AESKULISA Cenp-B

REF 3112

Instruction manual

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1. Intended Use

AESKULISA Cenp-B is a solid phase enzyme immunoassay employing purified recombinant human 80 kDa centromere protein B (Cenp-B) for the quantitative and qualitative detection of IgG antibodies against Cenp-B in human serum. The assay ensures the highest specificity and sensitivity for the detection of antibodies against centromere protein B, which serves as an aid in the diagnosis of systemic sclerosis and CREST syndrome.

2. Clinical Application and Principle of the Assay

The Centromere is the primary constriction site of eukaryotic chromosomes where sister chromatids appear most tightly paired. It is responsible for the coordinated segregation of chromosomes in mitosis and meiosis. The centromere is a complex area composed of particular nucleotidsequences, and various proteins. The three main centromere proteins are Cenp-A (17 kDa), Cenp-B (80 kDa) and Cenp-C (140 kDa).

Systemic sclerosis is a multisystemic autoimmune disease with systemic fibrosis of the connective tissue and typical occurrence of autoantibodies against centromere proteins as well as DNA topoisomerase I (Scl 70). Antibodies against centromere protein B are characteristic for the CREST syndrome, a slower progressing variant of systemic sclerosis. The CREST syndrome exhibits symptoms of Calcinosis cutis, **R**aynaud's syndrome, **E**sophageal motility disturbances, **S**clerodactyly and **T**elangiectasis. Up to 70-80% of CREST syndrome patients and 25% of patients with Raynaud syndrome exhibit centromere antibodies.

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 rate 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.

3. Kit Contents

<i>To be reconstitute</i> 5x Sample Buffer	ed: 1 vial, 20 ml - 5x concentrated (capped white: yellow solution) Containing: Tris, NaCl, BSA, sodium azide < 0.1% (preservative)
50x Wash Buffer	1 vial, 20 ml - 50x concentrated (capped white: green solution) Containing: Tris, NaCl, Tween 20, sodium azide < 0.1% (preservative)
Ready to use: Negative Control	1 vial, 1.5 ml (capped green: colorless solution) Containing: Human serum (diluted), sodium azide < 0.1% (preservative)
Positive Control	1 vial, 1.5 ml (capped red: yellow solution) Containing: Human serum (diluted), sodium azide < 0.1% (preservative)
Cut-off Calibrator	1 vial, 1.5 ml (capped blue: yellow solution) Containing: Human serum (diluted), sodium azide < 0.1% (preservative)
Calibrators	6 vials, 1.5 ml each 0, 3, 10, 30, 100, 300 U/ml (color increasing with concentration: yellow solutions) Containing: Human serum (diluted), sodium azide < 0.1% (preservative)
Conjugate	1 vial,15 ml IgG (capped blue: blue solution) Containing: Anti-human immunoglobulins conjugated to horseradish peroxidase
TMB Substrate	1 vial, 15 ml (capped black) Containing: Stabilized TMB/H ₂ O ₂
Stop Solution	1 vial, 15 ml (capped white: colorless solution) Containing: 1M Hydrochloric Acid
Microtiterplate	12x8 well strips with breakaway microwells Coating see paragraph 1

Material required but not provided:

Microtiter plate reader 450 nm reading filter and optional 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 (100-1000ml). Microplate washing device (300 μ l repeating or multi-channel 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 for 1 month at 4°C/39°F, at least. *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.*

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 normal 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.

5.2 General directions for use

Do not mix or substitute reagents 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.

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 immediately, respectively stored tightly closed at 2-8°C/35-46°F up to three days, or frozen at -20°C/-4°F for longer periods.

7.1 Preparations prior to pipetting

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).

Samples:

Dilute serum samples 1:101 with sample buffer (1x) e.g. 1000 μ l sample buffer (1x) + 10 μ l 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).

7.2 Work flow

For pipetting scheme see Annex A, for the test procedure see Annex B We recommend pipetting samples and calibrators in duplicate. Cut-off calibrator should be used for qualitative testing only.

- Pipette 100 µl of each patient's diluted serum into the designated microwells.
- Pipette 100 µl calibrators OR cut-off calibrator and negative and positive controls into the designated wells.
- Incubate for 30 minutes at 20-32°C/68-89.6°F.
- Wash 3x with 300 µl washing buffer (diluted 1:50).
- Pipette 100 µl conjugate into each well.
- Incubate for 30 minutes at 20-32°C/68-89.6°F.
- Wash 3x with 300 µl washing buffer (diluted 1:50).
- Pipette 100 µl TMB substrate into each well.
- Incubate for 30 minutes at 20-32°C/68-89.6°F, protected from intense light.
- Pipette 100 µl stop solution into each well, using the same order as pipetting the substrate.
- Incubate 5 minutes minimum.
- Agitate plate carefully for 5 sec.
- Read absorbance at 450 nm (optionally 450/620 nm) within 30 minutes.

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

We recommend pipetting calibrators in parallel for each run.

Calibrators IgG	OD 450/620 nm	CV % (Variation)
0 U/ml	0.049	1.9
3 U/ml	0.146	2.1
10 U/ml	0.337	2.7
30 U/ml	0.667	1.3
100 U/ml	1.246	1.6
300 U/ml	2.213	2.3

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	0.814/0.795	0.805	44.3
P 02	1.568/1.553	1.561	141.7

For lot specific data, see enclosed quality control leaflet. Medical laboratories might perform an inhouse Quality Control by using own controls and/or internal pooled sera, as foreseen by EU regulations.

Do not use this example for interpreting patients results!

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

For qualitative interpretation read the optical density of the cut-off calibrator and the patient samples. Compare patient'sOD 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:	$0.8 \times OD_{cut-off} \le OD_{patient} \le 1.2 \times OD_{cut-off}$
Positive	OD patient > 1.2 x OD cut-off

9. Technical Data

Sample material:	serum
Sample volume:	10 μl 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 Cenp-B gave an analytical sensivity of 1.0 U/ml.

10.2 Specificity and sensitivity

The microplate is coated with *human recombinant 80 kDa centromere protein B*. No crossreactivities to other autoantigens have been found. Up to 80% of CREST syndrome patients and 25% of patients with Raynaud syndrome exhibit centromere antibodies.

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.

		measured	expected	
Sample	Dilution	concentration	concentration	Recovery
No.	Factor	(U/ml)	(U/ml)	(%)
1	1 / 100	271.0	275.0	98.5
	1 / 200	135.0	137.8	98.0
	1 / 400	69.0	68.8	100.3
	1 / 800	34.1	34.4	99.1
2	1 / 100	164.0	166.0	98.8
	1 / 200	84.0	83.0	101.2
	1 / 400	42.1	41.5	101.5
	1 / 800	21.1	20.8	101.4

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.

In	tra-Assa	ay
Sample	Mean	CV
No.	(U/ml)	(%)
1	265.0	1.5
2	122.0	2.3
3	44.0	4.1

In	ter-Assa	ay
Sample	Mean	CV
No.	(U/ml)	(%)
1	261.0	1.4
2	119.0	2.5
3	46.0	3.8

10.5 Calibration

The *AESKULISA* Cenp-B is calibrated against reference sera from the CDC Atlanta (Centers for Disease Control and Prevention). The results are expressed in U/ml.

11. Literature

- Earnshaw, WC, Bordwell, B, Marino, C, Rothfield, N. (1986): The three human chromosomal autoantigens are recognized by sera from patients with anticentromere antibodies. J Clin Invest 77: 426-430.
- 2. von Mühlen, CA, Tan, EM (1995): Autoantibodies in the diagnosis of systemic rheumatic diseases. Semin Arthritis Rheum 24: 323-358.

3. Tan, EM (1989):

Antinuclear antibodies: diagnostic markers for autoimmune diseases and probes for cell biology. Adv Immunol 44: 93-151.

4. Fritzler, MJ (1993):

Autoantibodies in scleroderma. J Dermatol 24: 323-58.

ANNEX A: Pipetting scheme

We suggest pipetting calibrators, controls and samples as follows: For **quantitative interpretation** use calibrators to establish a standard curve. For **qualitative interpretation** use cut-off calibrator.

	-			e rpreta a stand			-	alitativ ibrator	e inter	pretati	on use	cut-
	1	2	3	4	5	6	7	8	9	10	11	12
Α	CalA	CalE	P1				NC	P2				
В	CalA	CalE	P1				NC	P2				
С	CalB	CalF	P2				CC	P3				
D	CalB	CalF	P2				CC	P3				
Е	CalC	PC	P3				PC					
F	CalC	PC	P3				PC					
G	CalD	NC					P1					
Н	CalD	NC					P1					

CalA: calibrator A, CalB: calibrator B, CalC: calibrator C, CalD: calibrator D, CalE: calibrator E, CalF: calibrator F

PC: positive control

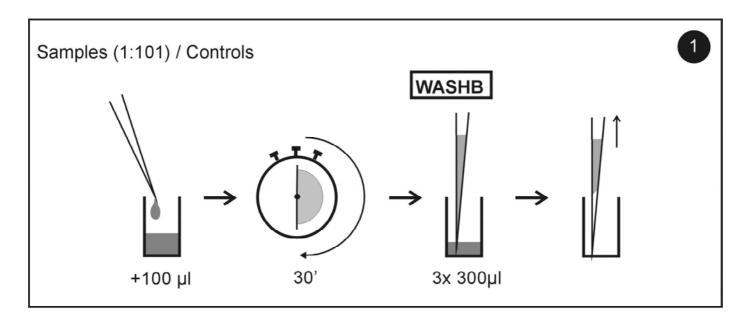
NC: negative control

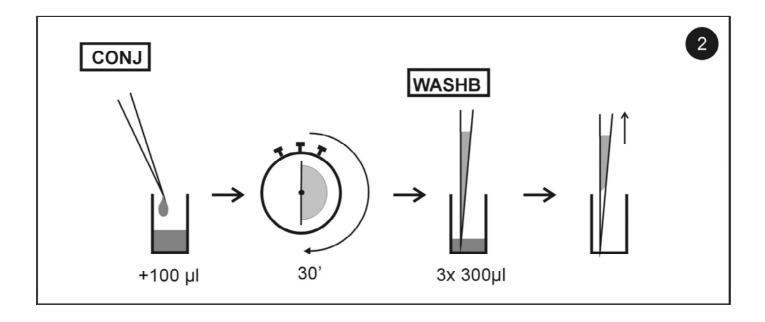
CC: Cut-off calibrator

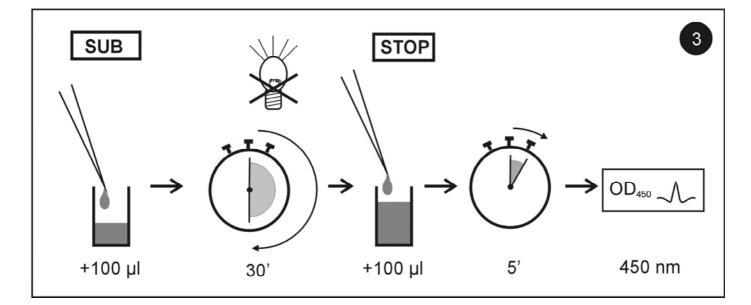
- P1: patient 1
- P2: patient 2

P3: patient 3

Annex B: Test Procedure







Assay/Test:				Incubation / Inkub. :	nkub. :	 	min		Date/	Date/ Datum:		
Temperature/Temperatur: Name:	e/Tempera	tur:	년 년	°C		. v		Ň	Signature/Unterschrift	nterschrift:.		
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• 96 Testes • Rispettare le istruz • Voir les instructions • Gebrauchsanweisi • Ver as instructors • Da utilizzarsi entro • Utilise avant le • Verwendbar bis • Utilizzar antes de • Conserver à 2-8°C • Lagerung be 2-8°C • Conservar entre 2-	en \$96 προσδιορισμοί ruzioni per l'uso ons d'utilisation eisung beachten iss de uso tro \$0 Use by Utilizar antes de Xρήση μέχρι • • • • • • • • • • • • • • • • • • •
• 96 Testes • Rispettare le istruz • Voir les instructions • Gebrauchsanweisi • Ver as instructors • Da utilizzarsi entro • Utilise avant le • Verwendbar bis • Utilizzar antes de • Conserver à 2-8°C • Lagerung be 2-8°C • Conservar entre 2-	ruzioni per l'uso See instructions for use Ver las instrucciones de uso
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Utilizar antes de Utilizar antes de Conservare a 2-8°C Conserver à 2-8°C Lagerung bei 2-8°C Conservar entre 2-	************************************
+2°C	*8°C
+2°C	β°C ♦ Conservar a 2-8°C 8°C ♦ Φυλάσσεται στους 2-8°C 2-8°C
+2°C-1 +2	β°C ♦ Conservar a 2-8°C 8°C ♦ Φυλάσσεται στους 2-8°C 2-8°C
+2°C-1 • Lagerung bei 2-8°C • Conservar entre 2-	8°C ♦ Φυλάσσεται στους 2-8°C 2-8°C
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 Prodotto da 	 Manufactured by
◆ Fabriqué par	 Fabricado por
 Hergestellt von 	 Κατασκευάζεται από
 Fabricado por 	
♦ Calibratore cut-off	off Cut off Calibrator
CO CAI ♦ Etalon Seuil	 Calibrador de cut-off
♦ Grenzwert Kalibrat	rator Οριακός ορός Αντιδραστήριο βαθμονόμηση
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	 Θετικός όρος ελεγχου
Controllo negativo	vo
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CON - Contrôle Négatif Negativ Kontrolle Contrôlo negativo	νο Negative Control f Control Negativo e Αρνητικός ορός ελέγχου
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CON - Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrador Recupero	vo Negative Control Control Negativo Aρνητικός ορός ελέγχου Calibrator Calibrator Calibrador Aντιδραστήριο βαθμονόμησης Recovery Recuperado
CON - + Contrôle Négatif Negativ Kontrolle - Contrôle negativo CAL + Calibratore + CAL + Etalon + Kalibrator - Calibrator CAL + Recupero + Corrélation + Wiederfindung	vo + Negative Control f Control Negativo e + Αρνητικός ορός ελέγχου ////////////////////////////////////
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CON - CON - Contrôle Négatif - Negativ Kontrolle - Contrôle negativo - CAL - Calibratore - Etalon - Kalibrator - Calibrador - Recupero - Corrélation - Viederfindung - Recuperação - CONJ - CONJ - Conjugát - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - <th>vo + Negative Control f Control Negativo e Aρνητικός ορός ελέγχου ////////////////////////////////////</th>	vo + Negative Control f Control Negativo e Aρνητικός ορός ελέγχου ////////////////////////////////////
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CON - + Contrôle Négatif Negativ Kontrolle - Contrôle négativ CAL + Calibratore Etalon + Kalibrator CAL + Calibrador RCC + Recupero Corrélation + Wederfindung Recuperação + Coniugato CONJ + Conjugé Konjugat - Conjugádo MICropiastra rivesti - Micropiastra rivesti MEP + Beschichtete Mikro	vo + Negative Control f Control Negativo e Aρνητικός ορός ελέγχου /0 Calibrator Calibrator Calibrator Calibrator Calibrator Aντιδραστήριο βαθμονόμησης Recovery Recuperado Aνάκτηση Conjugate Conjugate Conjugate Conjugate Conjugado Σύζευγμα estita sibilisée Microplaca sensibilizada krotiterplatte Eπικαλυμμένη μικροπλάκα
CON- Contrôle Négatif Negativ Kontrolle Contrôle négativ Negativ Kontrolle Contrôle négativ Calibratore Etalon Kalibrator Calibrator Contrôle Négatif Recupero Corrigato Conjugé Konjugat Conjugád Microplaque sensit Beschichtete Mikro Microplaca revestit Pinstra ad agh irw 	vo + Negative Control f Control Negativo e Aρνητικός ορός ελέγχου O Calibrator Calibrator Calibrator Calibrator Calibrator Aντιδραστήριο βαθμονόμησης Recovery Recuperado Aντάκτηση Conjugate Conjugate Conjugate Conjugato Σύζευγμα estita sibilisée Microplaca sensibilizada krotiterplatte Eπικαλυμμένη μικροπλάκα stida
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CON - CON - Contrôle Négatif - Negativ Kontrolle - Contrôle negativo - CAL - CAL - Calibratore - Etalon - Kalibrator - Calibrador - Recupero - Corrélation - Viederfindung - Recuperação - CONJ - Conjugáb - Konjugat - Conjugado - Microplacue sensiti - Beschichtete Mikro - Microplaca revestic - PINPE -	vo + Negative Control f Control Negativo e Aρνητικός ορός ελέγχου ////////////////////////////////////
CONI- Contrôle Négatif Negativ Kontrolle Contrôle negativo Calibratore Etalon Kalibrator Calibrator Contrôle Négatif Negativ Kontrolle Corrélation Wiederfindung Recuperacão Conjugá Konjugat Conjugádo Microplaque sensiti Beschichtete Mikrov Microplaca revestid Pinplate sensibilisé Beschichtete Pinpl. Pinplate revestida	νο • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου νο • Calibrator • Calibrator • Calibrador • Αντιδραστήριο βαθμονόμησης • Recovery • Recouperado • Δνάκτηση • Conjugate • Conjugato • Σύζευγμα estita • Coated microtiter plate nsibilisée • Microplaca sensibilizada trivestita • Coated pinplate lisée • Pinplate sensibilizada nplatte • Επικαλυμμένη πλάκα Pin da • Επικαλυμμένη πλάκα Pin
CON- + Contrôle Négatif Negativ Kontrolle - Contrôle négativ CAL + Calibratore Etalon + Kalibrator Calibrador + Calibrador RCC + Recupero CONJ + Recuperação CONJ + Coniugato CONJ + Conjugé Konjugat - Conjugáo Micropiastra rivesti + Micropiaque sensit Beschichtete Mikro + Miscropiaca revestid PINP + Pinplate sensibilisé Beschichtete Pinpla + Pinplate revestida	νο • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου νο • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Aντιδραστήριο βαθμονόμησης • Recovery • Recuperado • Aνάκτηση • Conjugate • Conjugate • Conjugado • Σύζευγμα • Stideuropiaca sensibilizada estita • Coated microtiter plate nsibilisée • Micropiaca sensibilizada rivestita • Coated pinplate lisée • Pinplate sensibilizada e Emικαλυμμένη πλάκα Pin • Emikaλυμμένη πλάκα Pin da • Wash buffer
CON- + Contrôle Négatif Negativ Kontrolle - Contrôle négativ CAL + Calibratore Etalon + Kalibrator Calibrador + Calibrador RCC + Recupero CONJ + Recuperação CONJ + Coniugato CONJ + Conjugé Konjugat - Conjugáo Micropiastra rivesti + Micropiaque sensit Beschichtete Mikro + Miscropiaca revestid PINP + Pinplate sensibilisé Beschichtete Pinpla + Pinplate revestida	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Aντιδραστήριο βαθμονόμησης • Recovery • Recovery • Recovery • Recoperado • Aνάκτηση • Conjugate • Conjugate • Conjugado • Σύζευγμα • Coated microtiter plate stibilisée • Microplaca sensibilizada krotiterplatte • Επικαλυμμένη μικροπλάκα stida • Coated pinplate Iséé • Pinplate sensibilizada • Eπικαλυμμένη πλάκα Pin da aggio • Wash buffer age • Solución de lavado
CON- Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Contrôle Négatif Kalibrator Calibrator Consugato Conjugato Conjugato Conjugato Conjugato Conjugato Conjugato Microplastra rivesti Microplace sensiti Beschichtete Mikro Pinplate sensibilisé Beschichtete Pinpliet Penspilisé Beschichtete Pinpliet Penspilisé Beschichtete Pinpliet revestida WASHB 50x	vo Negative Control Control Negativo Control Negativo Apvητικός ορός ελέγχου Calibrator Calibrator Calibrator Avτιδραστήριο βαθμονόμησης Recovery Recovery Recuperado Avάκτηση Conjugate Conjugate Conjugado Σύζευγμα estita Coated microtiter plate Microplaca sensibilizada krotiterplatte Eπικαλυμμένη μικροπλάκα stida Coated pinplate Isida Coated pinplate Eπικαλυμμένη πλάκα Pin da Baggio Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης
CON- Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Contrôle Négatif Kalibrator Calibrator Consultator Consultator Recupero Corridation Wiederfindung Recuperação Conjugato Conjugato Conjugato Conjugato Microplaca revestiti Microplaca revestiti Microplaca revestiti Pinplate sensibilisé Beschichtete Pinpli Pinplate revestida WASHE 50x	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrador • Aντιδραστήριο βαθμονόμησης • Recovery • Recuperado • Aνάκτηση • Conjugate • Conjugate • Conjugato • Conjugate • Conjugado • Súζευγμα • Coated microtiter plate nsibilisée • Microplaca sensibilizada krotiterplatte • Emικαλυμμένη μικροπλάκα stida • Coated pinplate lisée • Pinplate sensibilizada aggio • Wash buffer agg • Solución de lavado • Puθμιστικό διάλυμα πλύσης gem • Puθμιστικό διάλυμα πλύσης
CON- Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Contrôle Négatif Kalibrator Calibrator Contrôle Négatif Recupero Corrélation Wiederfindung Recuperação Conjugato Conjugato Conjugato Conjugato Conjugato Conjugato Conjugato Seschichtete Mikro Beschichtete Mikro Pinplate sensibilisé Beschichtete Pinpli Pinplate revestida WASHB 50x	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrador • Aντιδραστήριο βαθμονόμησης • Recovery • Recuperado • Aνάκτηση • Conjugate • Conjugate • Conjugato • Conjugate • Conjugado • Súζευγμα • Coated microtiter plate nsibilisée • Microplaca sensibilizada krotiterplatte • Emικαλυμμένη μικροπλάκα stida • Coated pinplate lisée • Pinplate sensibilizada aggio • Wash buffer agg • Solución de lavado • Puθμιστικό διάλυμα πλύσης gem • Puθμιστικό διάλυμα πλύσης
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CON- + Contrôle Négatif Negativ Kontrolle - Controlo negativo CAL + Calibratore Etalon + Etalon Kalibrator - Calibrator CAL + Recupero RCC + Recupero CONJ + Recuperação CONJ + Conjugát CONJ + Conjugat CONJ + Konjugat COnjugado + Microplaque sensit MICOPlace revestid + Piastra ad aghi rive PINP + Pinplate revestid WASHB 50X + Tampone di lavagg Vaschuffer + Solução de lavage	vo Negative Control Control Negativo Control Negativo Apvητικός ορός ελέγχου Calibrator Calibrator Calibrator Calibrator Avrιδραστήριο βαθμονόμησης Recovery Recovery Recovery Recovery Recovery Conjugate Conjugato Σύζευγμα Estita Coated microtiter plate Microplaca sensibilizada Emικαλυμμένη μικροπλάκα stida rivestita Coated pinplate Pinplate sensibilizada Emικαλυμμένη πλάκα Pin da Aggio Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης gem
CON- Contrôle Négatif Negativ Kontrolle Contrôle negativo Calibratore Etalon Kalibrator Calibrator Corrélation Wicederfindung Recupero Conjugati Conjugati Conjugato Microplaque sensiti Beschichtete Mikro Microplaca revestid Pinplate sensibilisé Beschichtete Pinpl. Pinplate revestida WASHB 50x Tampone di lavaggi Tampone substrator Solucão de lavagei Tampone substrator Substrat 	vo Negative Control Control Negativo Control Negativo Apvητικός ορός ελέγχου Calibrator Avriopacripio βαθμονόμησης Recovery Recovery Recuperado Avrixingn Conjugate Conjugate Conjugado Σύζευγμα Conjugado Σύζευγμα Solucion esensibilizada Coated microtiter plate Bisée Pinplate sensibilizada Pinplate sensibilizada Pinplate Emκαλυμμένη μικροπλάκα Pin da Qiglio Wash buffer Solución de lavado Puθμιστικό διάλυμα πλύσης Gem Substrate buffer Tampón sustrato
CONI- Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Contrôle Négatif Kalibrator Calibrator Contrôle Négatif Kalibrator Contrôle Négatif Viederfindung Recuperação CONJ Conjugát Conjugát Conjugato Conjugato Conjugato Micropiastra rivesti Micropiaque sensiti Beschichtete Mikro Micropiaca revestida PINP Pinplate revestida Beschichtete Pinpl Pinplate revestida Beschichtete Pinpl Pinplate revestida Tampone di lavagg Vaschpuffer Solucão de lavage Tampone substrato Substrat Substrat Substrato 	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Aντιδραστήριο βαθμονόμησης • Recovery • Recovery • Recovery • Recouperado • Aνάκτηση • Conjugate • Conjugate • Conjugado • Súξευγμα • Coated microtiter plate stibilisée • Microplaca sensibilizada krotiterplatte • Επικαλυμμένη μικροπλάκα stida • Coated pinplate nijsibilisée • Microplaca sensibilizada krotiterplatte • Επικαλυμμένη πλάκα stida • Coated pinplate stida • Coated pinplate sigaio • Wash buffer aggio • Wash buffer agg • Solución de lavado • Puθμιστικό διάλυμα υποστρώματος • Puθμιστικό διάλυμα υποστρώματος
CONI- Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Conversion Corrigato Conjugát Conjugát Conjugát Conjugato Conjugato Conjugato Conjugato Conjugato Microplaque sensit Beschichtete Mikro Microplaca revestid Pinplate sensibilisé Beschichtete Pinpl Pinplate revestida WASHB 50x Tampone di lavagg Tampone di lavagg Waschpuffer Substrato	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrador • Αντιδραστήριο βαθμονόμησης • Recovery • Recouperado • Avάκτηση • Conjugate • Conjugate • Conjugate • Conjugate • Conjugado • Súčευγμα • Coated microtiter plate stida • Coated microtiter plate nsibilisée • Microplaca sensibilizada krotiterplatte • Emικαλυμμένη μικροπλάκα stida • Coated pinplate Isée • Pinplate sensibilizada aggio • Wash buffer agg • Solución de lavado • Puθμιστικό διάλυμα πλύσης gem rato • Substrate buffer • Puθμιστικό διάλυμα υποστρώματος • Puθμιστικό διάλυμα υποστρώματος
CON Contrôle Négatif Negativ Kontrolle Contrôlo negativo Calibratore Etalon Kalibrator Calibrator Coniugato Corridation Wiceplace Conjugado MICO Conjugado Microplaca revestio Microplaca revestio Microplaca revestio Beschichtete Mikro Pinplate sensibilisé Beschichtete Pinpl Pinplate revestida WASHB 50X Tampone di lavagge	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrador • Αντιδραστήριο βαθμονόμησης • Recovery • Recovery • Recovery • Recovery • Recovery • Recovery • Conjugate • Conjugate • Conjugate • Conjugado • Súčευγμα • Coated microtiter plate stida • Coated microtiter plate nrivestita • Coated pinplate lisée • Pinplate sensibilizada nplatte • Emικαλυμμένη μικροπλάκα aggio • Wash buffer agge • Solución de lavado • Puθμιστικό διάλυμα πλύσης · Puθμιστικό διάλυμα πλύσης gem • Substrate buffer · Tampón sustrato • Puθμιστικό διάλυμα υποστρώματος ante • Stop solution • Solución de parada · Solución de parada
CONI- Contrôle Négatif Negativ Kontrolle Contrôlo negativo CAL Calibratore Etalon Kalibrator Calibrator Etalon Kalibrator Calibrator Corrélation Wicoplace revestid Conjugát Conjugát Conjugado Microplace revestid Beschichtete Mikro Pinplate sensibilisé Beschichtete Pinple Pinplate revestid Beschichtete Pinple Pinplate sensibilisé	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου vo • Calibrator • Calibrator • Calibrator • Calibrator • Avriõpaorripio βαθμονόμησης • Recovery • Recovery • Recovery • Recovery • Recovery • Recovery • Conjugate • Conjugate • Conjugate • Conjugato • Súčευγμα • Súčευγμα estita • Coated microtiter plate nsibilisée • Microplaca sensibilizada • Emικαλυμμένη μικροπλάκα stida rivestita • Coated pinplate lisée • Pinplate sensibilizada nplatte • Emικαλυμμένη πλάκα Pin da • aggio • Wash buffer agge • Solución de lavado • Puθμιστικό διάλυμα πλύσης gem rato • Substrate buffer • Tampón sustrato • Puθμιστικό διάλυμα υποστρώματος ante • Stop solution • Solución de parada • Avriõpαστήριο διακοπής αντίδρασης
CONI-• Contrôle Négatif • Negativ Kontrolle • Controlo negativoCAL• Calibratore • Etalon • Calibrator •	vo • Negative Control f • Control Negativo e • Αρνητικός ορός ελέγχου /0 • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Aντιδραστήριο βαθμονόμησης • Recovery • Recovery • Recovery • Recovery • Conjugate • Conjugato • Conjugate • Conjugado • Súčευγμα • Súčευγμα sstita • Coated microtiter plate nsibilisée • Microplaca sensibilizada krotiterplatte • Επικαλυμμένη μικροπλάκα stida • Coated pinplate lisée • Pinplate sensibilizada nplatte • Επικαλυμμένη πλάκα Pin da • Solución de lavado aggio • Wash buffer agg • Solución de lavado • Puθμιστικό διάλυμα πλύσης • Puθμιστικό διάλυμα υποστρώματος ante • Stop solution • Solución de parada • Αντιδραστήριο διακοπής αντίδρασης
CON + Contrôle Négatif Negativ Kontrolle - Contrôlo negativo CAL - Calibratore Etalon + Kalibrator - Calibrador - Calibrator REC - Recupero RC - Recuperação CONJ - Coniugato CONJ - Conjugé - Konjugat - Conjugé - Conjugato - Conjugato - Conjugato - Conjugato - Conjugato - Conjugato - Conjugato - Conjugato - Micropiastra rivesti Micropiaque sensiti - Beschichtete Mikro - Micropiaca revestida MIPP - Pinplate revestida WASHB 50X - Tampone di lavagg - Tampone di lavagg - Tampone substrato - Substrato - Substrato SUBB - Substrato - Substrato - Reagente bloccant - Solução de parage - Solução de parage - Solução de parage - Solução de parage	vo • Negative Control f • Control Negativo e • Aρνητικός ορός ελέγχου vo • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Aντιδραστήριο βαθμονόμησης • Recovery • Recovery • Recovery • Recovery • Conjugate • Conjugate • Conjugate • Conjugado • Eŭčευγμα • Conjugado stita • Coated microtiter plate stida • Coated microtiter plate stida • Coated microtiter plate stida • Coated pinplate stida • Coated pinplate stida • Coated pinplate ilsée • Pinplate sensibilizada stida • Coated pinplate ilsée • Pinplate sensibilizada aggio • Wash buffer agge • Solución de lavado • Puθμιστικό διάλυμα υποστρώματος
CONI-• Contrôle Négatif • Negativ Kontrolle • Controlo negativoCAL• Calibratore • Etalon • Calibrator •	vo • Negative Control f • Control Negativo e • Aρνητικός ορός ελέγχου vo • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Calibrator • Aντιδραστήριο βαθμονόμησης • Recovery • Recovery • Recovery • Recovery • Conjugate • Conjugate • Conjugate • Conjugado • Eŭčευγμα • Conjugado stita • Coated microtiter plate stida • Coated microtiter plate stida • Coated microtiter plate stida • Coated pinplate stida • Coated pinplate stida • Coated pinplate ilsée • Pinplate sensibilizada stida • Coated pinplate ilsée • Pinplate sensibilizada aggio • Wash buffer agge • Solución de lavado • Puθμιστικό διάλυμα υποστρώματος
Calibrador de cut-c Controllo positivo Contrôle Positif Positiv Kontrolle Controlo positivo	ut-off ro ♦ Positive Control ♦ Control Positivo