AESKULISA tTg-G New Generation

Ref 3504





Product Ref.	3504
Product Desc.	tTg-G "New Generation"
Manual Rev. No.	004 : 2013-10-10

Instruction Manual

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1 Intended Use

The **AESKULISA tTg-G New Generation** is a solid phase enzyme immunoassay for the quantitative and qualitative detection of IgG antibodies against neo-epitopes of tissue transglutaminase (tTG) in human serum. The assay employing human recombinant transglutaminase crosslinked with gliadin-specific peptides displays neo-epitopes of tTg which ensures a significantly increased sensitivity and specificity of the test.

The assay is a tool for the diagnosis and monitoring of celiac disease (gluten-sensitive enteropathy).

2 Clinical Application and Principle of the Assay

Gluten-sensitive enteropathy or celiac disease is characterized by atrophy of the small intestinal villi leading to a so-called flat mucosa. It is caused by a pathological intolerance to gliadin, the alcohol-soluble fraction of gluten in wheat, rye and barley. As celiac disease is caused by the uptake of gluten, consequently a gluten-free diet cures the disease completely and thus has to be maintained for life-time. Renewed consumption of gliadin leads to a return of the symptoms. The disease is HLA-associated (>95% of patients have DQ2 enREFd by DQA1*0501 and DQB1*0201) and manifests at any age with a peak onset in early childhood, even in neonatals. The incidence rates range from 1 in 4000 to 1 in 300 in european countries.

Diagnosis of celiac disease is made by small intestinal biopsy (demonstrating flat mucosa) supported by serological markers. Antibodies against gliadin and anti-endomysium antibodies (EMA) are of major significance. They are detected so far by indirect immunofluorescence, which is restricted to subclass IgA only. The identification of tissue transglutaminase (tTG) as the major target antigen of EMA provided the opportunity of a more easy and reliable diagnosis of celiac disease. tTG is an enzyme that upon wounding is released from cells where it is thought to aid in tissue repair.

Anti-tTG antibodies show higher sensitivity and specificity than anti-Gliadin antibodies. Furthermore they correlate tightly with the activity of the disease and thus are especially useful for diet monitoring. The cross-link of tTg with gliadin-specific peptides results in neoepitopes of tTg. As these neo-epitopes are structurally closer to the physiological antigens, the new generation AESKULISA tTg tests show a markedly increased sensitivity and specificity. These epitopes show no cross-reactivities with gliadin.

The determination of IgG antibodies to tTG is the only available specific serology for those 2% to 5% of patients with IgA deficiency. A high number of subclinical cases have been detected by screening for anti-tTg, fostering the theory that the majority of celiac disease cases is undetected and untreated (Iceberg model).

Principle of the test

Serum samples diluted 1:101 are incubated in the microplates coated with the specific antigen. Patient's antibodies, if present in the specimen, bind to the antigen. The unbound fraction is washed off in the following step. Afterwards anti-human immunoglobulins conjugated to horseradish peroxidase (conjugate) are incubated and react with the antigen-antibody complex of the samples in the microplates. Unbound conjugate is washed off in the following step. Addition of TMB-substrate generates an enzymatic colorimetric (blue) reaction, which is stopped by diluted acid (color changes to yellow). The intensity of color formation from the chromogen is a function of the amount of conjugate bound to the antigen-antibody complex and this is proportional to the initial concentration of the respective antibodies in the patient sample.



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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)	
		RE	ADY TO USE	Ē	
Item	Quantity	Cap color	Solution color	Description / Contents	
Negative Control	1 x 1.5ml	Green	Colorless	Human serum (diluted), bovine serum albumin (BSA) sodium azide < 0.1% (preservative)	
Positive Control	1 x 1.5ml	Red	Yellow	Human serum (diluted), bovine serum albumin (BSA) sodium azide < 0.1% (preservative)	
Cut-off Calibrator	1 x 1.5ml	Blue	Yellow	Human serum (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. Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)	
Conjugate, IgG	1 x 15ml	Blue	Blue	Containing: Anti-human 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.	

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 μ l) or adjustable multipipette (100-1000 μ l). Microplate washing device (300 μ l 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 microplate 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 at least 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 microplates in designated foil, including the desiccant, and seal tightly.

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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 human source material used for some reagents of this kit (controls, standards e.g.) 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 microplates 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.



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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

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 μ l 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).

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7.2 Pipetting Scheme

We suggest pipetting calibrators, controls and samples as follows:

For QUANTITATIVE interpretation					
	1	2	3	4	
Α	Cal A	Cal E	P1		
В	Cal A	Cal E	P1		
С	Cal B	Cal F	P2		
D	Cal B	Cal F	P2		
Е	Cal C	PC	P3		
F	Cal C	PC	P3		
G	Cal D	NC			
н	Cal D	NC			

For QUALITATIVE interpretation

	1	2	3	4
Α	NC	P2		
В	NC	P2		
С	CC	P3		
D	CC	P3		
Е	PC			
F	PC			
G	P1			
Н	P1			

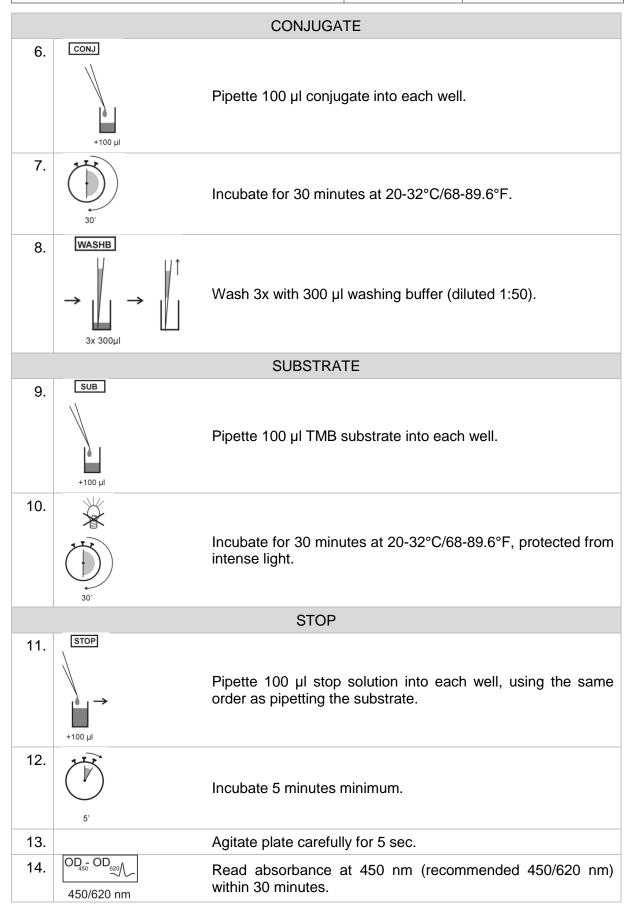
CalA: calibrator A	CaID: calibrator D	PC: positive control	P1: patient 1
CalB: calibrator B	CalE: calibrator E	NC: negative control	P2: patient 2
CalC: calibrator C	CalF: calibrator F	CC: cut-off calibrator	P3: patient 3

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 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) Patients diluted serum (P1, P2) Additional control (PC) Additional control (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2) Patients diluted serum (P1, P2)		
4.	Incubate for 30 minutes at 20-32°C/68-89.6°F.		
5.	WASHE $\rightarrow \downarrow \downarrow \downarrow$ $3 \times 300 \mu l$ Wash 3x with 300 µl washing buffer (diluted 1:50).		

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8 Quantitative and Qualitative Interpretation

For **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	Equivocal Range	Positive Results
< 12 U/ml	12 - 18 U/ml	>18 U/ml

Example of a standard curve

Do NOT use this example for interpreting patient's result

Calibrators IgG	OD 450/620 nm	CV % (Variation)					
0 U/ml	0.073	3.1					
3 U/ml	0.179	2.3					
10 U/ml	0.342	1.2					
30 U/ml	0.662	0.1					
100 U/ml	1.310	0.9					
300 U/ml	2.263	0.3					

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	0.808/0.831	0.820	39.6
P 02	1.081/1.071	1.076	66.1

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.

For **qualitative interpretation** read the optical density of the cut-off calibrator and the patient samples. Compare patient's OD with the OD of the cut-off calibrator. For qualitative interpretation we recommend to consider sera within a range of 20% around the cut-off value as equivocal. All samples with higher ODs are considered positive, samples with lower ODs are considered negative.

Negative:OD patient<</th>Equivocal:0.8 xOD cut-off≤Positive:OD patient>

0.8 x OD cut-off OD patient ≤ 1.2 x OD cut-off 1.2 x OD cut-off



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9	Technical Data	
	Sample material:	serum
	Sample volume:	10 μ l of sample diluted 1:101 with 1x sample buffer
	Total incubation time:	90 minutes at 20-32°C/68-89.6°F
	Calibration range:	0-300 U/ml
	Analytical sensitivity:	1.0 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

Testing sample buffer 30 times on AESKULISA tTg-G New Generation gave an analytical sensivity of 1.0 U/ml.

10.2 Specificity and sensitivity

The microplates are coated with recombinant human tissue-transglutaminase and gliadinspecific peptides. No crossreactivities to other autoantigens have been found. To test crossreactivity with gliadin, 7 sera positive for gliadin were tested and did not react with this assay, though this can be different for other gliadin positive sera.

For determination of sensitivity and specificity sera of 185 patients suffering from Celiac disease (n=122) and related diseases (data in bottom table) were assessed on the AESKULISA and a predicate device. The results as a comparison to the predicate device and disease information are shown in the tables below.

-			diagnos	sis
		Pos	Neg	Total
AESKULISA	Pos	80	5	85
tTg-G	Neg	4	96	100
	Total	84	101	185
Agreement:		ç	95.1 %	
Sensitivity:		(95.2 %	
Specificity:		9	95.1 %	

		Pre	dicate d	device
		Pos	Neg	Total
AESKULISA	Pos	18	67	85
tTg-G	Neg	4	96	100
	Total	22	163	185
rel. agreement:		(51.6 %	
rel. sensitivity :		8	81.8 %	
rel. specificity:		ļ	58.9 %	

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Disease	# Tested	# positive AESKU	# positive pred dev
Celiac Disease	64 / 64	59 (96.5)	9 (14.0)
Celiac Disease (IgA deficient)	20 / 20	18 (90.0)	9 (45.0)
Celiac Disease (gluten free diet)	38 / 38	0 (0.0)	0 (0.0)
Disease control (total)	70 / 217	11 (5.1)	4 (5.7)
Crohns Disease	51 / 51	3 (5.9)	2 (3.9)
Crohns Disease	0 / 58	0 (0.0)	n / d
Ulcerative Colitis	4/4	1 (25.0)	1 (25.0)
Ulcerative Colitis	0/2	1 (50.0)	n / d
Helminthiasis	2/2	2 (100.0)	1 (50.0)
Lactose Intolerance	2/2	2 (100.0)	0 (0.0)
Gliadin positive sera	0/7	0 (0.0)	n / d
Healthy donors	4/4	0 (0.0)	0 (0.0)
Healthy donors	0 / 80	2 (2.5)	n / d

10.3 Linearity

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

Sample No.	Dilution Factor	Measured (U/ml)	Expected (U/ml)	Recovery (%)
1	1 / 100	41.3	41.0	100.8
	1 / 200	22.2	20.5	108.3
	1 / 400	11.2	10.3	109.3
	1 / 800	5.5	5.1	107.1
2	1 / 100	86.6	87.0	99.5
	1 / 200	42.9	43.5	98.5
	1 / 400	23.9	21.8	109.7
	1 / 800	11.9	10.9	109.4

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10.4 Precision

To determine the precision of the assay, the variability (intra and inter-assay) was assessed by examining its reproducibility on three serum samples selected to represent a range over the standard curve. (n=18). The accepted range for CV is 10%. (n=24 / 18)

Intra-assay		
Sample No.	Mean (U/ml)	CV (%)
1	19.2	3.1
2	100.8	3.5
3	152.8	4.6

Inter-assay		
Sample No.	Mean (U/ml)	CV (%)
1	16.7	4.3
2	97.4	7.6
3	194.4	9.1

10.5 Calibration

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



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11 Literature

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Recuperacão Conjugato Conjugado * Conjugado * Conjugado * Conjugado * Konjugat * Cúcjuyado * Konjugat * Cúcjuyado * Microplacar arivestita * Contectruitor plate * Microplacar sensibilisée * Microplaca sensibilizada * Beschichtete Mikrotiterplatte * EmicaNupµcry µkçomAkca * Microplacar servestida * * Tampone di lavaggio * Solución de lavado * Solucão de lavage * Solución de lavado * Solucão de lavagem * * Substrat * Tampone substrato * Substrato * Substrate buffer * Substrato * Tampón sustrato * Substrato * Tampón sustrato * Substrato * Substrato * Substrato * Substrato * Substrato * Solución de paragem * Solucão de paragem * Solucão de paragem * Substrato * Substrato * Substrato * Tampón sustrato * Substrato * Solución de parada * Solucão de paragem * Solución de parada		Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero	[°] Control Positivo [°] Θετικός ορός ελέγχου [°] Negative Control [°] Control Negativo [°] Αρνητικός ορός ελέγχου [°] Calibrator [°] Calibrator [°] Calibrator [°] Αντιδραστήριο βαθμονόμησης [°] Recovery
CONJ - Conjugato - Conjugate - Conjugát - Conjugado - Konjugat - Súččuvjua - Conjugado - Súččuvjua - Conjugado - Súččuvjua - Conjugado - Conjugado - Conjugado - Súččuvjua - Conjugato - Conjugado - Conjugato - Conjugado - Conjugato - Conjugato - Microplastra rivestita - Coated microtiter plate - Tampon edi Lavage - Solución de lavado - Tampon edu Lavage - Solución de lavado - Vuêguorikó δidkulu urtoorpuújuorç - Solución de lavado - Substrat - Substrato - Substrato - Substrato - Solución de parada <td></td> <td>Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation</td> <td>[°] Control Positivo [°] Θετικός ορός ελέγχου [°] Negative Control [°] Control Negativo [°] Control Negativo [°] Aρνητικός ορός ελέγχου [°] Calibrator [°] Calibrator [°] Aντδραστήριο βαθμονόμησης [°] Recovery [°] Recuperado</td>		Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation	[°] Control Positivo [°] Θετικός ορός ελέγχου [°] Negative Control [°] Control Negativo [°] Control Negativo [°] Aρνητικός ορός ελέγχου [°] Calibrator [°] Calibrator [°] Aντδραστήριο βαθμονόμησης [°] Recovery [°] Recuperado
CONJ ⁻ Conjugá ⁻ Conjugado ⁻ Konjugat ⁻ Σύζευγμα ⁻ Conjugado ⁻ Conjugado MP ⁻ Microplastra rivestita ⁻ Coated microtiter plate ⁻ Microplaque sensibilisée ⁻ Microplaca sensibilizada ⁻ Beschichtete Mikrotiterplatte ⁻ Eπικαλυμμένη μικροπλάκα ⁻ Microplaca revestida ⁻ ⁻ Tampone di lavaggio ⁻ Wash buffer ⁻ Tampone di lavaggio ⁻ Solución de lavado ⁻ Waschpuffer ⁻ Puθμιστικό διάλυμα πλύσης ⁻ Solucão de lavagem ⁻ ⁻ Substrato ⁻ Substrato ⁻ Substrat ⁻ Tampón substrato ⁻ Substrat ⁻ Tampón sustrato ⁻ Substrato ⁻ Stop solution ⁻ Substrato ⁻ Stop solution ⁻ Solucão de paragem ⁻ ⁻ Tampon e Cahantillons ⁻ Tampón Muestras ⁻ Tampon Echantillons ⁻ Tampón Muestras		Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrator Calibrator Corrélation Wiederfindung	[°] Control Positivo [°] Θετικός ορός ελέγχου [°] Negative Control [°] Control Negativo [°] Control Negativo [°] Aρνητικός ορός ελέγχου [°] Calibrator [°] Calibrator [°] Aντδραστήριο βαθμονόμησης [°] Recovery [°] Recuperado
· Konjugat · Σύζενγμα · Conjugado · Micropiastra rivestita · Coated microtiter plate · Micropiaque sensibilisée · Micropiaca sensibilizada · Beschichtete Mikrotiterplatte · EmicaJuµ£vn µikpomAáka · Micropiaca revestida · · Tampon el lavaggio · Wash buffer · Tampon el lavagge · Solución de lavado · Washpuffer · Pu@µiortikó δidλuµa πλύσης · Solucão de lavagem · · Tampon esubstrato · Substrate buffer · Substrat · Tampón sustrato · Substrat · Tampón sustrato · Substrato · Substrato · Substrato · Substrato · Substrato · Substrato · Substrato · Stop solution · Solucão de paragem · Solucão de paragem · Substrato · Stop solution · Solucão de paragem · Tampón chantillons · Subica de paragem · Tampón chantillons · Solucão de paragem · Tampón Muestras · Solucão de paragem · Tampón Muestras · Solucão de paragem · Tampón Muestras · Tampón Echantillons · Tamp		Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Controlo negativo Calibratore Etalon Kalibrator Calibrator Corrélation Wiederfindung Recuperacão	[°] Control Positivo [°] Θετικός ορός ελέγχου [°] Negative Control [°] Control Negativo [°] Control Negativo [°] Apvητικός ορός ελέγχου [°] Calibrator [°] Calibrator [°] Calibrador [°] Aντιδραστήριο βαθμονόμησης [°] Recovery [°] Recuperado [°] Ανάκτηση
Conjugado "Conjugado Micropiastra rivestita "Coated microtiter plate Microplaque sensibilisée "Microplaca sensibilizada Beschichtete Mikrotiterplatte "Errikaλuµµένη µikporπλάκα "Microplaca revestida " "Tampone di lavaggio "Wash buffer "Tampon de Lavage "Solución de lavado "Waschpuffer "Puθµιστικό διάλuµα πλύσης "Solucão de lavagem " "Substrate "Tampon esubstrato "Substrato "Substrate buffer "Substrato "Substrato "Substrato "Stapstrato" "Solución de parada "Stopreagenz "Solución de parada "Solución de parada "Stopreagenz "Avriõpaorn(pio διακοπής αντιδρασης "Solucão de paragem "Tampon ecampione "Tampone campione "Sample buffer "Tampon	RC	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Controlo negativo Calibratore Etalon Kalibrator Kalibrator Carfélation Wiederfindung Recuperacão Coniugato	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Αρνητικός ορός ελέγχου Calibrator Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανκιτηση Conjugate
MP * Micropiastra rivestita * Coated microtiter plate * Micropiaque sensibilisée * Micropiaca sensibilizada * Beschichtete Mikrotiterplatte * ErrikaAuµµévŋ µikpomAdka * Micropiaca revestida * * Tampon de Lavage * Solución de lavado * Washpuffer * Puθµютikó δidλuµa πλύσης * Solucão de lavagem * * Substrato * Substrato * Substrato * Substrato * Solucão de paragem * * Tampone campione * * Solucão de paragem * * Tampone substrato * * Solucão de paragem * * Solucão de paragem * * Solucão de paragem * * Tampone campione * * Tampone campione * * Tampo Echantillons * *	RC	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Contrôle Négatif Negativ Kontrolle Contrôle negativo Calibratore Etalon Kalibrator Calibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato Conjugé	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Αρνητικός ορός ελέγχου Calibrator Calibrator Avrιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado
MP "Microplaque sensibilisée "Microplaca sensibilizada "Beschichtete Mikrotiterplatte "Erriκαλυμμένη μικροπλάκα "Microplaca revestida "Wash buffer "Tampon di lavaggio "Wash buffer "Tampon di lavage "Solución de lavado "Waschpuffer "Puθμιστικό διάλυμα πλύσης "Solucão de lavagem " "Tampon substrato "Substrate buffer "Substrat "Tampón sustrato "Substrato "Substrato "Substrato "Solución de parada "Substrato "Solución de parada "Solucão de paragem "Solución de parada "Solução de paragem "Arniţo acorriţio acorriţio actritopaonţi "Substrato "Solución de parada "Solução de paragem "Arniţo acorriţio actritopaonţi "Solução de paragem "Arniţo acorriţio actritopaonţi "Solução de paragem "Arniţo acorriţio actritopaonţi "Tampon e campione "Sample buffer "Tampon e campione "Sample buffer "Tampon e campione "Sample buffer "Tampon Echantillons "Tampón Muestras "Probenpuffer "Puθμιστικό διάλυμα δειγμάτων	RC	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato Conjugé Konjugat	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Αρνητικός ορός ελέγχου Calibrator Calibrator Avrιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado
IVIP "Веschichtete Mikrotiterplatte "Етикаλиµµέvŋ µкроπλάκа "Microplaca revestida "Tampone di lavaggio "Wash buffer "Tampon e di lavaggio "Solución de lavado "Solución de lavado "WASHB 500x "Solución de lavado "Solución de lavado "Tampon e Lavage "Solución de lavado "Solución de lavado "Waschpuffer "Puθµµorukó διάλυµα πλύσης "Solución de lavado "Substrato "Substrate buffer "Substrate buffer "Substrato "Substrato "Substrato "Substrato "Solución de parada "Solución de parada "Solucão de paragem "Avriõpaornýpio biakornýp avriõpaonyc "Solución de parada "Solucão de paragem "Avriõpaornýpio biakornýp avriõpaonyc "Solucão de paragem "Solucão de paragem "Avriõpaornýpio biakornýp avriõpaonyc "Solucão de paragem "Tampone campione "Sample buffer "Sample buffer "Tampone campione "Sample buffer "Tampón Muestras "Probenpuffer "Puθµµorikó διάλυµa δειγµµáτων "Puθµµorikó διάλυµa δειγµµáτων	RC	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Conjugáb Konjugat Conjugado	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Αρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα
· Microplaca revestida · Microplaca revestida · Tampone di lavaggio · Wash buffer · Tampon de Lavage · Solución de lavado · Waschpuffer · Puθµiorikó δίάλυµα πλύσης · Solucão de lavagem · Substrate buffer · Substrat · Tampon substrato · Substrat · Tampón sustrato · Substrat · Substrate buffer · Substrato · Substrato · Substrato · Substrato · Substrato · Substrato · Substrato · Stop solution · Solucão de paragem · Solución de parada · Solucão de paragem · Sample buffer · Solucão de paragem · Tampone campione · Sample compione · Sample buffer · Tampone campione · Sample buffer · Tampone campione · Sample buffer · Tampon Echantillons · Tampón Muestras · Probenpuffer · Puθµiorikó δίάλυµu δειγµμάτων		Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo positivo Contrôlo negativo Contrôle Négatif Negativ Kontrolle Contrôlo negativo Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato Conjugé Konjugat Conjugado Micropiastra rivestita	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Aντιδραστήριο βαθμονόμησης Recovery Recuperado - Χοτάκτηση Conjugate Conjugate Σύζευγμα Coated microtiter plate
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SUB "Substratpuffer "Puθμιστικό διάλυμα υποστρώματος "Substrato " * Reagente bloccante "Stop solution "Solución de parada "Solución de parada * Stopreagenz "Avriδpaστήριο διακοπής αντίδρασης * Solucão de paragem " "Tampone campione "Sample buffer "Tampon Echantillons "Tampón Muestras "Probenpuffer "Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Conjugáb Konjugat Conjugáb Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Aντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα Coated microtiter plate Μicroplaca sensibilizada Έτικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης
Substrato STOP "Reagente bloccante "Solution d'Arrêt "Solución de parada "Stop reagenz "Solucão de paragem "Tampone campione "Tampon Echantillons "Probenpuffer "Probenpuffer	RC CONJ MP	Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo positivo Contrôlo negativo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Calibrador Kalibrator Corrélation Wiederfindung Recuperação Conjugáb Konjugát Conjugáb Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Tampon de Lavage Waschpuffer Solução de lavagem Tampone substrato	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Aντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα Coated microtiter plate Μicroplaca sensibilizada Έτικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης
STOP [°] Reagente bloccante [°] Stop solution Solution d'Arrêt [°] Solución de parada [°] Stopreagenz [°] Avriðpaστήριο διακοπής αντίδρασης [°] Solucão de paragem [°] Tampone campione [°] Sample buffer [°] Tampon Echantillons [°] Tampón Muestras [°] Probenpuffer [°] Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo positivo Contrôlo negativo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Calibrador Kalibrator Corrélation Wiederfindung Recuperação Conjugáb Konjugát Conjugáb Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Tampon de Lavage Waschpuffer Solução de lavagem Tampone substrato	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Recovery Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα "Uroplaca sensibilizada Έπικαλυμμένη μικροπλάκα "Wash buffer "Solución de lavado Puθμιστικό διάλυμα πλύσης "Substrate buffer
STOP [°] Solución d'Arrêt [°] Solución de parada [°] Stopreagenz [°] Avriδραστήριο διακοπής αντίδρασης [°] Solucão de paragem [°] Sample buffer [°] Tampon Echantillons [°] Tampón Muestras [°] Probenpuffer [°] Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo positivo Contrôlo negativo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Calibrator Calibrator Calibrator Calibrador Kalibrator Corrélation Wiederfindung Recuperacão Conjugá Conjugáto Conjugáto Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Seschichtete Mikrotiterplatte Microplaque sensibilisée Tampone di lavaggio Tampone substrato Substrat	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Recovery Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα "Uroplaca sensibilizada Έπικαλυμμένη μικροπλάκα "Wash buffer "Solución de lavado "Puθμιστικό διάλυμα πλύσης "Substrate buffer
STOP [°] Solución d'Arrêt [°] Solución de parada [°] Stopreagenz [°] Avriδραστήριο διακοπής αντίδρασης [°] Solucão de paragem [°] Sample buffer [°] Tampon Echantillons [°] Tampón Muestras [°] Probenpuffer [°] Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo negativo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Calibratore Etalon Kalibrator Calibrator Calibrator Carélation Wiederfindung Recuperoa Corríugato Conjugé Konjugat Conjugé Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Tampone di lavaggio Tampone de Lavage Waschpuffer Sulucão de lavagem Tampone substrato Substrat Substratpuffer	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Recovery Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα "Uroplaca sensibilizada Έπικαλυμμένη μικροπλάκα "Wash buffer "Solución de lavado "Puθμιστικό διάλυμα πλύσης "Substrate buffer
STOP [°] Stopreagenz [°] Aντιδραστήριο διακοπής αντίδρασης [°] Solução de paragem [°] Sample buffer [°] Tampone campione [°] Sample buffer [°] Tampon Echantillons [°] Tampón Muestras [°] Probenpuffer [°] Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Contrôle negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Contrôle negativo Calibratore Etalon Kalibrator Calibrator Calibrator Calibratore Corrélation Wiederfindung Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugato Conjugato Micropiastra rivestita Microplace sensibilisée Beschichtete Mikrotiterplatte Microplace revestida Tampone di lavaggio Tampone de Lavage Waschpuffer Substrat Substrat Substrato	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα Wash buffer Solución de lavado "Puθμιστικό διάλυμα υποστρώματος
Solucão de paragem "Solucão de paragem "Tampone campione "Tampon Echantillons "Tampón Muestras "Probenpuffer	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Contrôle negativo Contrôle Négatif Negativ Kontrolle Contrôle negativo Calibratore Etalon Kalibrator Calibrator Calibrador Calibrador Calibrador Corrélation Wiederfindung Recuperacão Conjugato Conjugato Conjugato Micropiastra rivestita Micropiastra rivestita Micropiaca revestida Tampone di lavaggio Tampone de Lavage Waschpuffer Substratu Substratu Reagente bloccante Reagente bloccante	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrador Aντιδραστήριο βαθμονόμησης Recovery Recovery Recovery Conjugate Conjugato Σύζευγμα Coated microtiter plate Microplaca sensibilizada Έπκαλυμμένη μικροπλάκα Wash buffer Solución de lavado Ρυθμιστικό διάλυμα υποστρώματος Stop solution
SB 5x ^a Tampone campione ^a Sample buffer ^a Tampón Muestras ^a Tampón Muestras ^a Probenpuffer ^a Probenpuffer ^b Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Calibrador Calibrador Corrélation Wiederfindung Recuperacão Conjugato Conjugáb Konjugat Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Tampone di lavaggio Tampone di lavagge Waschpuffer Substratu Substratu Reagente bloccante Solution d'Arrêt	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recovery Recorery Conjugate Conjugato Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επκαλυμμένη μικροπλάκα Wash buffer Solución de lavado Ρυθμιστικό διάλυμα υποστρώματος Stop solution Stop solution
SB 5x "Tampon Echantillons "Tampón Muestras "Probenpuffer "Ρυθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Kalibrator Caríbarador Kecupero Corrélation Wiederfindung Recuperacão Conjugáb Konjugát Konjugát Konjugát Microplace sensibilisée Beschichtete Mikrotiterplatte Microplace revestida Tampone di lavaggio Tampone substrato Substrat Substrat Substrat Substrato Reagente bloccante Solution d'Arrêt Stopreagenz	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recovery Recorery Conjugate Conjugato Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επκαλυμμένη μικροπλάκα Wash buffer Solución de lavado Ρυθμιστικό διάλυμα υποστρώματος Stop solution Stop solution
SB SX ["] Probenpuffer ["] Ρυθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x	 Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Contrôlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugát Conjugát Konjugat Conjugáto Microplazte arivestita Microplaze sensibilisée Beschichtete Mikrotiterplatte Microplaze arevestida Tampone di lavaggio Tampone substrato Solução de lavagem Tampone substrato Substrat Substrat Substrat Substrat Solução de paragem 	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Recovery Recovery Recuperado Δνάκτηση Conjugate Conjugato Σύζευγμα Coated microtiter plate Microplaca sensibilizada Έπικαλυμμένη μικροπλάκα Wash buffer Solución de lavado "Puθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato "Puθμιστικό διάλυμα υποστρώματος "Stop solution Solución de parada "Avriδραστήριο διακοπής αντίδρασης
	RC CONJ MP WASHB 50x SUB STOP	 Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Conjugáb Conjugáb Konjugat Conjugáb Microplaçue sensibilisée Beschichtete Mikrotiterplatte Microplaçue sensibilisée Beschichtete Mikrotiterplatte Microplaçue sensibilisée Tampon de Lavage Waschpuffer Solução de lavagem Tampone substrato Substrat Substrat Substrato Stopreagenz Solução de paragem Tampone campione 	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Recovery Recovery Recuperado Δνάκτηση Conjugate Conjugato Σύζευγμα Costed microtiter plate Microplaca sensibilizada Έπικαλυμμένη μικροπλάκα Wash buffer Solución de lavado "Puθμιστικό διάλυμα πλύσης Stop solution Stop solution Solución de parada " Stop solution Solución de parada "Avτιδραστήριο διακοπής αντίδρασης
	RC CONJ MP WASHB 50x SUB STOP	 Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo Contrôle Négatif Negativ Kontrolle Controlo negativo Controlo negativo Controlo negativo Controlo negativo Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Conjugáto Conjugáto Conjugato Conjugato Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Tampone di lavaggio Tampone substrato Substrat Substrat Substrato Reagente bloccante Solucão de paragem Tampone campione Tampone campione Tampone campione Tampone campione 	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα "Coated microtiter plate Microplaca sensibilizada "Eπικαλυμμένη μικροπλάκα "Vash buffer Solución de lavado "Puθμιστικό διάλυμα πλύσης "Substrate buffer "Tampón sustrato "Puθμιστικό διάλυμα υποστρώματος "Stop solution "Solución de parada "Aντιδραστήριο διακοπής αντίδρασης "Sample buffer
	RC CONJ MP WASHB 50x SUB STOP	 Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugá Konjugat Conjugá Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplace revestida Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substratu Solucão de paragem Tampone campione Probenpuffer 	Control Positivo Θετικός ορός ελέγχου Negative Control Control Negativo Άρνητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrador Aντιδραστήριο βαθμονόμησης Recovery Recoperado Ανάκτηση Conjugate Conjugato Σύζευγμα "Coated microtiter plate Microplaca sensibilizada "Eπικαλυμμένη μικροπλάκα "Wash buffer Solución de lavado "Puθμιστικό διάλυμα πλύσης "Substrate buffer "Tampón sustrato "Puθμιστικό διάλυμα υποστρώματος "Stop solution "Solución de parada "Aντιδραστήριο διακοπής αντίδρασης "Sample buffer