AESKULISA DGP-G

Ref 30-7514US

Instruction Manual

CLIA Complexity HIGH

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1 Intended Use

AESKULISA DGP-G is an in-vitro diagnostic device. This solid phase enzyme immunoassay employs synthetic, deamidated gliadin-derived peptides for the semiquantitative and qualitative detection of IgG antibodies against deamidated Gliadin-specific peptides (DGP) in human serum.

The assay is an aid in the diagnosis of celiac disease (gluten-sensitive enteropathy) and should be used in conjunction with other serological tests and clinical findings.

2 Clinical Application and Principle of the Assay

Gluten-sensitive enteropathy or celiac disease is characterized by atrophy of the small intestinal villi leading to a so-called flat mucosa. It is caused by a pathological intolerance to Gliadin, the alcohol-soluble fraction of gluten in wheat, rye and barley. It is caused by a pathological intolerance to gliadin, the alcohol-soluble fraction of gluten in wheat, rye and barley. As celiac disease and dermatitis herpetiformis are aggravated by the uptake of gluten, consequently a gluten-free diet relieves the symptoms (Schuppan et al., 2009; Losowsky, 2008). Renewed consumption of gluten often leads to a return of the symptoms. The disease is HLA-associated (>95% of patients have DQ2 enREFd by DQA1*0501 and DQB1*0201) and manifests at any age with a peak onset in early childhood, even in neonatals (Liu et al., 2007). The incidence rates range from 1 in 4000 to 1 in 300 (Lagerqvist et al., 2008; Fasano, 2009; Not et al., 1998) .
Diagnosis of celiac disease is made by small intestinal biopsy (demonstrating the flat mucosa) supported by serological markers. Antibodies against Gliadin and tissue Transglutaminase (tTG) are of major significance (Ivarsson et al., 2002). tTG has been identified as the major target antigen of antibodies binding to endomysium (extracellular constituent of smooth muscle) in indirect immunofluorescence test (EMA-IFT)(Salmi et al., 2006), which has been so far an important tool for the diagnosis of celiac diseases.
Circulating IgG and IgA antibodies to Gliadin are found in the serum of most but not all celiac disease patients, though the specificity of these antibodies are significantly lower compared to tTG and EMA (Fasano, 2009; Lagerqvist et al., 2008).
Recent work has revealed that gliadin reactive antibodies from celiac patients bind a very limited number of specific epitopes on the gliadin molecule. The selective deamidation of gliadin by tissue transglutaminase results in enhanced binding by anti-gliadin antibodies. Assays using deamidated and defined peptides have been shown to have higher diagnostic accuracy for celiac disease when compared to standard anti-gliadin assays. The determination of IgG antibodies to Gliadin (and/or tTG) is expecially of high value as approximately 2% - 5% of celiac patients display an IgA deficiency (Salmi et al., 2006; Vermeersch et al., 2010), thus being missed by IgA subclass tests.
Moreover, antibodies to Gliadin and DGP may be the only serological marker in neonatals, as anti-tTG and EMA autoantibodies are not present at this age (Liu et al., 2007; Lagerqvist et al., 2008; Maglio et al., 2010).

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.

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)
READY TO USE				
Item	Quantity	Cap color	Solution color	Description / Contents
Negative Control	1 x 1.5ml	Green	Colorless	Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Positive Control	1 x 1.5ml	Red	Yellow	Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Cut-off Calibrator	1 x 1.5ml	Blue	Yellow	Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Calibrators	6 x 1.5ml	White	Yellow *	Concentration of each calibrator: 0, 3, 10, 30, 100, 300 U/ml. Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
Conjugate, IgG	1 x 15ml	Blue	Blue	Containing: Goat Anti-human immunoglobulins conjugated to horseradish peroxidase, bovine serum albumin (BSA)
TMB Substrate	1 x 15ml	Black	Colorless	Stabilized tetramethylbenzidine and hydrogen peroxide (TMB/H_2O_2)
Stop Solution	1 x 15ml	White	Colorless	1M Hydrochloric Acid
Microtiter plate	12 x 8 well strips	N/A	N/A	With breakaway microwells coated with deamidated gliadin specific peptides.
* 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 µl) or adjustable multipipette (100-1000µl). Microplate washing device (300 µl 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. Opened components are stable for 1 month. Avoid intense exposure of TMB solution to light. Store microplate in designated foil, including the desiccant, and seal tightly.

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 FDA 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 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.

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 previously with other reagents.

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 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 (according to CLSI Guideline H18-A3).

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 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 Pipetting Scheme

We suggest pipetting calibrators, controls and samples as follows:

For *QUANTITATIVE* interpretation

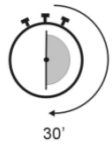
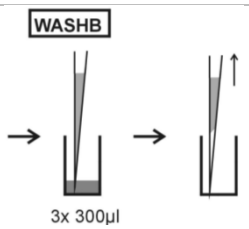
	1	2	3	4...
A	Cal A	Cal E	P1	
B	Cal A	Cal E	P1	
C	Cal B	Cal F	P2	
D	Cal B	Cal F	P2	
E	Cal C	PC	P3	
F	Cal C	PC	P3	
G	Cal D	NC	…	
H	Cal D	NC	…	

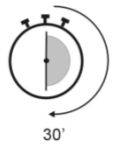
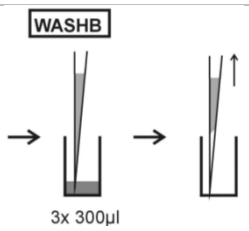
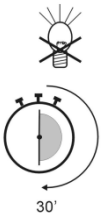
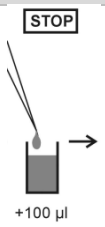
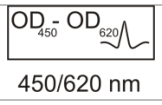
For *QUALITATIVE* interpretation

	1	2	3	4...
A	NC	P2		
B	NC	P2		
C	CC	P3		
D	CC	P3		
E	PC	…		
F	PC	…		
G	P1	…		
H	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

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.	 Wash 3x with 300 µl washing buffer (diluted 1:50).

	CONJUGATE	
6.		Pipette 100 µl conjugate into each well.
7.		Incubate for 30 minutes at 20-32°C/68-89.6°F.
8.		Wash 3x with 300 µl washing buffer (diluted 1:50).
	SUBSTRATE	
9.		Pipette 100 µl TMB substrate into each well.
10.		Incubate for 30 minutes at 20-32°C/68-89.6°F, protected from intense light.
	STOP	
11.		Pipette 100 µl stop solution into each well, using the same order as pipetting the substrate.
12.		Incubate 5 minutes minimum.
13.		Agitate plate carefully for 5 sec.
14.		Read absorbance at 450 nm (recommended 450/620 nm) within 30 minutes.

8 Semiquantitative and qualitative interpretation

For **semiquantitative interpretation** establish the standard curve by plotting the **optical density** (**OD) of each calibrator (y-axis)** with respect to the corresponding concentration values in U/ml (x-axis). For best results we recommend log/lin coordinates and 4-Parameter Fit. From the OD of each sample, read the corresponding antibody concentrations expressed in U/ml.

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

Example of a standard curve

Do NOT use this example for interpreting patient´s result

Calibrators IgG	OD 450/620 nm	CV % (Variation)
0 U/ml	0.040	0.0
3 U/ml	0.126	1.5
10 U/ml	0.287	2.7
30 U/ml	0.513	4.0
100 U/ml	1.086	4.5
300 U/ml	1.974	5.6

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	1.007/1.011	1.009	98.4
P 02	0.533/0.523	0.528	38.2

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. Equivocal samples should be considered “non-conclusive” and should be further investigated.

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. 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**		

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:	1.83 U/ml
Reportable range:	2.09 – 300 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 62 times on AESKULISA DGP-G gave a limit of blank of 0.3 U/ml and 8 low negative samples for 8 times gave a limit of detection of 1.83 U/ml.

10.2 Method Comparison

The microplates are coated with synthetic, deamidated gliadin-derived peptides. No crossreactivity with other autoantibodies have been found.
A total of 218 adult and pediatric samples (for composition see table) have been tested on the AESKULISA DGP-G and a predicate device reacting in the reportable range. Results are summarized in the following table (samples out of reportable range were excluded from the comparison but were included in the clinical validation below):

DGP-G	**AESKU**	**Predicate**	
Diagnosis	**POS (>18)**	**POS**	**Total**
CD	62 (93.9%)	59 (89.4%)	66
CD IgA Def	15 (100%)	15 (100%)	15
CD suspect	30 (81.1%)	31 (83.8%)	37
CD suspect IgA Def	0 (0%)	0 (0%)	2
DH	39 (86.7%)	38 (84.4%)	45
Controls (non-DH/CD)	3 (5.7%)	1 (1.9%)	53
Total	**149 (68.3%)**	**144 (66.1%)**	**218**

DGP-G		**predicate**		
		POS (>20)	**Neg (≤20)**	**Total**
AESKU	**Pos (>18)**	136	13	149
	Neg (≤18)	8	61	69
	Total	144	74	218

Positive agreement	95% C.I.	
94.44% (136/144)	89.42%	97.16%
Negative agreement		
82.43% (61/74)	72.23%	89.44%
Overall Agreement		
90.37% ((136+61)/218)	85.72%	93.61%

(*) Agreements were calculated regarding equivocal results as negative and low positive results as positive

Of the 21 samples with discrepant results the AESKULISA outperformed the predicate device in 11 cases based on additional information such as EMA, biopsy and results from DGP assays of other immunoglobulin classes.

10.3 Clinical Evaluation

The diagnostic sensitivity of 93.8% and diagnostic specificity of 97.3% was calculated using the above CD and DH, non-DH/CD and autoimmune controls samples ignoring the results for the suspected samples and healthy controls (for composition see table below).

DGP-G	**AESKU**	
Disease Group	**POS (>18)**	**Total**
Autoimmune Controls *	0(0%)	54
CD	75(94.9%)	79
CD IgA Def	16(100%)	16
DH	59(90.8%)	65
Controls (non-DH/CD)	3(5.4%)	56
Total		**270**

(*) contains additional samples only determined on the AESKULISA and not determined on the predicate device and samples which showed high positivity out of measurable range.

DGP-G	Diagnosis		
Test	**POS**	**neg**	**Total**
POS>18	150	3	153
neg ≤18	10	107	117
Total	160	110	270

Diagnostic Sensitivity*	**95% C.I.**	
93.75% (150/160)	88.88%	96.57%
Diagnostic Specificity*		
97.27% (107/110)	92.29%	99.07%

*equivocal results were regarded as negative

10.4 Linearity

Chosen sera have been tested with this kit and found to dilute linearly with a negative serum according to CLSI EP06-A. However, due to the heterogeneous nature of human autoantibodies there might be samples that do not follow this rule.

Composition		High			Medium			Low		
Pos. sample	Neg. sample	Mean [U/ml]	Expected [U/ml]	Recovery [%]	Mean [U/ml]	Expected [U/ml]	Recovery [%]	Mean [U/ml]	Expected [U/ml]	Recovery [%]
100.0%	0.0%	313.9	313.9	100.0%	119.2	119.2	100.0%	16.7	16.7	100.0%
87.5%	12.5%	264.1	274.7	96.1%	100.8	104.3	96.7%	15.8	14.6	108.2%
75.0%	25.0%	243.3	235.4	103.3%	91.9	89.4	102.8%	12.4	12.5	98.7%
67.5%	32.5%	199.8	211.9	94.3%	76.0	80.4	94.4%	9.8	11.3	86.5%
50.0%	50.0%	162.5	157.0	103.5%	52.6	59.6	88.2%	8.0	8.4	95.6%
37.5%	62.5%	106.4	117.7	90.4%	46.0	44.7	103.0%	6.7	6.3	107.5%
25.0%	75.0%	84.1	78.5	107.2%	24.5	29.8	82.1%	3.0	4.2	71.1%
12.5%	87.5%	42.3	39.2	107.8%	13.7	14.9	91.6%	1.2	2.1	58.0%

Taken this data, the linear range for AESKULISA DGP-G is from 2.09 U/ml to 300 U/ml.

10.5 Precision

To determine the precision of the assay, the variability (intra, inter-assay and Lot-to-Lot) was assessed by examining its reproducibility on five serum samples selected to represent a range over the standard curve, in 8 repetitions in 5 runs. Lot-to-Lot variability was assessed measuring five serum samples in 8 repetitions on 3 different lots.

Inter-assay variability			Intra-assay variability			Lot-to-Lot variability		
Sample No.	Mean (U/ml)	CV (%)	Sample No.	Mean (U/ml)	CV (%)	Sample No.	Mean (U/ml)	CV (%)
1	3.24	21.5	1	3.24	11.3	1	2.67	7.6
2	12.1	14.8	2	12.1	10.4	2	11.5	12.4
2b	19.5	10.0	2b	19.5	9.0	-	-	-
3	24.3	13.0	3	24.3	11.7	3	22.4	9.1
4	86.2	10.8	4	86.2	9.3	4	79.8	7.2
5	256.9	11.8	5	256.9	8.5	5	265.6	8.6

Acceptance criteria are ≤15% for positive samples, ≤15% for equivocal samples and ≤25% for negative samples

10.6 Calibration

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

10.7 Normal Range

DGP-G antibodies are reported in up to 13.7% of the normal population.

133 random blood donors were tested for DGP-G antibodies. Of these; 116 ranged in the age of 16-45 and 17 were 46+; they included a similar number of males and females. One sample was positive (0.8%) with a value of 18.2 Units, the rest were negative. The mean value of the samples was 3.2 units with a standard deviation of 2.2 units. The mean value is 6.9 standard deviations below the 18-unit limit of positivity.

11 Literature

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IVD	- Diagnosi in vitro	- For in vitro diagnostic use
	- Pour diagnostic in vitro	- Para uso diagnóstico in vitro
	- In Vitro Diagnostikum	- In Vitro Διαγνωστικό μέσο
	- Para uso Diagnóstico in vitro	
REF	¨ Numero d'ordine	¨ Cataloge number
	¨ Référence Catalogue	¨ Numéro de catálogo
	¨ Bestellnummer	¨ Αριθμός παραγγελίας
	¨ Número de catálogo	
LOT	¨ Descrizione lotto	¨ Lot
	¨ Lot	¨ Lote
	¨ Chargen Bezeichnung	¨ Χαρακτηρισμός παρτίδας
	¨ Lote	
CE	¨ Conformità europea	¨ EC Declaration of Conformity
	¨ Déclaration CE de Conformité	¨ Declaración CE de Conformidad
	¨ Europäische Konformität	¨ Ευρωπαϊκή συμφωνία
	¨ Déclaracão CE de Conformidade	
Σ 96	¨ 96 determinazioni	¨ 96 tests
	¨ 96 tests	¨ 96 pruebas
	¨ 96 Bestimmungen	¨ 96 προσδιορισμοί
	¨ 96 Testes	
i	¨ Rispettare le istruzioni per l'uso	¨ See instructions for use
	¨ Voir les instructions d'utilisation	¨ Ver las instrucciones de uso
	¨ Gebrauchsanweisung beachten	¨ Λάβετε υπόψη τις οδηγίες χρήσης
	¨ Ver as instrucões de uso	
	¨ Da utilizzarsi entro	¨ Use by
	¨ Utilise avant le	¨ Utilizar antes de
	¨ Verwendbar bis	¨ Χρήση μέχρι
	¨ Utilizar antes de	
+2°C +8°C	¨ Conservare a 2-8°C	¨ Store at 2-8°C (35-46°F)
	¨ Conserver à 2-8°C	¨ Conservar a 2-8°C
	¨ Lagerung bei 2-8°C	¨ Φυλάσσεται στους 2-8°C
	¨ Conservar entre 2-8°C	
	¨ Prodotto da	¨ Manufactured by
	¨ Fabriqué par	¨ Fabricado por
	¨ Hergestellt von	¨ Κατασκευάζεται από
	¨ Fabricado por	
CO-CAL	¨ Calibratore cut-off	¨ Cut off Calibrator
	¨ Etalon Seuil	¨ Calibrador de cut-off
	¨ Grenzwert Kalibrator	¨ Οριακός ορός Αντιδραστήριο βαθμονόμησης
	¨ Calibrador de cut-off	
CON +	¨ Controllo positivo	¨ Positive Control
	¨ Contrôle Positif	¨ Control Positivo
	¨ Positiv Kontrolle	¨ Θετικός ορός ελέγχου
	¨ Controlo positivo	
CON −	¨ Controllo negativo	¨ Negative Control
	¨ Contrôle Négatif	¨ Control Negativo
	¨ Negativ Kontrolle	¨ Αρνητικός ορός ελέγχου
	¨ Controlo negativo	
CAL	¨ Calibratore	¨ Calibrator
	¨ Etalon	¨ Calibrador
	¨ Kalibrator	¨ Αντιδραστήριο βαθμονόμησης
	¨ Calibrador	
RC	¨ Recupero	¨ Recovery
	¨ Corrélation	¨ Recuperado
	¨ Wiederfindung	¨ Ανάκτηση
	¨ Recuperacão	
CONJ	¨ Coniugato	¨ Conjugate
	¨ Conjugé	¨ Conjugado
	¨ Konjugat	¨ Σύζευγμα
	¨ Conjugado	
MP	¨ Micropiastra rivestita	¨ Coated microtiter plate
	¨ Microplaque sensibilisée	¨ Microplaca sensibilizada
	¨ Beschichtete Mikrotiterplatte	¨ Επικαλυμμένη μικροπλάκα
	¨ Microplaca revestida	
WASHB 50x	¨ Tampone di lavaggio	¨ Wash buffer
	¨ Tampon de Lavage	¨ Solución de lavado
	¨ Waschpuffer	¨ Ρυθμιστικό διάλυμα πλύσης
	¨ Solucão de lavagem	
SUB	¨ Tampone substrato	¨ Substrate buffer
	¨ Substrat	¨ Tampón sustrato
	¨ Substratpuffer	¨ Ρυθμιστικό διάλυμα υποστρώματος
	¨ Substrato	
STOP	¨ Reagente bloccante	¨ Stop solution
	¨ Solution d'Arrêt	¨ Solución de parada
	¨ Stopreagenz	¨ Αντιδραστήριο διακοπής αντίδρασης
	¨ Solucão de paragem	
SB 5x	¨ Tampone campione	¨ Sample buffer
	¨ Tampon Echantillons	¨ Tampón Muestras
	¨ Probenpuffer	¨ Ρυθμιστικό διάλυμα δειγμάτων
	¨ Diluente de amostra	