Instruction manual

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002 : 2007-08-28 REF 3104 U1-70

1. Intended Use

AESKULISA U1-70 is a solid phase enzyme immunoassay employing recombinant human 70 kDa protein of the U1-snRNP complex for the quantitative and qualitative detection of antibodies against the 70 kDa U1-RNP in human serum.

The assay is a tool in the diagnosis of mixed connective tissue diseases (MCTD) and systemic lupus erythematosus (SLE).

2. Clinical Application and Principle of the Assay

The U1-snRNP complex is a **s**mall **n**uclear **r**ibonucleo**p**rotein particle composed of uridine rich (thus U) small nuclear RNA and a set of proteins: the 70 kDa U1-specific ribonucleoprotein plus proteins A and C (all formerly summarized as RNPs) and the Sm (Smith) antigen which comprises eight proteins: B,/ B`, D1, D2, D3, E, F,and G. Because of its protein components, the Sm and RNPs, the complex is often named RNP/Sm complex. The U1-snRNP complex is a part of the splicosomal complex, that facilitates the processing of pre-mRNA to mature mRNA in the nucleus.

Antibodies against the 70 kDa protein of the U1-snRNP complex belong to the heterogenous group of anti-nuclear antibodies (ANA), which are associated with various autoimmune diseases. They are directed against various proteins of the nucleus. Indirect immunofluorescence test (IFT) on eucaryotic cells like HeLa has been the established method for the detection of ANAs. Single antibody specificities are distinguished by fluorescence patterns but more specific testing by ELISAs employing the target antigens are available too for a simple and reliable differentiation of ANAs.

Antibodies against the 70 kDa U1-specific protein are found in 95% of mixed connective tissue diseases (MCTD) but do also occur in systemic lupus erythematosus (SLE) with a prevalence of 40%. Isolated occurrence of anti-70 kDa antibodies is typical for the Sharp syndrome. Whilst antibodies against Sm are highly specific for systemic lupus erythematosus (SLE) and thus are included in diagnostic and classification criteria for SLE. Anti-Sm antibodies are found in 20-30% of patients with SLE.

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.

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3. Kit Contents

To be reconstituted:

5x Sample Buffer 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 lgG (capped blue: blue solution)

Containing: Anti-human immunoglobulins conjugated to horseradish peroxidase

TMB Substrate 1 vial, 15 ml (capped black)

Containing: Stabilized TMB/H2O2

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 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 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.**

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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 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 (NaN₃) as a preservative. NaN₃ may be toxic if ingested or adsorbed by skin or eyes. NaN₃ 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 $2-8^{\circ}\text{C}/35-46^{\circ}\text{F}$ up to three days, or frozen at $-20^{\circ}\text{C}/-4^{\circ}\text{F}$ for longer periods.

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7. Assay Procedure

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

Washing:

Prepare 20 ml of diluted wash buffer (1x) per 8 wells or 200 ml for 96 wells e.g. 4 ml concentrate plus 196 ml distilled water.

Automated washing:

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

Manual washing:

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

Microplates:

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

7.2 Work flow

For pipetting scheme see Annex A, for 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	0.044	3.2
3 U/ml	0.132	0.6
10 U/ml	0.300	2.1
30 U/ml	0.557	2.8
100 U/ml	1.224	1.9
300 U/ml	2.130	0.3

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	1.156/1.108	1.132	86.9
P 02	0.543/0.564	0.554	29.9

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

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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 U1-70 (REF7104)* gave an analytical sensivity of 1.0 U/ml.

10.2 Specificity and sensitivity

The microplate is coated with recombinant human 70kDa U1-snRNP.

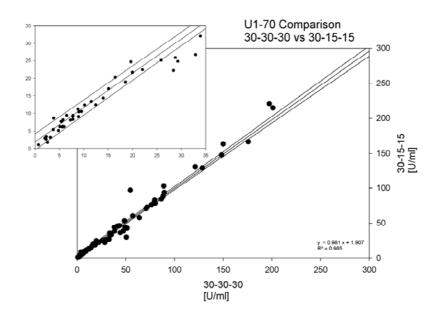
No crossreactivities to other autoantigens have been found. Antibodies against 70kDa protein of the U1 snRNP complex occur in different diseases which are shown in the table below:

Disease	prevalence
MCTD	95%
SLE	40%

The data has been aquired with the AESKULISA U1-70 (REF7104).

Correlation:

The comparability of performance data was assessed with 74 sera tested on both, *AESKULISA* 7104 and *AESKULISA* 3104. A linear regression analysis of the two products showed that the two products are equivalent. Included in these sera are 40 sera close to cut-off.



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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	144.0	148.0	97.3
	1 / 200	73.5	74.0	99.3
	1 / 400	36.5	37.0	98.6
	1 / 800	18.0	18.5	97.3
2	1 / 100	54.3	55.0	98.7
	1 / 200	26.4	27.5	96.0
	1 / 400	12.9	13.8	93.5
	1 / 800	6.5	6.9	94.2

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	151.0	2.3
2	72.0	3.6
3	26.0	4.5

ln	ter-Assa	ay
Sample	Mean	CV
No.	(U/ml)	(%)
1	148.0	2.6
2	70.0	4.1
3	24.0	3.9

10.5 Calibration

The AESKULISA U1-70 is calibrated against reference sera from the CDC (Centers for Disease Control and Prevention) Atlanta. The results are expressed in U/ml.

11. Literature

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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.

			ive inte	•				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				
Ε	CalC	PC	P3				PC					
F	CalC	PC	P3				PC					
G	CalD	NC					P1					
Н	CalD	NC					P1					

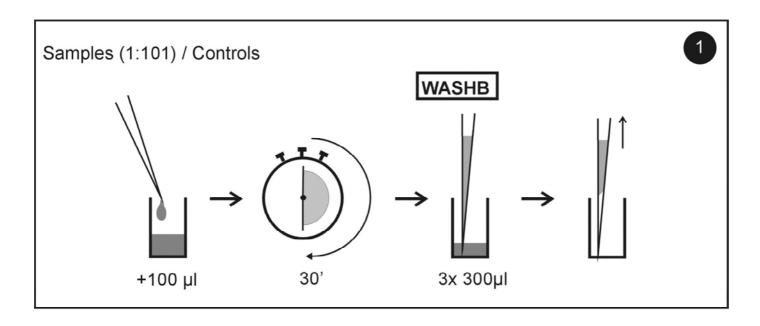
CalA: calibrator A, CalB: calibrator B, CalC: calibrator C, CalD: calibrator D, CalE: calibrator E,

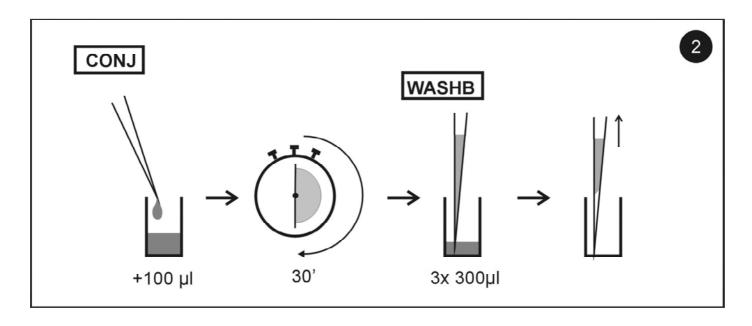
CalF: calibrator F PC: positive control NC: negative control CC: Cut-off calibrator

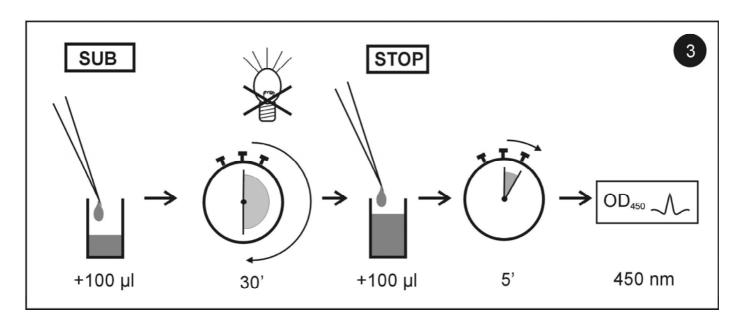
P1: patient 1 P2: patient 2 P3: patient 3

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Annex B: Test Procedure







Assay/Test:			II	Incubation / Inkub.:	nkub. :	-	min _		Date/	Date/ Datum:		
Temperature/Temperatur:	e/Temperat	ur:	- A-	J.		2.	mim	č	71/0000	1000		
Name:						3.	min	<u>o</u>	ignature/ Or	Signature/Ontersentific		
	1	2	3	4	5	9	7	8	6	10	111	12
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	♦ Diagnosi in vitro	♦ For in vitro diagnostic use
IVD	 Pour diagnostic in vitro 	 Para uso diagnóstico in vitro
IVD	◆ In Vitro Diagnostikum	♦ In Vitro Διαγνωστικό μέσο
	 Para uso Diagnóstico in vitro 	
	♦ Numero d'ordine	 ◆ Cataloge number
DEE	 Référence Catalogue 	 Numéro de catálogo
REF	◆ Bestellnummer	◆ Αριθμός παραγγελίας
	 Número de catálogo 	
	Descrizione lotto	♦ Lot
	♦ Lot	♦ Lote
LOT	Chargen Bezeichnung	Χαρακτηρισμός παρτίδας
	◆ Lote	 ▼ Λαρακτηρισμός παρτίσας
		. 500 1 " (0 ("
	♦ Conformità europea	◆ EC Declaration of Conformity
C€	◆ Déclaration CE de Conformité	◆ Declaración CE de Conformidad
	◆ Europäische Konformität	◆ Ευρωπαϊκή συμφωνία
	◆ Déclaração CE de Conformidade	
	 96 determinazioni 	♦ 96 tests
\96/	♦ 96 tests	 ◆ 96 pruebas
	 96 Bestimmungen 	 96 προσδιορισμοί
·	♦ 96 Testes	
	♦ Rispettare le istruzioni per l'uso	♦ See instructions for use
—	◆ Voir les instructions d'utilisation	◆ Ver las instrucciones de uso
i	Gebrauchsanweisung beachten	
	<u> </u>	 Λάβετε υπόψη τις οδηγίες χρήσης
	 ◆ Ver as instrucões de uso ◆ Da utilizzarsi entro 	♦ Use by
<u> </u>	Utilise avant le	♦ Utilizar antes de
	Verwendbar bis	Χρήση μέχρι
	◆ Utilizar antes de	
∩ .—+8°C	♦ Conservare a 2-8°C	♦ Store at 2-8°C (35-46°F)
∐ +8℃	♦ Conserver à 2-8°C	♦ Conservar a 2-8°C
+2°C ~	♦ Lagerung bei 2-8°C	♦ Φυλάσσεται στους 2-8°C
$oldsymbol{\omega}$	♦ Conservar entre 2-8°C	,
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	♦ Frodotto da ♦ Fabriqué par	*
		♦ Fabricado por
	Hergestellt von Febrierde per	 Κατασκευάζεται από
	◆ Fabricado por	
	◆ Calibratore cut-off	 Cut off Calibrator
CO-CΔ	◆ Etalon Seuil	 Calibrador de cut-off
CO-CAL	 Grenzwert Kalibrator 	 Οριακός ορός Αντιδραστήριο βαθμονόμησης
	 Calibrador de cut-off 	
	◆ Controllo positivo	◆ Positive Control
CONI	◆ Contrôle Positif	◆ Control Positivo
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	◆ Controllo negativo	♦ Negative Control♦ Control Negativo
CONI-	◆ Contrôle Négatif	•
CON-	♦ Negativ Kontrolle	◆ Αρνητικός ορός ελέγχου
CON -	◆ Negativ Kontrolle ◆ Controlo negativo	 Αρνητικός ορός ελέγχου
CON -	◆ Negativ Kontrolle ◆ Controlo negativo ◆ Calibratore	Αρνητικός ορός ελέγχουCalibrator
CON-	◆ Negativ Kontrolle ◆ Controlo negativo ◆ Calibratore ◆ Etalon	 Αρνητικός ορός ελέγχου Calibrator Calibrador
CON -	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator	Αρνητικός ορός ελέγχουCalibrator
CAL	◆ Negativ Kontrolle ◆ Controlo negativo ◆ Calibratore ◆ Etalon	 Αρνητικός ορός ελέγχου Calibrator Calibrador
CON -	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator	 Αρνητικός ορός ελέγχου Calibrator Calibrador
CAL	 Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador 	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης
CON - CAL RC	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery
CON -	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation	 Αρνητικός ορός ελέγχου Calibrator Aντιδραστήριο βαθμονόμησης Recovery Recuperado
CON - CAL RC	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση
	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate
CON - CAL RC CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Coniugato Conjugé	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado
	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Coniugato Conjugé Konjugat	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate
	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Konjugat Conjugado	 Αρνητικός ορός ελέγχου Calibrator Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Conjugé Konjugat Conjugado Micropiastra rivestita	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugé Konjugat Conjugado Micropiastra rivestita Microplaque sensibilisée	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada
	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Conjugé Konjugat Conjugado Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugé Konjugat Conjugado Micropiastra rivestita Microplaque sensibilisée	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperação Conjugé Konjugat Conjugado Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugé Konjugat Conjugato Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugat Conjugat Conjugate Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita	 Αρνητικός ορός ελέγχου Calibrator Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Coated pinplate
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Recupero Corrélation Widedrfindung Recuperacão Conjugát Conjugát Konjugat Conjugate Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Pinplate sensibilisée Beschichtete Pinplatte	 Αρνητικός ορός ελέγχου Calibrator Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widerfindung Recuperacão Conjugat Conjugat Conjugat Conjugat Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Ρίηρlate sensibilizada Επικαλυμμένη πλάκα Pin
CONJ MP PINP	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugato Conjugé Konjugat Conjugáe Konjugat Microplastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Pinplate revestida Pinplate revestida Tampone di lavaggio	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer
CONJ MP PINP	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widerfindung Recuperado Conjugat Conjugat Conjugat Conjugat Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Ρίηρlate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado
CONJ	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widederfindung Recuperacão Conjugát Conjugát Conjugát Conjugat Conjugate Microplastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer
CONJ MP PINP	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widederfindung Recuperacão Conjugát Conjugát Conjugát Conjugado Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplada revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem	 Αρνητικός ορός ελέγχου Calibrator Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης
CONJ MP PINP	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Recupero Corrélation Wiederfindung Recuperacão Conjugát Conjugát Konjugat Conjugate Microplastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer
CONJ MP PINP WASHB 50x	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widederfindung Recuperacão Conjugát Conjugát Conjugát Conjugado Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplada revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem	 Αρνητικός ορός ελέγχου Calibrator Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης
CONJ MP PINP	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Recupero Corrélation Wiederfindung Recuperacão Conjugát Conjugát Konjugat Conjugate Microplastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer
CONJ MP PINP WASHB 50x	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Recupero Corrélation Widedrfindung Recuperacão Conjugat Conjugat Conjugat Conjugat Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Pinstra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate ΡίηρΙαte sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato
CONJ MP PINP WASHB 50x	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Conjugát Conjugát Conjugát Microplastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substratpuffer	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate ΡίηρΙαte sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato
CONJ MP PINP WASHB 50x SUB	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Conjugat Conjugat Conjugad Microplastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrat Substrate	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato Pυθμιστικό διάλυμα υποστρώματος Stop solution
CONJ MP PINP WASHB 50x SUB	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widedrfindung Recuperacão Conjugát Konjugat Conjugát Conjugado Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrato Reagente bloccante Solution d'Arrêt	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato Ρυθμιστικό διάλυμα υποστρώματος Stop solution Solución de parada
CONJ MP PINP WASHB 50x	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widedrfindung Recuperacão Conjugat Conjugat Conjugat Conjugat Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Beschichtete Pinplatte Pinplate sensibilisée Beschichtete Pinplatte Pinplate ad lavage Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrato Reagente bloccante Solution d'Arrêt Stopreagenz	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Microplaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Tampón sustrato Pυθμιστικό διάλυμα υποστρώματος Stop solution
CONJ MP PINP WASHB 50x SUB	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Conjugat Conjugat Conjugado Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque sensibilisée Beschichtete Pinplatte Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrato Substrat Substrato Reagente bloccante Solucão de paragem	 Αρνητικός ορός ελέγχου Calibrator Calibrator Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Pinplate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Ταπρόη sustrato Ρυθμιστικό διάλυμα υποστρώματος Stop solution Solución de parada Αντιδραστήριο διακοπής αντίδρασης
CONJ MP PINP WASHB 50x SUB	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Conjugat Conjugat Conjugado Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrato Reagente bloccante Solucão de paragem Solucão de paragem Tampone campione	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate ΡίπρΙα sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Ταπρόn sustrato Ρυθμιστικό διάλυμα υποστρώματος Stop solution Solución de parada Αντιδραστήριο διακοπής αντίδρασης Sample buffer
CONJ MP PINP WASHB 50x SUB STOP	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Widederfindung Recuperado Conjugato Conjugato Conjugato Micropiastra rivestita Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Microplaca revestida Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrat Substrato Reagente bloccante Solucão de paragem Tampone campione	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate Μίστορlaca sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate Ρίηρlate sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Ταπρόη sustrato Ρυθμιστικό διάλυμα υποστρώματος Stop solution Solución de parada Αντιδραστήριο διακοπής αντίδρασης Sample buffer Ταπρόη Muestras
CONJ MP PINP WASHB 50x SUB	Negativ Kontrolle Controlo negativo Calibratore Etalon Kalibrator Calibrador Recupero Corrélation Wiederfindung Recuperacão Conjugat Conjugat Conjugat Conjugado Microplaque sensibilisée Beschichtete Mikrotiterplatte Microplaque revestida Piastra ad aghi rivestita Pinplate sensibilisée Beschichtete Pinplatte Pinplate revestida Tampone di lavaggio Tampon de Lavage Waschpuffer Solucão de lavagem Tampone substrato Substrat Substrato Reagente bloccante Solucão de paragem Solucão de paragem Tampone campione	 Αρνητικός ορός ελέγχου Calibrator Calibrador Αντιδραστήριο βαθμονόμησης Recovery Recuperado Ανάκτηση Conjugate Conjugado Σύζευγμα Coated microtiter plate ΜίστορΙαςα sensibilizada Επικαλυμμένη μικροπλάκα Coated pinplate ΡίπρΙα sensibilizada Επικαλυμμένη πλάκα Pin Wash buffer Solución de lavado Ρυθμιστικό διάλυμα πλύσης Substrate buffer Ταπρόn sustrato Ρυθμιστικό διάλυμα υποστρώματος Stop solution Solución de parada Αντιδραστήριο διακοπής αντίδρασης Sample buffer