COSMO BIO CO., LTD.

User's Manual

HPV IgG ELISA

Enzyme Immunoassay for the determination of IgG antibodies to Human Papilloma Virus in human serum and plasma

RUO

REF EIA-4907

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Please use only the valid version of the package insert provided with the kit.
Verwenden Sie nur die jeweils gültige, im Testkit enthaltene, Arbeitsanleitung.
Si prega di usare la versione valida dell'inserto del pacco a disposizione con il kit.
Por favor, se usa solo la version valida de la metodico técnico incluido aqui en el kit.

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For Research Use Only. Not for in vitro diagnostic use

1 INTENDED USE

Enzyme ImmunoAssay (ELISA) for the semi-quantitative determination of IgG class antibodies to Human Papilloma Virus (or HPV) in human plasma and sera.

The product is supplied for research purpose only. It is not for use in the diagnosis or for the follow-up of patients administered with the vaccines containing HPV antigens.

2 INTRODUCTION

Human Papilloma Viruses are double stranded DNA organisms, without envelope, bearing to the group of Papovavirus.

HPV infects epithelial cells and are associated with benign and malign lesions as papillomas, condilomas and carcinomas.

Human Papilloma Viruses are pretty heterogenic and are classified in several types that include high-risk oncogenic types (16,18,31,33,35,39,45,51,52,56,58,59,68) and low risk non oncogenic types. Synthetic antigens have been recently used to produce vaccines able to protect against infections due to the most carcinogenic strains of HPV, whose distribution has started in many countries of the world and whose real efficacy as vaccine is under field investigation.

3 PRINCIPLE OF THE TEST

Microplates are coated with recombinant VLP's derived from HPV Type 6, 11, 16 e 18.

In the 1st incubation, the solid phase is treated with diluted samples and anti-HPV IgG are captured, if present, by the antigens. After washing out all the other components of the sample, in the 2nd incubation bound anti-HPV IgG are detected by the addition of anti hIgG antibody, labeled with peroxidase (HRP).

The enzyme captured on the solid phase, acting on the substrate/chromogen mixture, generates an optical signal that is proportional to the amount of anti-HPV IgG antibodies present in the sample.

A cut-off value turns the measured optical densities into positive or negative results.

4 COMPONENTS

Each kit contains sufficient reagents to perform 96 tests.

1. **Microplate: [MICROPLATE]**
   12 strips x 8 breakable microwells coated with recombinant VLP's derived from HPV Type 6, 11, 16 e 18. Plates are sealed into a bag with desiccant. Allow the microplate to reach room temperature before opening; reseal unused strips in the bag with desiccant and store at 4°C.
2. **Negative Control: [CONTOL -]**
   1 x 2.0 mL/vial. Ready to use and pale yellow color coded.
   Contains human serum negative for IgG anti HPV, 2% casein, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.1% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives.
3. **Positive Control**: **[CONTROL +]**
   1 x 2.0 mL/vial. Ready to use and dark green color coded.
   Contains human serum positive for IgG anti HPV, 2% casein, 10 mM Na-citrate buffer pH 6.0 ± 0.1, 0.1% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives. .
4. **Wash buffer** concentrate, 20X **[WASHBUF 20X]**
   1 x 60 mL/bottle. 20x concentrated solution. Once diluted, the wash solution contains 10 mM phosphate buffer pH 7.0+/-0.2, 0.05% Tween 20 and 0.05% Kathon GC.
5. **Enzyme Conjugate** : **[CONJ]**
   1x16 mL/vial. Ready to use and red colour coded.
   It contains Horseradish peroxidase conjugated polyclonal antibodies to human IgG, 5% BSA, 10 mM Tris buffer pH 6.8+/-0.1, 0.1% Kathon GC and 0.02% gentamicine sulphate as preservatives.
6. **Chromogen/Substrate**: **[SUBS TMB]**
   1 x 16 mL/vial. It contains 50 mM citrate-phosphate buffer pH 3.5-3.8, 4% dimethylsulphoxide, 0.03% tetra-methyl-benzidine (or TMB) and 0.02% hydrogen peroxide (or H_2O_2).
   Note: To be stored protected from light as sensitive to strong illumination.
7. **Sulphuric Acid**: **[H2SO4 0.3M]**
   1 x 15 mL/vial. It contains 0.3 M H_2SO_4 solution. *Attention !: Irritant (Xi R36/38; S2/26/30)*
8. **Specimen Diluent**: **[DILSPE]**
   2 x 60mL/vial. It contains 2% casein, 10 mM Na-citrate buffer pH 6.0 +/-0.1, 0.1% Tween 20, 0.09% Na-azide and 0.1% Kathon GC as preservatives.
   To be used to dilute the sample.
9. **Plate sealing foils** n°2
10. **Package insert** n°1

5 MATERIALS REQUIRED BUT NOT PROVIDED

1. Calibrated Micropipettes (1000, 100 and 10 µL and disposable plastic tips.
2. EIA grade water (bidistilled or deionised, charcoal treated to remove oxidizing chemicals used as disinfectants).
3. Timer with 60 minute range or higher.
4. Absorbent paper tissues.
5. Calibrated ELISA microplate thermostatic incubator (dry or wet) set at +37°C (± 0.5°C tolerance).
6. Calibrated ELISA microwell reader with 450nm (reading) and possibly with 620 - 630nm (blanking) filters.
7. Calibrated ELISA microplate washer.
8. Vortex or similar mixing tools.

6 WARNINGS AND PRECAUTIONS

For Research Use Only. Not for in vitro diagnostic use

1. The kit has to be used by skilled and properly trained technical personnel only, under the supervision of a medical doctor responsible of the laboratory.
2. All the personnel involved in performing the assay have to wear protective laboratory clothes, talc-free gloves and glasses. The use of any sharp (needles) or cutting (blades) devices should be avoided. All the personnel involved should be trained in biosafety procedures, as recommended by the Center for Disease Control, Atlanta, U.S. and reported in the National Institute of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
3. All the personnel involved in sample handling should be vaccinated for HBV and HAV, for which vaccines are available, safe and effective.
4. The laboratory environment should be controlled so as to avoid contaminants such as dust or air-born microbial agents, when opening kit vials and microplates and when performing the test. Protect the Chromogen (TMB) from strong light and avoid vibration of the bench surface where the test is undertaken.
5. Upon receipt, store the kit at 2°C - 8°C into a temperature controlled refrigerator or cold room.
6. Do not interchange components between different lots of the kits. It is recommended that components between two kits of the same lot should not be interchanged.
7. Check that the reagents are clear and do not contain visible heavy particles or aggregates. If not, advise the laboratory supervisor to initiate the necessary procedures for kit replacement.
8. Avoid cross-contamination between serum/plasma samples by using disposable tips and changing them after each sample.
9. Avoid cross-contamination between kit reagents by using disposable tips and changing them between the use of each one.
10. Do not use the kit after the expiration date stated on the external container and internal (vials) labels. A study conducted on an opened kit did not pointed out any relevant loss of activity up to six 6 uses of the device and up to 6 months.
11. Treat all specimens as potentially infective. All human serum specimens should be handled at Biosafety Level 2, as recommended by the Center for Disease Control, Atlanta, U.S. in compliance with what reported in the Institutes of Health's publication: "Biosafety in Microbiological and Biomedical Laboratories", ed. 1984.
12. The use of disposable plastic-ware is recommended in the preparation of the liquid components or in transferring components into automated workstations, in order to avoid cross contamination.
13. Waste produced during the use of the kit has to be discarded in compliance with national directives and laws concerning laboratory waste of chemical and biological substances. In particular, liquid waste generated from the washing procedure, from residuals of controls and from samples has to be treated as potentially infective material and inactivated before waste. Suggested procedures of inactivation are treatment with a 10% final concentration of household bleach for 16-18 hrs or heat inactivation by autoclave at 121°C for 20 min..
14. Accidental spills from samples and operations have to be adsorbed with paper tissues soaked with household bleach and then with water. Tissues should then be discarded in proper containers designated for laboratory/hospital waste.
15. The Sulphuric Acid is an irritant. In case of spills, wash the surface with plenty of water
16. Other waste materials generated from the use of the kit (example: tips used for samples and controls, used microplates) should be handled as potentially infective and disposed according to national directives and laws concerning laboratory wastes.

7 SPECIMEN: PREPARATION AND WARNINGS

1. Blood is drawn aseptically by venepuncture and *plasma or serum* is prepared using standard techniques of preparation of samples for clinical laboratory analysis.
   No influence has been observed in the preparation of the sample with citrate, EDTA and heparin.
2. Samples have to be clearly identified with codes or names in order to avoid misinterpretation of results. Bar code labeling and electronic reading is strongly recommended.
3. Haemolysed ("red") and visibly hyperlipemic ("milky") samples have to be discarded as they could generate false results. Samples containing residues of fibrin or heavy particles or microbial filaments and bodies should be discarded as they could give rise to false results.
4. Sera and plasma can be stored at +2°C - 8°C for u p to five days after collection. For longer storage periods, samples can be stored frozen at –20°C for several months. Any frozen samples should not be frozen/thawed more than once as this may generate particles that could affect the test result.
5. If particles are present, centrifuge at 2.000 rpm for 20 min or filter using 0.2-0.8 µ filters to clean up the sample for testing.

8 PREPARATION OF COMPONENTS AND WARNINGS

Microplate:

Allow the microplate to reach room temperature (about 1 hr) before opening the container. Check that the desiccant is not turned to dark green, indicating a defect of storage. In this case call DRG's customer service.

Unused strips have to be placed back into the aluminium pouch, in presence of desiccant supplied, firmly zipped and stored at +2°C - 8°C. When opened the first time, residual strips are stable till the indicator of humidity inside the desiccant bag turns from yellow to green.

Controls

Ready to use. Mix well on vortex before use.

Wash buffer concentrate:

The whole content of the concentrated solution has to be diluted 20x with bidistilled water and mixed gently end-over-end before use. During preparation avoid foaming as the presence of bubbles could impact on the efficiency of the washing cycles.

Note: Once diluted, the wash solution is stable for 1 week at +2°C - 8° C.

Enzyme Conjugate:

Ready to use. Mix well on vortex before use.

Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes.

If this component has to be transferred use only plastic, possibly sterile disposable containers.

Chromogen/Substrate:

Ready to use. Mix well on vortex before use.

Be careful not to contaminate the liquid with oxidizing chemicals, air-driven dust or microbes. Do not expose to strong illumination, oxidizing agents and metallic surfaces. If this component has to be transferred use only plastic, possible sterile disposable container

Sample Diluent

Ready to use component. Mix carefully on vortex before use.

Sulphuric Acid:

Ready to use. Mix well on vortex before use.

Legenda: R 36/38 = Irritating to eyes and skin.
S 2/26/30 = In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

9 INSTRUMENTS AND TOOLS USED IN COMBINATION WITH THE KIT

1. Micropipettes have to be calibrated to deliver the correct volume required by the assay and must be submitted to regular decontamination (household alcohol, 10% solution of bleach, hospital grade disinfectants) of those parts that could accidentally come in contact with the sample. They should also be regularly maintained in order to show a precision of 1% and a trueness of +/-2%. Decontamination of spills or residues of kit components should also be carried out regularly.
2. The ELISA incubator has to be set at +37°C (tolerance of +/-0.5°C) and regularly checked to ensure the correct temperature is maintained. Both dry incubators and water baths are suitable for the incubations, provided that the instrument is validated for the incubation of ELISA tests.
3. The ELISA washer is extremely important to the overall performances of the assay. The washer must be carefully validated and correctly optimised using the kit controls and reference panels, before using the kit for routine laboratory tests. Usually 4-5 washing cycles (aspiration + dispensation of 350 µL/well of washing solution = 1 cycle) are sufficient to ensure that the assay performs as expected.
   A soaking time of 20-30 seconds between cycles is suggested. In order to set correctly their number, it is recommended to run an assay with the kit controls and well characterized negative and positive reference samples, and check to match the values reported below in the section O “Internal quality Control”. Regular calibration of the volumes delivered by, and maintenance (decontamination and cleaning of needles) of the washer has to be carried out according to the instructions of the manufacturer.
4. Incubation times have a tolerance of +5%.
5. The ELISA microplate reader has to be equipped with a reading filter of 450nm and ideally with a second filter (620-630 nm) for blanking purposes. Its standard performances should be (a) bandwidth < 10 nm; (b) absorbance range from 0 to > 2.0; (c) linearity to > 2.0; repeatability > 1%.
   Blanking is carried out on the well identified in the section “Assay Procedure”.
   The optical system of the reader has to be calibrated regularly to ensure that the correct optical density is measured. It should be regularly maintained according to the manufacturer‘s instructions.
6. When using an ELISA automated work station, all critical steps (dispensation, incubation, washing, reading, data handling) have to be carefully set, calibrated, controlled and regularly serviced in order to match the values reported in the section “Internal quality Control”. The assay protocol has to be installed in the operating system of the unit and validated as for the washer and the reader. In addition, the liquid handling part of the station (dispensation and washing) has to be validated and correctly set. Particular attention must be paid to avoid carry over by the needles used for dispensing and for washing. This must be studied and controlled to minimize the possibility of contamination of adjacent wells. The use of ELISA automated work stations is recommended when the number of samples to be tested exceed 20-30 units per run.

10 PRE-ASSAY CONTROLS AND OPERATIONS

1. Check the expiration date of the kit printed on the external label (primary container). Do not use if expired.
2. Check that the liquid components are not contaminated by visible particles or aggregates.
3. Check that the Chromogen (TMB) is colourless or pale blue by aspirating a small volume of it with a sterile plastic pipette.
4. Check that no breakage occurred in transportation and no spillage of liquid is present inside the box (primary container). Check that the aluminium pouch, containing the microplate, is not punctured or damaged.
5. Dilute all the content of the 20x concentrated Wash Solution as described above.
6. Allow all the other components to reach room temperature (about 1 hr) and then mix gently on vortex all liquid reagents.
7. Set the ELISA incubator at +37°C and prepare the ELISA washer by priming with the diluted washing solution, according to the manufacturer’s instructions. Set the right number of washing cycles as found in the validation of the instrument for its use with the kit.
8. Check that the ELISA reader is turned on or ensure it will be turned on at least 20 minutes before reading.
9. If using an automated work station, turn on, check settings and be sure to use the right assay protocol.
10. Check that the micropipettes are set to the required volume.
11. Check that all the other equipment is available and ready to use.
12. In case of problems, do not proceed further with the test and advise the supervisor.

11 ASSAY PROCEDURE

The assay has to be carried out according to what reported below, taking care to maintain the same incubation time for all the samples in testing.

1. **Dilute samples 1:101** into a properly defined dilution tube (example: 1000 µL Sample Diluent + 10 µL sample). Do not dilute the Controls as they are ready to use. Mix carefully all the liquid components on vortex and then proceed as described below.
2. Place the required number of Microwells in the microwell holder. Leave A1 well empty for the operation of blanking.
3. Dispense 100 µL of Negative Control and of Positive Control in duplicate.
   Then dispense 100 µL of diluted samples in each properly identified well.
4. **Incubate the microplate for 60 min at +37°C.**

   Important note: Strips have to be sealed with the adhesive sealing foil, supplied, only when the test is carried out manually. Do not cover strips when using ELISA automatic instruments.
5. Wash the microplate with an automatic washer as reported previously (section 9.3).
6. Pipette 100 µL Enzyme Conjugate into each well, except the A1 well, and cover with the sealer.
   Check that this red coloured component has been dispensed in all the wells, except A1.

   Important note: Be careful not to touch the plastic inner surface of the well with the tip filled with the Enzyme Conjugate. Contamination might occur.
7. **Incubate the microplate for 60 min at +37°C.**
8. Wash microwells as in step 5.
9. Pipette 100 µL Chromogen/Substrate mixture into each well, the blank well included.
   Then **incubate the microplate at room temperature (18-24°C) for 20 minutes**.

   Important note: Do not expose to strong direct illumination. High background might be generated.
10. Pipette 100 µL Sulphuric Acid into all the wells using the same pipetting sequence as in step 9. Addition of acid will turn the positive control and the positive samples from blue to yellow.
11. Measure the colour intensity of the solution in each well, as described in section 9.5, at 450 nm filter (reading) and possibly at 620-630 nm (background subtraction), blanking the instrument on A1.

General Important notes:

1. If the second filter is not available ensure that no finger prints are present on the bottom of the microwell before reading at 450 nm. Finger prints could generate false positive results on reading.
2. Reading has to be carried out just after the addition of the Stop Solution and anyway not any longer than 20 minutes after its addition. Some self oxidation of the chromogen can occur leading to high background.

12 ASSAY SCHEME

Method	Operations
Controls	100 µL
Samples diluted 1:101	100 µL
1st incubation	**60 min**
Temperature	+37°C
Wash step	4-5 cycles
Enzyme conjugate	100 µL
2nd incubation	**60 min**
Temperature	+37°C
Wash step	4-5 cycles
TMB/H_2O_2	100 µL
3rd incubation	**20 min**
Temperature	r.t.
Sulphuric Acid	100 ul
Reading OD	450nm

An example of dispensation scheme is reported below:

Microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLK	S 4										
B	NC	S 5										
C	NC	S 6										
D	PC	S 7										
E	PC	S 8										
F	S 1	S 9										
G	S 2	S 10										
H	S 3	S 11										

Legenda: BLK = Blank, NC = Negative Control, PC = Positive Control, S = Sample

13 INTERNAL QUALITY CONTROL

A validation check is carried out on the controls and the calibrator any time the kit is used in order to verify whether the performances of the assay are as expected and required by the IVDD directive 98/79/EC.

Control that the following data are matched:

Check	Requirements
Blank well A1	< 0.100 OD 450 nm
Negative Control	< 0.150 OD 450 nm after blanking
Positive Control	> 0.500 OD 450 nm after blanking

If the results of the test match the requirements stated above, proceed to the next section. If they do not, do not proceed any further and operate as follows:

Problem	Check
Blank well > 0.100 OD450nm	1. that the Chromogen/Sustrate solution has not got contaminated during the assay
Negative Control > 0.150 OD450nm after blanking	1. that the washing procedure and the washer settings are as validated in the pre qualification study; 2. that the proper washing solution has been used and the washer has been primed with it before use; 3. that no mistake has been done in the assay procedure (dispensation of a positive calibrator instead of the negative one; 4. that no contamination of the negative calibrator or of their wells has occurred due spills of positive samples or the enzyme conjugate; 5. that micropipettes haven't got contaminated with positive samples or with the enzyme conjugate, 6. that the washer needles are not blocked or partially obstructed.
Positive Control < 0.500 OD450nm	1. that the procedure has been correctly executed; 2. that no mistake has been done in its distribution (dispensation of a wrong calibrator instead); 3. that the washing procedure and the washer settings are as validated in the pre qualification study; 4. that no external contamination of the positive control has occurred.

Should one of these problems have happened, after checking, report to the supervisor for further actions.

14 CUT-OFF CALCULATION

If data are valid, calculate the mean OD 450 nm value of the Negative Control (or NC) and then apply the following formulation to calculate the cut-off value:

NC + 0.250 = Cut-Off

Important Note:
When the calculation of results is made by an automatic work station, assure that the system has been loaded with the right formulation.

15 INTERPRETATION OF RESULTS

Samples with an OD 450 nm lower that the Cut-Off value are considered ***not reactive*** for IgG specific to the HPV antigens present in the vaccine.

Samples with an OD 450nm higher than the Cut-Off value are considered ***positive*** for IgG specific to the HPV antigens present in the vaccine..

In case the quantification of IgG present in positive samples is required to better monitor the immunological response to the vaccine in a prolonged time, calculate for each sample the value

OD Sample/Cut-Off (or S/Co)

that provide an index whose value is directly proportional to the content of IgG in the sample..

Important notes:

1. The product is not intended to provide any diagnosis of Human Papilloma Virus infection or active immulogical protection against HPV. The device provides only an indication about the presence, or not, of antibodies elicited specifically by the vaccination treatment, despite any therapeutically effect that such antibodies could have or not in protecting the vaccinated individual against HPV infection.
2. Other tests for HPV as PAP test and RT PCR assays should be carried out on patients suspected to bear a HPV infection.
3. Interpretation of results should be done under the supervision of the laboratory supervisor to reduce the risk of judgment errors and misinterpretations.
4. When test results are transmitted from the laboratory to another facility, attention must be paid to avoid erroneous data transfer.

16 PERFORMANCE CHARACTERISTICS

As no data were available on the presence of IgG to HPV specific VLPs so far ,as this test is pretty new, the evaluation of the kit **performances** has been first conducted on panels of female teenagers aging up to 14 years as IgG negative specimens to define a range of negativity, and then a random population of adult individuals to define a range of positivity due to natural HPV infection.

Finally the device was studied on a panel of female teenagers before and after the process of vaccination.

Reproducibility was studied on three samples of different IgG reactivity, examined in 16 replicates in three separate runs; the study has shown CV% values ranging 4-20% depending on the OD450nm readings.

The variability observed did not result in any sample misclassification.

17 LIMITATIONS

The product is for research use only.

The product is not intended to provide any diagnosis of Human Papilloma Virus infection or active immulogical protection against HPV.

The device provides only an indication about the presence, or not, of antibodies elicited specifically by the vaccination treatment, despite any therapeutically effect that such antibodies could have or not in protecting the vaccinated individual against HPV infection.

18 REFERENCES

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3. Wang X et al.. Journal of General Virology (2005), vol.86, pp.65-73.
4. Coissard CJ et al.. Modern Pathology (2005), vol.18, pp.1606-1609.
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SYMBOLS USED WITH DRG ASSAYS

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
				
	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by				
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..