

**REF 10502** 

Glia-G











# **Instruction Manual**

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Manual Rev. No.	005 : 2014-01-15

#### 1 Intended Use

**Glia-G** is a solid phase enzyme immunoassay employing highly purified alpha-Gliadin for the quantitative detection of IgG antibodies against Gliadin in human serum.

The assay is a tool in the diagnosis of celiac disease (gluten-sensitive enteropathy).

### 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. As celiac disease is caused by the uptake of gluten, consequently a gluten-free diet cures the disease completely and thus has to be maintained for life-time. Renewed consumption of Gliadin 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. The incidence rates range from 1 in 4000 to 1 in 300 in european countries.

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. tTG has been identified as the major target antigen of EMA, antibodies binding to endomysium (extracellular constituent of smooth muscle) in indirect immunofluorescence test (IFT), 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. 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, thus being missed by IgA subclass tests.

Antibodies to Gliadin may be the only serological marker in neonatals, as anti-tTG and EMA autoantibodies are not present at this age. Consequently anti-Gliadin antibodies are the earliest serological marker for pediatricians when diagnosing celiac disease..

### Principle of the test

Serum samples diluted 1:101 are incubated in the microplates coated with the specific antigen. Patient's antibodies, if present in the specimen, bind to the antigen. The unbound fraction is washed off in the following step. Afterwards anti-human immunoglobulins conjugated to horseradish peroxidase (conjugate) are incubated and react with the antigen-antibody complex of the samples in the microplates. Unbound conjugate is washed off in the following step. Addition of TMB-substrate generates an enzymatic colorimetric (blue) reaction, which is stopped by diluted acid (color changes to yellow). The intensity of color formation from the chromogen is a function of the amount of conjugate bound to the antigen-antibody complex and this is proportional to the initial concentration of the respective antibodies in the patient sample.



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#### 3 **Kit Contents**

Quantity  1 x 20ml	Cap	Solution color	Description / Contents
1 x 20ml			
1 / 201111	White	Yellow	5 x concentrated Tris, sodium chloride (NaCl), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
1 X 20ml	White	Green	50 x concentrated Tris, NaCl, Tween 20, sodium azide < 0.1% (preservative)
<u>'</u>	REA	ADY TO USE	
Quantity	Cap color	Solution color	Description / Contents
1 x 1.5ml	Green	Colorless	Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
1 x 1.5ml	Red	Yellow	Human serum (diluted), bovine serum albumin (BSA), sodium azide < 0.1% (preservative)
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)
1 x 15ml	Blue	Blue	Containing: Anti-human immunoglobulins conjugated to horseradish peroxidase, bovine serum albumin (BSA)
1 x 15ml	Black	Colorless	Stabilized tetramethylbenzidine and hydrogen peroxide (TMB/H <sub>2</sub> O <sub>2</sub> )
1 x 15ml	White	Colorless	1M Hydrochloric Acid
12 x 8 well strips	N/A	N/A	With breakaway microwells. Refer to paragraph 1 for coating.
	Quantity  1 x 1.5ml  1 x 1.5ml  6 x 1.5ml  1 x 15ml  1 x 15ml  1 x 15ml  1 x 15ml  1 x 8 well	Quantity Cap color  1 x 1.5ml Green  1 x 1.5ml Red  6 x 1.5ml White  1 x 15ml Blue  1 x 15ml Black  1 x 15ml White	READY TO USE  Quantity  Cap color  1 x 1.5ml  Green  Colorless  1 x 1.5ml  Red  Yellow  6 x 1.5ml  White  Yellow*  1 x 15ml  Blue  Blue  1 x 15ml  Black  Colorless  1 x 15ml  White  Colorless  1 x 15ml  N/A

#### 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.).

#### Storage and Shelf Life 4

Store all reagents and the microplate at 2-8°C/35-46°F, in their original containers. Once prepared, reconstituted solutions are stable at 2-8°C/35-46°F for at least 1 month. Reagents and the microplate shall be used within the expiry date indicated on each component, only. Avoid intense exposure of TMB solution to light. Store microplates in designated foil, including the desiccant, and seal tightly.



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### 5 Precautions of Use

#### 5.1 Health hazard data

THIS PRODUCT IS FOR IN VITRO DIAGNOSTIC USE ONLY. Thus, only staff trained and specially advised in methods of in vitro diagnostics may perform the kit. Although this product is not considered particularly toxic or dangerous in conditions of the intended use, refer to the following for maximum safety:

#### Recommendations and precautions

This kit contains potentially hazardous components. Though kit reagents are not classified being irritant to eyes and skin we recommend to avoid contact with eyes and skin and wear disposable gloves.

WARNING! Calibrators, Controls and Buffers contain sodium azide (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.

The kit contains material of animal origin as stated in the table of contents, handle according to national requirements.

#### 5.2 General directions for use

In case that the product information, including the labeling, is defective or incorrect please contact the manufacturer or the supplier of the test kit.

Do not mix or substitute Controls, Calibrators, Conjugates or microplates from different lot numbers. This may lead to variations in the results.

Allow all components to reach room temperature (20-32°C/68-89.6°F) before use, mix well and follow the recommended incubation scheme for an optimum performance of the test.

Incubation: We recommend test performance at 30°C/86°F for automated systems.

Never expose components to higher temperature than 37°C/98.6°F.

Always pipette substrate solution with brand new tips only. Protect this reagent from light. Never pipette conjugate with tips used with other reagents prior.

A definite clinical diagnosis should not be based on the results of the performed test only, but should be made by the physician after all clinical and laboratory findings have been evaluated. The diagnosis is to be verified using different diagnostic methods.



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### 6 Sample Collection, Handling and Storage

Use preferentially freshly collected serum samples. Blood withdrawal must follow national requirements. Do not use icteric, lipemic, hemolysed or bacterially contaminated samples. Sera with particles should be cleared by low speed centrifugation (<1000 x g). Blood samples should be collected in clean, dry and empty tubes.

After separation, the serum samples should be used during the first 8h, respectively stored tightly closed at 2-8°C/35-46°F up to 48h, or frozen at -20°C/-4°F for longer periods

### 7 Assay Procedure

### 7.1 Preparations prior to starting

Dilute concentrated reagents:

Dilute the concentrated sample buffer 1:5 with distilled water (e.g. 20 ml plus 80 ml).

Dilute the concentrated wash buffer 1:50 with distilled water (e.g. 20 ml plus 980 ml).

To avoid mistakes we suggest to mark the cap of the different calibrators.

#### Samples:

Dilute serum samples 1:101 with sample buffer (1x)

e.g. 1000 µl sample buffer (1x) + 10 µl serum. Mix well!

#### Washing:

Prepare 20 ml of diluted wash buffer (1x) per 8 wells or 200 ml for 96 wells

e.g. 4 ml concentrate plus 196 ml distilled water.

#### **Automated washing:**

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

### Manual washing:

Discard liquid from wells by inverting the plate. Knock the microwell frame with wells downside vigorously on clean adsorbent paper. Pipette 300 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).



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# 7.2 Pipetting Scheme

We suggest pipetting calibrators, controls and samples as follows:

### For QUANTITATIVE interpretation

	1	2	3	4
Α	Cal A	Cal E	P1	
В	Cal A	Cal E	P1	
С	Cal B	Cal F	P2	
D	Cal B	Cal F	P2	
E	Cal C	PC	P3	
F	Cal C	PC	P3	
G	Cal D	NC		
Н	Cal D	NC		

CalA: calibrator A CalD: calibrator D PC: positive control P1: patient 1
CalB: calibrator B CalE: calibrator E NC: negative control P2: patient 2
CalC: calibrator C CalF: calibrator F 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 interpretation results desired:		
	CONTROLS & SAMPLES		
3.	Pipette into the designated wells as described in chapter 7.2 above, 100 µl of either:  Calibrators (CAL.A to CAL.F)  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.	WashB  → Wash 3x with 300 µl washing buffer (diluted 1:50).		



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



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## 8 Quantitative Interpretation

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

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

### Example of a standard curve

Do NOT use this example for interpreting patient's result

Calibrators IgG	OD 450/620 nm	CV % (Variation)
0 U/ml	0.059	1.4
3 U/ml	0.182	1.2
10 U/ml	0.323	2.2
30 U/ml	0.667	0.7
100 U/ml	1.316	0.9
300 U/ml	2.203	0.1

#### Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	0.654/0.633	0.644	27.6
P 02	1.284/1.263	1.274	89.9

Samples above the highest calibrator range should be reported as >Max. They should be diluted as appropriate and re-assayed. Samples below calibrator range should be reported as < Min.

For lot specific data, see enclosed quality control leaflet. Medical laboratories might perform an in-house quality control by using own controls and/or internal pooled sera, as foreseen by national regulations.

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

In case that the values of the controls do not meet the criteria the test is invalid and has to be repeated.

The following technical issues should be verified: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, photometer, incubation conditions and washing methods.

If the items tested show aberrant values or any kind of deviation or that the validation criteria are not met without explicable cause please contact the manufacturer or the supplier of the test kit.



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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 Glia-G gave an analytical sensivity of 1.0 U/ml.

### 10.2 Specificity and sensitivity

The microplates are coated with highly purified alpha gliadin. No crossreactivities to other autoantigens have been found. Positive IgG and IgA anti-gliadin antibodies give a diagnostic specificity of 96-97% for celiac disease. The diagnostic sensitivity for anti-gliadin antibodies for IgG and IgA ranges between 96 and 100%.

### 10.3 Linearity

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

Sample No.	Dilution Factor	Measured (U/ml)	Expected (U/ml)	Recovery (%)
1	1 / 100	51.6	53.0	97.3
	1 / 200	26.1	26.5	98.5
	1 / 400	12.4	13.3	93.2
	1 / 800	6.0	6.6	90.9
2	1 / 100	114.0	110.0	103.6
	1 / 200	51.4	55.0	93.5
	1 / 400	25.7	27.5	93.5
	1 / 800	13.4	13.8	97.1



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#### 10.4 Precision

To determine the precision of the assay, the variability (intra and inter-assay) was assessed by examining its reproducibility on three serum samples selected to represent a range over the standard curve.

Ir	ntra-assay	
Sample No.	Mean (U/ml)	CV (%)
1	89.6	4.67
2	89.8	3.61
3	45.4	2.11

Inter-assay		
Sample No.	Mean (U/ml)	CV (%)
1	83.7	4.43
2	98.5	4.56
3	43.5	2.37

### 10.5 Calibration

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

#### 11 Literature

**Dietrich W, Ehnis T, Bauer M, Donner P, Volta U, Riecken EO, Schuppan D**. Identification of tissue transglutaminase as the autoantigen of celiac disease. Nat Med 1997; 3: 797-801.

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Recupero   Recupero   Recuperado   Recuperado   Recuperado   Recuperado   Recuperado   Recuperacão   Recuperação   Recuperação   Recuperação   Recuperação   Conjugate   Conjugate   Conjugado   Roujugato   Roujugado   Ro	CON +	"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore	" Control Positivo " Θετικός ορός ελέγχου  " Negative Control " Control Negativo " Αρνητικός ορός ελέγχου " Calibrator
Recupero   Recuperado   Recu	CON +	"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon	"Control Positivo "Θετικός ορός ελέγχου "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου "Calibrator "Calibrador
Corrélation   Recuperado   Vividedrifindung   Recuperado   Vividedrifindung   Recuperado   Re	CON +  CON -  CAL	"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator	"Control Positivo "Θετικός ορός ελέγχου "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου "Calibrator "Calibrador
* Recuperacão         Conjugato       * Conjugato         * Conjugado       * Σύζευγμα         * Konjugat       * Σύζευγμα         * Microplaca * Conjugado         * Microplaca * Suchichite de incrotiter plate         * Microplaca sensibilisée       * Microplaca sensibilizada         * Beschichtete Mikrotiterplatte       * Emkαλυμμένη μικροπλάκα         * Microplaca revestida       * Wash buffer         * Tampone di lavaggio       * Wash buffer         * Tampon de Lavage       * Solución de lavado         * Waschpuffer       * Pυθμιστικό διάλυμα πλύσης         * Solución de lavagem       * Substrate buffer         * Substrat       * Tampón sustrato         * Substrate       * Pυθμιστικό διάλυμα υποστρώματος         * Substrato       * Pυθμιστικό διάλυμα υποστρώματος         * Substrato       * Stop solution         * Solución de parada       * Stopreagenz         * Solución de parada       * Aντιδραστήριο διακοτής αντίδρασης         * Solución de paragem       * Sample buffer         * Tampon Echantillons       * Tampón Muestras         * Puθμιστικό διάλυμα δειγμάτων	CON +  CON -  CAL	"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador	"Control Positivo "Θετικός ορός ελέγχου  "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου  "Calibrator "Calibrador "Αντιδραστήριο βαθμονόμησης
* Recuperacão         Conjugato       * Conjugato         * Conjugado       * Σύζευγμα         * Konjugat       * Σύζευγμα         * Microplaca * Conjugado         * Microplaca * Suchichite de incrotiter plate         * Microplaca sensibilisée       * Microplaca sensibilizada         * Beschichtete Mikrotiterplatte       * Emkαλυμμένη μικροπλάκα         * Microplaca revestida       * Wash buffer         * Tampone di lavaggio       * Wash buffer         * Tampon de Lavage       * Solución de lavado         * Waschpuffer       * Pυθμιστικό διάλυμα πλύσης         * Solución de lavagem       * Substrate buffer         * Substrat       * Tampón sustrato         * Substrate       * Pυθμιστικό διάλυμα υποστρώματος         * Substrato       * Pυθμιστικό διάλυμα υποστρώματος         * Substrato       * Stop solution         * Solución de parada       * Stopreagenz         * Solución de parada       * Aντιδραστήριο διακοτής αντίδρασης         * Solución de paragem       * Sample buffer         * Tampon Echantillons       * Tampón Muestras         * Puθμιστικό διάλυμα δειγμάτων		"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero	"Control Positivo "Θετικός ορός ελέγχου  "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου  "Calibrator "Calibrator "Calibrador "Αντιδραστήριο βαθμονόμησης "Recovery
CONJ  Conjugato Conjugat Conjugat Conjugat Conjugado  Micropiastra rivestita Micropiastra rivestita Micropiastra rivestita Micropiaca sensibilisée Beschichtete Mikrotiterplatte Micropiaca revestida  Tampone di lavaggio Tampon de Lavage Solución de lavado Waschpuffer Solución de lavado  Tampone substrato Substrate		"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corrélation	"Control Positivo "Θετικός ορός ελέγχου  "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου  "Calibrator "Calibrator "Aντιδραστήριο βαθμονόμησης  "Recovery "Recuperado
CONJ  Conjugé Konjugat Conjugado  Micropiastra rivestita Microplacue sensibilisée Beschichtete Mikrotiterplatte Microplaca revestida  Tampone di lavaggio  Tampon de Lavage Solucián de lavado  Solucián de lavado  Tampone substrato  Substrate Substrate Substrate  Reagente bloccante Solucián de parada  Reagente bloccante Solucián de parada  Solucián de parada  Tampone campione  Tampone campione  Tampone campione  Tampone Muestras  Tampón Muestras  Conjugádo  Túcγεμγμα  Conjugado  Túcγεμγμα  Conjugado  Túcγεμγμα  Conjugado  Túcγεμγμα  Conjugado  Túcγεμγμα  Conjugado  Coated microtiter plate  Conjugado  Coated microtiter plate  Coated microtiter plate  Conjugado  Coated microtiter plate  Coated microtite Plate  Coated micr		"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corrélation "Wiederfindung	"Control Positivo "Θετικός ορός ελέγχου  "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου  "Calibrator "Calibrator "Aντιδραστήριο βαθμονόμησης  "Recovery "Recuperado
"Conjugado "Micropiastra rivestita "Coated microtiter plate "Micropiastra rivestita" "Erπκαλυμμένη μικροπλάκα "Beschichtete Mikrotiterplatte "Eπκαλυμμένη μικροπλάκα "Microplaca revestida "Tampone di lavaggio "Wash buffer "Tampon de Lavage "Solución de lavado "Waschpuffer "Pυθμιστικό διάλυμα πλύσης "Solucão de lavagem "Tampone substrato "Substrate buffer "Substrate buffer "Substrate "Tampón sustrato "Substratio" "Substratio" "Reagente bloccante "Solución de parada "Stopreagenz "Aντιδραστήριο διακοπής αντίδρασης "Solucão de paragem "Tampone campione "Sample buffer "Tampón Muestras "Pυθμιστικό διάλυμα δειγμάτων		"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Recupero "Corrélation "Wiederfindung "Recuperação	"Control Positivo "Θετικός ορός ελέγχου  "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου  "Calibrator "Calibrador "Αντιδραστήριο βαθμονόμησης  "Recovery "Recuperado "Ανάκτηση
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MP  Microplastra rivestita  Microplaque sensibilisée  Beschichtete Mikrotiterplatte  Microplaca revestida  Tampone di lavaggio  Tampon de Lavage  Wash buffer  Tampon de Lavage  Waschpuffer  Solucão de lavagem  Tampon substrato  Tampon substrato  Substrate  Substrate  Substrate  Substrate  Substrate  Caude πίστομας sensibilizada  "Επικαλυμμένη μικροπλάκα  "Wash buffer  "Vash buffer  "Σουισίο de lavado  "Waschpuffer  "Solucão de lavagem  "Tampon substrato  "Tampon substrato  "Substrate  "Tampón sustrato  "Substrate  "Substrate  "Substrate  "Pυθμιστικό διάλυμα υποστρώματος  "Substrato  "Reagente bloccante  "Solución de parada  "Stopreagenz  "Solución de parada  "Stopreagenz  "Solucão de paragem  "Tampon campione  "Tampon campione  "Tampon Echantillons  "Tampón Muestras  "Pυθμιστικό διάλυμα δειγμάτων	RC	"Contrôle Positif "Positiv Kontrolle "Controlo positivo "Controllo negativo "Contrôle Négatif "Negativ Kontrolle "Controlo negativo "Calibratore "Etalon "Kalibrator "Calibrador "Calibrador "Recupero "Corrélation "Wiederfindung "Recuperacão "Coniugato "Conjugé	"Control Positivo "Θετικός ορός ελέγχου  "Negative Control "Control Negativo "Αρνητικός ορός ελέγχου  "Calibrator "Calibrador "Αντιδραστήριο βαθμονόμησης  "Recovery "Recuperado "Ανάκτηση  "Conjugate "Conjugado
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