









INSTRUCTION MANUAL

AESKULISA Choline-GM Ref 3212





Product Ref.	3212
Product Desc.	Choline-GM
Manual Rev. No.	003 : 2014-12-12

Instruction Manual

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1 Intended Use

AESKULISA Cholin-GM is a solid phase enzyme immunoassay with highly purified phosphatidyl-cholin and native human ß2-glycoprotein I for the quantitative and qualitative detection of IgG and/or IgM antibodies against phosphatidyl-cholin in human serum. These antibodies recognize specific epitopes on a complex composed out of phosphatidyl-cholin and ß2-glyco-protein I.

The assay is an aid in the diagnosis and risk estimation of thrombosis in patients with systemic lupus erythematosus (SLE) and the antiphospholipid syndrome (APS).

2 Clinical Application and Principle of the Assay

Antibodies against phosphatidyl-choline belong to the group of anti-phospholipid antibodies specific for phospholipids such as cardiolipin, phosphatidyl- serine, -inositol, sphingomyelin and phosphatidic acid. Phospholipids are components of biological membranes.

Anti-phospholipid antibodies are frequently found in sera of patients with systemic lupus erythematosus (SLE) and related diseases. The occurrence of anti-phospholipid antibodies in patients with SLE and related diseases is typical for a secondary anti-phospholipid syndrome (APS). In contrast, anti-phospholipid antibodies in patients with no other autoimmune diseases characterize the primary APS.

Many studies have shown a correlation between these autoantibodies and an enhanced incidence of thrombosis, thrombocytopenia and habitual abortions (as a consequence of placental infarction). The exact mechanisms by which pathogenic anti-phospholipid antibodies induce thrombosis is not yet revealed fully.

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)	
		REA	ADY TO USE	E Contraction of the second	
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 cal brator: 0, 3, 10, 30, 100, 300 U/ml. Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)	
Conjugate, IgG IgM	1 x 15ml 1 x 15ml	Blue Green	Blue Green	Containing: Anti-human immunoglobulins conjugated to horseradish peroxidase, bovine serum albumin (BSA)	
TMB Substrate	1 x 15ml	Black	Colorless	Stabilized tetramethy benzidine 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 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 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 $(2-8^{\circ}C/35-46^{\circ}F)$.



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7.2 Pipetting Scheme

We suggest pipetting calibrators, controls and samples as follows:

NOTE: If IgG and IgM are determined in parallel, calibrators, controls and samples have to be done twice, for each subclass separately.

	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 QUANTITATIVE 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			

For QUALITATIVE interpretation

CalA: calibrator A	CalD: 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) 		
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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		CONJUGA	TE			
6.	CONJ +100 µl	Pipette 100 μl conjugate into each well.				
7.	30'	Incubate for 30 minu	utes at 20-32°C/68	-89.6°F.		
8.	$\begin{array}{c} \hline \\ \\ \\ \hline \\$	Wash 3x with 300 µl washing buffer (diluted 1:50).				
	SUBSTRATE					
9.	SUB +100 µl	Pipette 100 µl TMB	substrate into each	n well.		
10.	₩ 30'	Incubate for 30 minu intense light.	utes at 20-32°C/68	-89.6°F, protected from		
		STOP				
11.	STOР → +100 µI	Pipette 100 µl stop order as pipetting th	solution into eacl e substrate.	n well, using the same		
12.	5'	Incubate 5 minutes i	minimum.			
13.		Agitate plate careful	ly for 5 sec.			
14.		Read absorbance a	at 450 nm (recon	nmended 450/620 nm)		
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within 30 minutes.

450/620 nm



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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/M	OD 450/620 nm	CV % (Variation)
0 U/ml	0.049	0.0
3 U/ml	0.164	2.6
10 U/ml	0.332	2.5
30 U/ml	0.675	0.9
100 U/ml	1.387	0.0
300 U/ml	2.272	0.5

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	1.093/1.105	1.099	77.8
P 02	0.804/0.820	0.812	46.7

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	<	0.8 x OD cut-off		
Equivocal:	0.8 x	OD cut-off	≤	OD patient	≤	1.2 x OD cut-off
Positive:		OD patient	>	1.2 x OD cut-off		



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9 Technical Data

Sample material:	serum
Sample volume:	10 μI 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 Choline-GM gave an analytical sensivity of 1.0 U/ml.

10.2 Specificity and sensitivity

The microplate is coated with phosphatidyl-cholin and native human beta-2-glycoprotein I. No crossreactivities to other autoantigens have been found.

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	Dilution Eactor	Measured	Expected	Recovery
INU.	T actor	(0/111)	(0/111)	(70)
1	1 / 100	141.0	140.0	100.7
	1 / 200	69.0	70.0	98.6
	1 / 400	36.9	35.0	105.4
	1 / 800	18.1	17.5	103.4
2	1 / 100	47.1	46.0	102.4
	1 / 200	24.6	23.0	107.0
	1 / 400	12.1	11.5	105.2
	1 / 800	6.2	5.8	106.9

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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.

Intra-assay					
Sample No. Mean (U/ml) CV (%)					
1	145.0	2.8			
2	48.0	3.6			
3	21.0	2.2			

Inter-assay			
Sample No.	Mean (U/ml)	CV (%)	
1	150.0	3.1	
2	53.0	4.2	
3	24.0	4.8	

10.5 Calibration

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

11 Literature

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CON+ CON- CAL	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Recupero	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Θειηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Aληφραζ τήριφ βαζκολόκεζες "Recovery
CON+ CON- CAL	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Contrôle negativo Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo Θειηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλειηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Aληφραζηρηφ βαζκολόκεζες "Recovery "Recovery
CON+ CON- CAL RC	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positir Controlo negativo Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Kalibrator Kalibrator Calibrador Wiederfindung Controlo negativo	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Θειηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλειηφός ορός ειέ γτοσ "Calibrator "Calibrator "Anφραζ τήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθης ξε
CON + CON - CAL RC	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Contrôle negativo Contrôle Négatif Negativ Kontrolle Contrôle negativo Contrôle negativo Calibratore Etalon Kalibrator Calibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Θειηθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθη: ζε
CON+ CON- CAL RC	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Contrôlo negativo Contrôlo Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Calibrator Corrélation Wiederfindung Recuperacão Coniugato	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Θειτιθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλειτιθός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθηεζε "Conjugate
CON+ CON- CAL RC	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Contrôle Positif "Positiv Kontrolle "Contrôle negativo "Contrôle Négatif "Negativ Kontrolle "Contrôle negativo "Calibratore "Etalon "Kalibrator "Calibratore "Calibratore "Recupero Corrélation "Wiederfindung "Recuperação "Coniugato "Conjugé	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo Θειηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλειηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Aληφραζιτήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθηξζε "Conjugate "Conjugate
CON+ CON- CAL RC	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positir Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Contrôle negativo Controlo negativo Conjugato Conjugat Konjucat	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ostrol Positivo "Ostrol Positivo "Negative Control "Control Negativo "Apλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Anφραζ τήριφ βαζκολόκεζες "Recovery "Recuperado "Aλθφεζε "Conjugate "Conjugado "Σύδισγκα
CON+ CON- CAL RC CONJ	Grénzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positir Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Conjugato	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oειηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugado Σύδαγκα
CON+ CON- CAL RC CONJ	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Contrôle Négatif Negativ Kontrolle Contrôle Négatif Negativ Kontrolle Contrôle negativo Calibratore Etalon Kalibrator Calibrator Calibrator Calibrador Keupero Corrélation Wiederfindung Recuperação Conjugato C	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Θεηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugado "Σύδεσγκα
CON+ CON- CAL RC CONJ	"Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controle negativo "Controle Négatif "Negativ Kontrolle "Controle negativo "Controle negativo "Controle negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Coniugato "Conjugát "Conjugát "Conjugáto "Micropiastra rivestita	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ostrive Control "Control Negativo "Apλεηφός ορός ειέ γτοσ "Calibrator "Conjugate "Conjugato "Σύδεσγκα
CON+ CON- CAL RC CONJ	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrator Calibrator Calibratore Corrélation Wiederfindung Recuperação Conjugato Conjugato Conjugato Microplaque sensibilisée Microplaque sensibilisée	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ornφός ορός είέ γτοσ "Negative Control "Control Negativo "Aρλειτιθός ορός είέ γτοσ "Calibrator "Calibrator "Calibrator "Aληφραζ τήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθιεζε "Conjugate "Conjugado "Σύδισογκα "Coated microtiter plate "Microplaca sensibilizada
CON+ CON- CAL RC CONJ MP	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Contrôle Positir "Positiv Kontrolle "Contrôle Négatif "Negativ Kontrolle "Contrôle Négatif "Negativ Kontrolle "Contrôle negativo "Controlo negativo "Corrélation "Wiederfindung "Recuperacão "Conjugato "Conjugato "Conjugato "Conjugato "Micropiastra rivestita "Micropiastra rivestita "Microplaque sensibilisée "Beschichtete Mikrotiterplatte = seschichtete Mikrotiterplatte "	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Θεηφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Aμφραζ τήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθιεζε "Conjugate "Conjugato Σύδιαγκα "Coated microtiter plate "Microplaca sensibilizada
CON+ CON- CAL RC CONJ MP	Grenzwert Kalibrator " Calibrador de cut-off " Contrôle Positiv " Contrôle Positiv " Contrôle Positivo " Contrôle Négatif " Negativ Kontrolle " Contrôle Négatif " Negativ Kontrolle " Contrôle Négatif " Negativ Kontrolle " Controlo negativo " Calibratore " Etalon " Kalibrator " Calibrador " Recupero " Coniugato " Conjugato " Conjugato " Conjugato " Konjugat " Conjugato " Micropiastra rivestita " Microplace sensibilisée " Beschichtete Mikrotiterplatte	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oεπιθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλε ηθός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθις ζε "Conjugate "Conjugado "Σύδαγκα "Coated microtiter plate "Microplaca sensibilizada
CON+ CON- CAL RC CONJ MP	Grenzwert Kalibrator Controllo positivo Controle Positif Positiv Kontrolle Controlo positivo Controlo negativo Calibratore Etalon Kalibrator Calibrator Calibrator Calibrator Calibrator Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugát Konjugat Conjugato Microplastra rivestita Microplastra rivestita Microplace sensibilisée Beschichtete Mikrotiterplatte Microplace revestida Tampone di lavaggio	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oεπιθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Recovery "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugado "Σύδασγκα "Coated microtiter plate "Microplaca sensibilizada "Kenowick κ κιθροπιάθα "Wash buffer
CON+ CON- CAL RC CONJ MP	Grenzwert Kalibrator " Calibrador de cut-off " Controllo positivo " Controle Positif " Positiv Kontrolle " Controle negativo " Calibratore " Etalon " Kalibrator " Calibrador " Recupero Corridation " Wiederfindung " Recuperação " Conjugá " Konjugat " Conjugáo " Microplaque sensibilisée " Beschichtete Mikrotiterplatte " Microplaca revestida " Tampone di lavaggio	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Original Control "Negative Control "Negative Control "Control Negativo "Aρλειτιβός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Aληφραζιτήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugado "Σύδαγκα "Coated microtiter plate "Microplaca sensibilizada "Ermθaio κκέλε κιθροπιάθα "Wash buffer "Solución de lavado
CON+ CON- CAL RC CONJ MP	Grénzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positif Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Controlo negativo Controlo negativo Calibratore Etalon Kalibrator Calibrator Calibratore Corrélation Wiederfindung Recuperação Conjugato Conjugato Conjugato Microplaçue sensibilisée Beschichtete Mikrotiterplatte Microplaçue revestida Tampon de Lavage Vaschpuffer	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ornφός ορός είε γτοσ "Negative Control "Control Negativo "Aρλειτιβός ορός είε γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Aληφραζ τήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθιεζε "Conjugate "Conjugado Σύδεσγκα "Kicropiaca sensibilizada "Emfiquic κέλε κιθροπιάθα "Wash buffer "Solución de lavado "Poζκιξιήφ δια σκα πύ ζες
CON+ CON- CAL RC CONJ MP VVASHB 50x	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Contrôle Positir Positiv Kontrolle Controlo negativo Contrôle Négatif Negativ Kontrolle Controlo negativo Microplaca revestida Tampon de Lavage Waschpuffer Solucão de lavanem	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oεπιθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλε ηθός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθιεζε "Conjugate "Conjugato "Σύδεγκια "Wash buffer "Solución de lavado "Wash buffer
CON+ CON- CAL RC CONJ MP	Grenzwert Kalibrator Calibrador de cut-off Controllo positivo Controle Positif Positiv Kontrolle Controlo positivo Controlo negativo Controlo negativo Controlo negativo Controlo negativo Calibratore Etalon Kalibrator Calibratore Etalon Kalibrator Calibrator Carifation Wiederfindung Recupero Coniugato Conjugé Konjugat Conjugé Microplastra rivestita Microplace revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Sume and constructore Coniugato Coniugato Conjugé Microplace revestida Tampone di lavagem Solucão de lavagem Solucão de lavagem Coniugato Coniugato Coniugato Coniugato Coniugato Conjugé Microplace revestida Tampone di lavagem Solucão de lavagem Solucão de lavagem Coniugato Coniugato Coniugato Coniugato Coniugato Coniugato Coniugato Conjugé Microplace revestida Tampone di lavagem Coniugato Coniugato Coniugato Coniugato Coniugato Coniugato Coniugato Conjugé Microplace revestida Tampone di lavagem Coniugato Coni	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oεπιθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recovery "Recouperado "Δλάθης ζε "Conjugate "Conjugado "Σύδαγκα "Nicroplaca sensibilizada "Eπιθαισ κκέλε κιθροπιάθα "Wash buffer "Solución de lavado "Poζκιξηφό διφι σκα πιύ ζες
CON+ CON- CAL RC CONJ CONJ WP	Grenzwert Kalibrator " Calibrador de cut-off " Controllo positivo " Controle Positif " Positiv Kontrolle " Controle negativo " Calibratore " Etalon " Kalibrator " Calibrador " Recupero " Coniugato " Conjugát " Conjugát " Conjugáto " Microplaque sensibilisée " Beschichtete Mikrotiterplatte " Tampone di lavaggio " Tampone substrato " Calibratori	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ornfol Positivo "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Conjugato "Conjugato "Conjugato "Coated microtiter plate "Microplaca sensibilizada "Emfeator κέλε κιφροπίdθα "Wash buffer "Solución de lavado "Poζ κιξ ηφό διξι σκα πιύ ζες
CON+ CON- CAL RC CONJ CONJ WP WASHB 50x	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controle negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corridation Wiederfindung "Recuperação "Conjugato "Conjugado "Microplaque sensibilisée "Beschichtete Mikrotiterplatte "Microplaca revestida "Tampon de lavaggio "Tampon de lavage "Waschpuffer "Solução de lavagem	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Regative Control "Control Negativo "Aρλειτιθός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλήθραζ τήριφ βαζκολόκεζες "Conjugate "Conjugato "Conjugato "Coated microtiter plate "Microplaca sensibilizada "Wash buffer "Solución de lavado "Poζκιξιτιθό διφι σκα πιύ ζες "Substrate buffer
CON+ CON- CAL RC CONJ CONJ WP VVASHB50x	Grénzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corrélation "Wiederfindung "Recuperação "Conjugato "Conjugato "Conjugado "Microplaca revestita "Microplaca revestida "Tampone di lavaggio "Tampone de Lavage "Waschpuffer "Solução de lavagem "Tampone substrato "Substrat	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oετηφός ορός είξ γτοσ "Negative Control "Control Negativo "Aρλετηφός ορός είξ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλήθραζ τήριφ βαζκολόκεζες "Conjugate "Conjugato "Σύδαργκα "Solución de lavado "Wash buffer "Solución de lavado "Poζκιξ ηφό διτμι σκα στιοζ τρώκατρς
CON+ CON- CAL RC CONJ CONJ WP WASHB 50x SUB	Grenzwert Kalibrator " Calibrador de cut-off " Controllo positivo Controle Positif " Positiv Kontrolle " Controle negativo " Calibratore " Etalon " Kalibrator " Calibrador Recupero " Corridation " Wiederfindung " Recuperacão " Conjugá " Konjugat " Conjugáo " Microplastra rivestita " Microplaca revestida " Tampone di lavaggio " Tampone de Lavage " Waschpuffer " Solucão de lavagem " Tampone substrato " Substrat " Substrato	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oεπιθός ορός ειέ γτοσ "Negative Control "Control Negativo "Apλετηθός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugato "Σύδαγκα "Wash buffer "Solución de lavado "Paζκιξ τηθό δηφι σκα στοζ τρώκατρς
CON+ CON- CAL RC CONJ CONJ WP VVASHB50x SUB	Grenzwert Kalibrator " Calibrador de cut-off " Controllo positivo " Controle Positif " Positiv Kontrolle " Controle negativo " Calibratore " Etalon " Kalibrator " Calibratore " Etalon " Kalibrator " Calibrador " Recupero Corrélation " Wiederfindung " Recuperação " Conjugato " Conjugato " Microplastra rivestita " Microplaque sensibilisée " Beschichtete Mikrotiterplatte " Microplaca revestida " Tampone di lavaggio " Tampone di lavagem " Xaoshpuffer " Solução de lavagem " Tampone substrato " Substratu " Substrato	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ornfol Positivo "Ornfol Positivo "Postive Control "Control Negativo "Apλεηφός ορός ειέ γτοσ "Calibrator "Conjugate "Conjugato "Conjugato "Substrate huffer "Solución de lavado "Wash buffer "Substrate buffer "Substrate buffer "Tampón sustrato
CON+ CON- CAL CAL RC CONJ CONJ WP VVASHB50x SUB	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controle negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero Corridation Wiederfindung "Recuperação "Conjugáto "Conjugádo "Microplaque sensibilisée "Beschichtete Mikrotiterplatte "Microplaque sensibilisée "Beschichtete blikrotiterplatte <tr< td=""><td>Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Regative Control "Control Negativo "Aρλειηφός ορός ειέ γτοσ "Calibrator "Conjugato "Conjugate "Conjugado "Coated microtiter plate "Microplaca sensibilizada "Ermθαισ κκέλε κιθροπιάθα "Wash buffer "Solución de lavado "Poζκιξ ηθό διφι σκα στις τρώκατρς "Stop solution "Stop solution</td></tr<>	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Regative Control "Control Negativo "Aρλειηφός ορός ειέ γτοσ "Calibrator "Conjugato "Conjugate "Conjugado "Coated microtiter plate "Microplaca sensibilizada "Ermθαισ κκέλε κιθροπιάθα "Wash buffer "Solución de lavado "Poζκιξ ηθό διφι σκα στις τρώκατρς "Stop solution "Stop solution
CON+ CON- CAL CAL RC CONJ CONJ WP WASHB50x SUB SUB	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controlo negativo "Controle Négatif "Negativ Kontrolle "Controlo negativo "Controlo negativo "Controlo negativo "Controlo negativo "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corrélation Wiederfindung "Recuperação "Conjugato "Conjugado "Microplaçue sensibilisée Beschichtete Mikrotiterplatte "Microplaca revestida "Tampone di lavaggio "Tampone di lavaggio "Tampone substrato "Substrat "Substrato "Substrato "Substrato "Substrato	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Ornφός ορός είέ γτοσ "Negative Control "Control Negativo "Aρλειηφός ορός είέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Aληφραζητριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθιεζε "Conjugate "Conjugato "Σύδοχκα "Vash buffer "Solución de lavado "Poζκιζηφό διήμι σκα σποζηρώκαηρς "Stop solution "Stop solution
CON+ CON- CAL CAL RC CONJ CONJ WP WASHB 50x SUB SUB	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrador "Recupero "Corrélation "Wiederfindung "Recuperação "Conjugato "Conjugato "Conjugado "Microplaca revestita "Microplaca revestida "Tampone di lavaggio "Tampon de Lavage "Waschpuffer "Solucão de lavagem "Tampone substrato "Substrat "Substrato "Reagente bloccante <	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oετηθός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλετηθός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugado "Σύδæγκα "Wash buffer "Solución de lavado "Poζκιξ ηθό διφι σκα σποζ τρώκαπρς "Stop solution "Stop solution
CON+ CON- CAL RC CONJ CONJ WP WASHB50x SUB SUB	Grenzwert Kalibrator " Calibrador de cut-off " Controllo positivo " Controle Positif " Positiv Kontrolle " Controle negativo " Calibratore " Etalon " Kalibrator " Calibratore " Etalon " Kalibrator " Calibrador " Recupero Corridation " Wiederfindung " Recuperação " Conjugato " Conjugato " Conjugato " Microplastra rivestita " Microplastra rivestita " Microplaca revestida " Tampone di lavaggio " Tampone di lavagem " Vaschpuffer " Solucão de lavagem " Tampone substrato " Substrat " Substrato " Reagente bloccante " Solucão de paragem " Tampone compriso"	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oerφός ορός ειέ γτοσ "Negative Control "Control Negativo "Aρλεηφός ορός ειέ γτοσ "Calibrator "Aληφραζηήριφ βαζκολόκεζες "Recuperado "Aλάφρζες "Conjugate "Conjugado "Σύδασγκα "Coated microtiter plate "Microplaca sensibilizada "Emφαισ κκέλε κιφροπιάθα "Wash buffer "Solución de lavado "Poζκιξ ηφό διφι σκα στοζ τρώκατρς "Substrate buffer "Tampón sustrato "Poζκιξ ηφό διφι σκα στοζ τρώκατρς "Stop solution "Solución de parada "Aληφραζ τήριφ διφιθοτής αληδραζες </td
CON+ CON- CAL RC CONJ CONJ VVASHB50x SUB SUB	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controle negativo "Calibratore "Etalon "Kalibrator "Calibratore "Etalon "Kalibrator "Conridation Wiederfindung "Recupero Conjugato "Conjugado "Microplaque sensibilisée "Beschichtete Mikrotiterplatte	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Regative Control "Negative Control "Control Negativo "Apλεηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Conjugato "Aλήφραζηήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθης ζε "Conjugate "Conjugado "Σύδεγγκα "Coated microtiter plate "Microplaca sensibilizada "Emfaior κκέλε κιφροπιάθα "Wash buffer "Solución de lavado "Poζκιξ ηφό διξιι σκα πιύ ζες "Substrate buffer "Tampón sustrato "Poζκιξ ηφό διξιι σκα σποζηρώκαης "Stop solution "Solución de parada "Aληφραζ ήρος διφι σκα σποζηρώκαης
CON+ CON- CAL RC RC CONJ KP WASHB50x SUB SUB	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controle negativo "Calibratore "Etalon "Kalibrator "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corridation Wiederfindung "Recuperação "Conjugato "Conjugado "Microplaque sensibilisée Beschichtete Mikrotiterplatte "Microplaca revestida "Tampone di lavaggio "Tampone de lavagem "Tampone substrato "Substrat "Substrato "Substrato "Substrato "Alboreagenz "Solução de paragem "Tampon ecampione "Tampone campione	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Regative Control "Control Negativo "Aρλειηφός ορός ειέ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Antφραζ τήριφ βαζκολόκεζες "Recovery "Recuperado "Aλάθιεζε "Conjugate "Conjugato "Cotated microtiter plate "Microplaca sensibilizada "Emflact κικλε κιφροπιάθα "Wash buffer "Solución de lavado "Poζκιξ τιφό διφι σκα πιύ ζες "Substrate buffer "Tampón sustrato "Poζκιξ τιφό διφι σκα στοζ τρώκατρς "Stop solution "Solución de parada "Antφραζ τήριφ διφθοτής αληδραζες "Stop solution
CON+ CON- CAL RC CONJ RC CONJ WP WASHB50x SUB SUB STOP SB 5x	Grenzwert Kalibrator "Calibrador de cut-off "Controllo positivo "Controle Positif "Positiv Kontrolle "Controle negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corrélation "Wiederfindung "Recuperação "Conjugato "Conjugato "Conjugado "Microplacar revestita "Microplacar revestida "Tampone di lavaggio "Tampone du Lavage "Waschpuffer "Solucão de lavagem "Tampone substrato "Substrat "Substrato "Reagente bloccante "Solucão de paragem "Tampone campione "Tampone campione "Tampone campione "Tampone campione <	Οριφθός ορός Αληφραζ τήριφ βαζκολόκεζες "Positive Control "Control Positivo "Oεπφός ορός είξ γτοσ "Negative Control "Control Negativo "Aρλειτιβός ορός είξ γτοσ "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Calibrator "Recovery "Recuperado "Aλήθραζ τήριφ βαζκολόκεζες "Conjugate "Conjugato "Conjugato "Conjugato "Conjugato "Cotated microtiter plate "Microplaca sensibilizada "Emfector κέλε κιθροπιάθα "Wash buffer "Solución de lavado "Poζκιξ ηθό διφι σκα στιό τρώκατρς "Stop solution "Stop solution "Solución de parada "Aληφραζ ήριφ διφι σκα στιοζ τρώκατρς "Stop solution "Solución de parada "Aληφραζ τήριφ διφθοτής αληδραζ ες