificity.

Important note: The test is used to determine the origin of chronic back pain and not as a screening assay and/or differential diagnosis for rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).

Disease groups	**POS (>18)**	**Sum**
Other Autoimmune diseases	6 (7.5 %)	80
*rheumatoid arthritis	24 (25%)	96
*SLE	16 (22.2%)	72
Healthy controls	5 (4.2 %)	120
Spondylarthritis	109 (90.8 %)	120
Sum	**121 (37.8 %)**	**320**

SpA detect	Diagnosis		
Test	**POS**	**NEG**	**Sum**
POS>18	109	11	120
NEG ≤18	11	189	200
Sum	120	200	320

Diagnostic Sensitivity*	95 % confidence interval (CI)	
90.8 % (109/120)	84.3 %	94.8 %
Diagnostic Specificity*		
94.5 % (189/200)	99.4 %	96.9%

*borderline values were evaluated as negative

10.3 Linearity

Chosen sera have been tested with this kit and found to dilute linearly with a negative serum according to CLSI EP06-A. However, due to the heterogeneous nature of human autoantibodies there might be samples that do not follow this rule.

Composition		High			Middle			Low		
Pos. Sample	Neg. Sample	Mean [U/ml]	Expected [U/ml]	Recovery [%]	Mean [U/ml]	Expected [U/ml]	Recovery [%]	Mean [U/ml]	Expected [U/ml]	Recovery [%]
100.0%	0.0%	270.3	270	100%	41.79	42	101%	13.50	14	104%
87.5%	12.5%	203.65	236,51	116%	37.24	36.56	98%	11.78	11.82	100%
75.0%	25.0%	183.57	152,73	83%	33.11	27.93	84%	9.64	8.84	92%
67.5%	32.5%	147.54	123,91	84%	22.09	22.34	101%	7.26	6.51	90%
50.0%	50.0%	104.19	73,77	71%	15.78	11.04	70%	3.74	3.63	97%
37.5%	62.5%	75.63	39,07	52%	17.98	5.92	33%	1.91	1.40	73%
25.0%	75.0%	46.07	18,91	41%	7.25	4.50	62%	0.87	0.485	55%
12.5%	87.5%	11.21	5,76	51%	4.25	0.91	21%	0.09	0.11	123%

For AESKULISA SpA detect, linearity of the data is evident in the 2.7 U/ml to 300 U/ml range.

10.4 Precision

To determine the precision of the assay, the variability (intra and inter-assay) was assessed by examining its reproducibility on eight serum samples selected to represent a range over the standard curve. Lot to Lot was assessed with 5 sera on 3 different Lots in 8 repetitions.

Interassay-Variance			Intraassay-Variance			Lot-to-Lot-Variance		
Sample No.	Mean [U/ml]	CV% (Variance)	Sample No.	Mean [U/ml]	CV% (Varianz)	Sample No.	Mean [U/ml]	CV% (Variance)
1	13.09	8.3%	1	13.09	6.5%	1	13.52	5.3%
2	22.96	4.2%	2	22.96	3.6%	2	23.28	3.5%
3	39.65	4.2%	3	39.65	4.3%	3	39.82	4.1%
4	106.08	3.4%	4	106.08	3.0%	4	105.51	2.2%
5	248.68	2.1%	5	248.68	1.6%	5	250.52	2.1%

The acceptance criteria for positive samples at ≤ 10%, for borderline samples at ≤ 15 and for negative sera at ≤ 25%.

10.5 Calibration

Due to the lack of international reference calibration this assay is calibrated in arbitrary units (U/ml).

11 Literature

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CLSI Guideline GP44-A4: Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests

IVD	- Diagnosi in vitro	- For in vitro diagnostic use
	- Pour diagnostic in vitro	- Para uso diagnóstico in vitro
	- In Vitro Diagnostikum	- In Vitro Διαγνωστικό μέσο
	- Para uso Diagnóstico in vitro	
REF	¨ Numero d'ordine	¨ Cataloge number
	¨ Référence Catalogue	¨ Numéro de catálogo
	¨ Bestellnummer	¨ Αριθμός παραγγελίας
	¨ Número de catálogo	
LOT	¨ Descrizione lotto	¨ Lot
	¨ Lot	¨ Lote
	¨ Chargen Bezeichnung	¨ Χαρακτηρισμός παρτίδας
	¨ Lote	
CE	¨ Conformità europea	¨ EC Declaration of Conformity
	¨ Déclaration CE de Conformité	¨ Declaración CE de Conformidad
	¨ Europäische Konformität	¨ Ευρωπαϊκή συμφωνία
	¨ Déclaracão CE de Conformidade	
Σ 96	¨ 96 determinazioni	¨ 96 tests
	¨ 96 tests	¨ 96 pruebas
	¨ 96 Bestimmungen	¨ 96 προσδιορισμοί
	¨ 96 Testes	
	¨ Rispettare le istruzioni per l'uso	¨ See instructions for use
	¨ Voir les instructions d'utilisation	¨ Ver las instrucciones de uso
	¨ Gebrauchsanweisung beachten	¨ Λάβετε υπόψη τις οδηγίες χρήσης
	¨ Ver as instrucões de uso	
	¨ Da utilizzarsi entro	¨ Use by
	¨ Utilise avant le	¨ Utilizar antes de
	¨ Verwendbar bis	¨ Χρήση μέχρι
	¨ Utilizar antes de	
+2°C +8°C	¨ Conservare a 2-8°C	¨ Store at 2-8°C (35-46°F)
	¨ Conserver à 2-8°C	¨ Conservar a 2-8°C
	¨ Lagerung bei 2-8°C	¨ Φυλάσσεται στους 2-8°C
	¨ Conservar entre 2-8°C	
	¨ Prodotto da	¨ Manufactured by
	¨ Fabriqué par	¨ Fabricado por
	¨ Hergestellt von	¨ Κατασκευάζεται από
	¨ Fabricado por	
CO-CAL	¨ Calibratore cut-off	¨ Cut off Calibrator
	¨ Etalon Seuil	¨ Calibrador de cut-off
	¨ Grenzwert Kalibrator	¨ Οριακός ορός Αντιδραστήριο βαθμονόμησης
	¨ Calibrador de cut-off	
CON +	¨ Controllo positivo	¨ Positive Control
	¨ Contrôle Positif	¨ Control Positivo
	¨ Positiv Kontrolle	¨ Θετικός ορός ελέγχου
	¨ Controlo positivo	
CON −	¨ Controllo negativo	¨ Negative Control
	¨ Contrôle Négatif	¨ Control Negativo
	¨ Negativ Kontrolle	¨ Αρνητικός ορός ελέγχου
	¨ Controlo negativo	
CAL	¨ Calibratore	¨ Calibrator
	¨ Etalon	¨ Calibrador
	¨ Kalibrator	¨ Αντιδραστήριο βαθμονόμησης
	¨ Calibrador	
RC	¨ Recupero	¨ Recovery
	¨ Corrélation	¨ Recuperado
	¨ Wiederfindung	¨ Ανάκτηση
	¨ Recuperacão	
CONJ	¨ Coniugato	¨ Conjugate
	¨ Conjugé	¨ Conjugado
	¨ Konjugat	¨ Σύζευγμα
	¨ Conjugado	
MP	¨ Micropiastra rivestita	¨ Coated microtiter plate
	¨ Microplaque sensibilisée	¨ Microplaca sensibilizada
	¨ Beschichtete Mikrotiterplatte	¨ Επικαλυμμένη μικροπλάκα
	¨ Microplaca revestida	
WASHB 50x	¨ Tampone di lavaggio	¨ Wash buffer
	¨ Tampon de Lavage	¨ Solución de lavado
	¨ Waschpuffer	¨ Ρυθμιστικό διάλυμα πλύσης
	¨ Solucão de lavagem	
SUB	¨ Tampone substrato	¨ Substrate buffer
	¨ Substrat	¨ Tampón sustrato
	¨ Substratpuffer	¨ Ρυθμιστικό διάλυμα υποστρώματος
	¨ Substrato	
STOP	¨ Reagente bloccante	¨ Stop solution
	¨ Solution d'Arrêt	¨ Solución de parada
	¨ Stopreagenz	¨ Αντιδραστήριο διακοπής αντίδρασης
	¨ Solucão de paragem	
SB 5x	¨ Tampone campione	¨ Sample buffer
	¨ Tampon Echantillons	¨ Tampón Muestras
	¨ Probenpuffer	¨ Ρυθμιστικό διάλυμα δειγμάτων
	¨ Diluente de amostra	