

Ref 3115





Product Ref.	3115
Product Desc.	ANA-HEp-2
Manual Rev. No.	004 : 2014-03-12

Instruction Manual

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1 Intended Use

AESKULISA ANA-HEp-2 is a solid phase enzyme immunoassay for the combined qualitative detection of IgG antibodies against HEp2 cells in human serum. Each well is coated with lysed HEp2 cells. The test collectively detects, in one well, total ANAs against double stranded DNA (dsDNA), histones, SS-A (Ro), SS-B (La), Sm, snRNP/Sm, ScI-70, PM-ScI, Jo-1 and centromeric antigens along with sera positive for HEp2 immunofluorescence test (IFT).

The assay is a tool in the diagnosis of systemic rheumatic diseases like systemic lupus erythematosus (SLE), mixed connective tissue diseases (MCTD), scleroderma, Sjögren's syndrome, polymyositis and dermatomyositis.

2 Clinical Application and Principle of the Assay

Anti-nuclear antibodies (ANA) directed against a variety of nuclear and cytoplasmic antigens occur in high frequency in systemic rheumatic diseases and thus are an important tool for the differential diagnosis. For instance, SS-A (Ro) and SS-B (La) antibodies are associated with SLE and Sjögren's syndrome (SS), anti-dsDNA and anti-Sm antibodies with SLE, anti-histone antibodies with SLE and drug-induced lupus, anti-RNP antibodies with mixed connective tissue disease (MCTD) and SLE, anti-Scl-70 antibodies with scleroderma (progressive systemic sclerosis [PSS]), anti-Jo-1 antibodies with polymyositis and dermatomyositis and anti-centromere antibodies with CREST syndrome.

Indirect immunofluorescence test (IFT) on eucaryotic cells like HeLa and HEp2 has been the established method for the detection of ANAs. Although the IFT is a sensitive test, it is laborious when testing large numbers of patient samples and is subject to errors from human interpretation and from variability in fluorescent microscope. The ELISA test system is an excellent alternative to the IFT for screening patient's serum for the presence of ANAs of clinical significance. Single antibody specificities have to be determined by more specific testing using ELISAs employing the specific target antigens for a simple and reliable differentiation of ANAs.

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	Ī	
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)	
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:

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

PC: positive control	P1: patient 1
NC: negative control	P2: patient 2
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 qualitative interpretation results desired:		
	CONTROLS & SAMPLES		
3.	Pipette into the designated wells as described in chapter 7.2 above, 100 µl of either: Cut-off Calibrator (CC) and 100 µl of each of the following:		
	 Negative control (NC) and Positive control (PC), and 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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CONJUGATE					
6.	СОNJ +100 µI	Pipette 100 µl conju	gate into each we	Ш.	
7.	30'	Incubate for 30 min	utes at 20-32°C/68	3-89.6°F.	
8.	$\begin{array}{c} \hline \\ \hline \\ \hline \\ \hline \\ \hline \\ \hline \\ \\ \hline \\ \\ \hline \\ \\ \\ \hline \\$	Wash 3x with 300 µI washing buffer (diluted 1:50).			
		SUBSTRA	TE		
9.	SUB +100 µl	Pipette 100 µl TMB	substrate into eac	h well.	
10.	₩ * 30'	Incubate for 30 minutes at 20-32°C/68-89.6°F, protected from intense light.			
		STOP			
11.	STOP → +100 µl	Pipette 100 µl stop order as pipetting th		ch well, using the same	
12.	5'	Incubate 5 minutes	minimum.		
13.		Agitate plate careful	lly for 5 sec.		
14.	OD ₄₅₀ OD ₆₂₀ /- 450/620 nm		-	mmended 450/620 nm)	



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8 Semiquantitative Interpretation

Read the optical density of the cut-off calibrator and the patient samples. Compare patient ODs with the OD of the cut-off calibrator. 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> $0.8 \times O$ Equivocal: $0.8 \times OD$ cut-off \leq OIPositive:OD patient> $1.2 \times O$

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

Calibrators	O.D. 450/620 nm	CV % (Variation)	
Negative Control	0.081	2.6	
Cut-off Calibrator	0.350	1.8	
Positive Control	1.259	0.7	

Example of interpretation.

We recommend pipetting cut-off calibrator in parallel for each run.

Cut-off calibrator	Patient sample	OD Quotient	Interpretation
0.35 OD	0.25 OD	0.75	Negative
0.35 OD	0.40 OD	1.14	Equivocal
0.35 OD	0.56 OD	1.60	Positive
0.35 OD	1.75 OD	5.00	Positive

Do not use this example for interpreting patients results!

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 semi-quantification of the results, each patient-OD value can be expressed by the Index-Value. The Index-Value is calculated by dividing the patient-OD by the cut-off OD:

Index Value = OD (patient sample) OD (cut-off calibrator)



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Negative:		Index Value	< 0.8
Equivocal:	28.0	Index Value	≤ 1.2
Positive:		Index Value	>1.2

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
Storage:	at 2-8°C/35-46°F use original vials only.
Number of determinations:	96 tests

10 Performance Data

10.1 Specificity and sensitivity

The microplate is coated with lysed HEp2 cells. No crossreactivities to other autoantigens have been found (tTG, PR3, TPO, TG, Gliadin). ANA are not specific for SLE but are found in a variety of rheumatic diseases. Detection of ANA is a very sensitive marker for an active SLE and is positive in >99% of all cases.

57 characterized sera of patients suffering from various autoimmune (AI) diseases (SLE, MCTD, CREST and Sjögrens syndrome; see table below) obtained from major hospitals which were positive on IFA HEp-2 ANA (≥1:160) were tested on a predicate device and the AESKULISA ANA-HEp-2. 2 sera which were negative in IFA were also found to be negative in the AESKULISA ANA-HEp-2. There was 100% agreement with the predicate device.

Disease	# of tested sera
SLE	39
MCTD	3
CREST	4
Sjoegrens Syndrome	4
Various AI diseases	7

		Predicate device		
		Pos	Neg	Total
AESKULISA	Pos	57	0	57
ANA-HEp-2	Neg	0	2	2
		57	2	59

A controlgroup (n=80) were all found negative on the AESKULISA ANA-HEp-2.

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10.2 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 concentration (OD-Ratio)	expected concentration (OD-Ratio)	Recovery (%)
1	1 / 100	4.10	4.200	97.6
	1 / 200	2.10	2.100	100.0
	1 / 400	1.00	1.050	95.2
	1 / 800	0.55	0.530	103.8
2	1 / 100	6.10	6.200	98.4
	1 / 200	3.00	3.100	96.8
	1 / 400	1.59	1.550	102.6
	1 / 800	0.79	0.775	102.0

10.3 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

Intra-assay			
Sample No.	Mean (OD-Ratio)	CV (%)	
1	4.6	1.5	
2	2.8	2.0	
3	1.4	1.8	

Inter-assay				
Sample No.	Mean (OD-Ratio)	CV (%)		
1	4.7	3.1		
2	3.0	2.5		
3	1.2	2.4		

10.4 Calibration

The AESKULISA ANA-HEp-2 is calibrated against reference sera from the CDC (Centers for Disease Control and Prevention) Atlanta

11 Literature

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* Tampone di lavaggio * Wash buffer * Tampon de Lavage * Solución de lavado * Waschpuffer * Puθμιστικό διάλυμα πλύσης * Solucão de lavagem * * Substrate * Substrate buffer * Substrat * Tampón sustrato * Substrat * Puθμιστικό διάλυμα πλύσης * Substrat * Substrate buffer * Substrat * Substrato * Substrat * Puθμιστικό διάλυμα υποστρώματος * Substrato * * Solucion d'Arrêt * * Solucion d'Arrêt * * Solucion de paragem * * Solucão de paragem * * Solucão de paragem * * Tampon Echantillons * * Puθμιστικό διάλυμα δειγιμάτων	RC CONJ	Etalon Kalibrator Calibrador Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato Conjugé Konjugat Conjugado Micropiastra rivestita Microplaque sensibilisée	Calibrador ``Aντιδραστήριο βαθμονόμησης ``Recovery ``Recuperado ``Aνάκτηση ``Conjugate ``Conjugato ``Σúζευγμα ``Coated microtiter plate ``Microplaca sensibilizada
WASHB 50x "Tampon de Lavage "Solución de lavado "Waschpuffer "Puθμιστικό διάλυμα πλύσης "Solucão de lavagem "Substrate buffer "Substrat "Tampón sustrato "Substrat "Tampón sustrato "Substrat "Puθμιστικό διάλυμα πλύσης "Substrat "Tampón sustrato "Substrat "Puθμιστικό διάλυμα υποστρώματος "Substrato "Substrato "Substrat "Stop solution "Solución de parada "Solución de parada "Stopreagenz "Avriδραστήριο διακοπής αντίδρασης Solucão de paragem "Tampon campione "Tampon campione "Sample buffer "Tampon Echantillons "Tampón Muestras "Probenpuffer "Puθμιστικό διάλυμα δειγμάτων	RC CONJ	Etalon Kalibrator Calibrador Calibrador Corrélation Wiederfindung Recuperacão Coniugato Conjugé Konjugat Conjugado Microplaque sensibilisée Beschichtete Mikrotiterplatte	Calibrador ``Aντιδραστήριο βαθμονόμησης ``Recovery ``Recuperado ``Aνάκτηση ``Conjugate ``Conjugato ``Σúζευγμα ``Coated microtiter plate ``Microplaca sensibilizada
Solução de lavagem SUB "Tampone substrato "Substrate buffer "Substrat "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Reagente bloccante "Solución de parada "Stopreagenz "Solución de paragem "Solución de paragem "Tampone campione "Tampon Echantillons "Probenpuffer "Puθμιστικό διάλυμα δειγιμάτων	RC CONJ	Etalon Kalibrator Calibrador Calibrador Corrélation Wiederfindung Wiederfindung Recuperacão Coniugato Conjugé Konjugat Conjugé Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida	 Calibrador Άντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα
Solução de lavagem SUB "Tampone substrato "Substrate buffer "Substrat "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Substrato "Reagente bloccante "Solución de parada "Stopreagenz "Solución de paragem "Solución de paragem "Tampone campione "Tampon Echantillons "Probenpuffer "Puθμιστικό διάλυμα δειγιμάτων	RC CONJ MP	Etalon Kalibrator Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato Conjugé Konjugat Conjugé Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Tampone di lavaggio	Calibrador ``Avτιδραστήριο βαθμονόμησης ``Recovery ``Recuperado ``Avάκτηση ``Conjugate ``Conjugado ``Σύζευγμα ``Coated microtiter plate ``Microplaca sensibilizada ``Επικαλυμμένη μικροπλάκα ``Wash buffer
SUB [*] Tampone substrato [*] Substrate bulfer SUB [*] Substratpulfer [*] Tampón sustrato SUB [*] Substratpulfer [*] Puθµiστικό διάλυμα υποστρώματος SUB [*] Reagente bloccante [*] Stop solution [*] Solución de parada [*] Solución de parada [*] Solución de paragem [*] Solución de paragem [*] Solución de paragem [*] Tampon ecampione [*] Tampon Echantillons [*] Tampón Muestras [*] Probenpuffer [*] Puθµiστικό διάλυμα δειγμάτων	RC CONJ MP		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Μicroplaca sensibilizada Επικαλυμμένη μικροπλάκα Wash buffer Solución de lavado
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Substrato STOP "Reagente bloccante "Solución de parada "Solución de parada "Stopreagenz "Solucão de paragem "Tampone campione "Tampon Echantillons "Probenpuffer "Probenpuffer	RC CONJ MP WASHB 50x	Etalon Kalibrator Calibrador Calibrador Calibrador Corrélation Wiederfindung Recuperacão Conjugato Conjugé Konjugé Konjugát Conjugádo Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato	Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugate Σύζευγμα Coated microtiter plate Μίcroplaca sensibilizada Έπικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer
STOP [°] Reagente bloccante [°] Stop solution Solution d'Arrêt [°] Solución de parada [°] Stopreagenz [°] Avriðpaσrήριο διακοπής αντίδρασης [°] Solucão de paragem [°] Tampone campione [°] Tampon Echantillons [°] Tampón Muestras [°] Probenpuffer [°] Puθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recouperado Ανάκτηση Conjugate Conjugate Conjugado Σύζευγμα Coated microtiter plate Μicroplaca sensibilizada Έπικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato
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SB 5x "Tampone campione "Sample buffer "Tampon Echantillons "Tampón Muestras "Probenpuffer "Pυθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα Coated microtiter plate Μicroplaca sensibilizada Επικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Stup solution Stop solution
SB 5x Tampon Echantillons Tampón Muestras "Probenpuffer "Ρυθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugato Σύζευγμα Coated microtiter plate Μicroplaca sensibilizada Επικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Stup solution Stop solution
SB 5X ^{···} Probenpuffer ^{···} Ρυθμιστικό διάλυμα δειγμάτων	RC CONJ MP WASHB 50x		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recoperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplace sensibilizada Έπικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato Puθμιστικό διάλυμα υποστρώματος Stop solution Solución de parada Αντιδραστήριο διακοπής αντίδρασης
	RC CONJ MP WASHB 50x SUB STOP		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recoperado Ανάκτηση Conjugate Conjugate Conjugado Σύζευγμα Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Stubstrate buffer Stup solution Solución de parada Aντιδραστήριο διακοπής αντίδρασης
	RC CONJ MP WASHB 50x SUB STOP		Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recoperado Ανάκτηση Conjugate Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato Puθμιστικό διάλυμα υποστρώματος Solución de parada Solución de parada Solución de parada Solución de parada Υκτιδραστήριο διακοπής αντίδρασης
	RC CONJ MP WASHB 50x SUB STOP	Etalon Kalibrator Kalibrator Calibrador Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugé Konjugat Conjugádo Micropiastra rivestita Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Solucão de lavage Tampone substrato Substrat Substrat Substrat Substrat Substrat Substrat Substrat Solucão de paragem Tampone campione Tampone campione	Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recoperado Ανάκτηση Conjugate Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato Puθμιστικό διάλυμα υποστρώματος Solución de parada Solución de parada Solución de parada Solución de parada Υκτιδραστήριο διακοπής αντίδρασης