Genie™ Fast HIV 1/2

25 tests 72327

RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF ANTI-HIV-1 AND ANTI-HIV-2 ANTIBODIES IN SERUM, PLASMA OR WHOLE HUMAN BLOOD

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IVD

Manufacturer's quality control

All products manufactured and marketed by Bio-Rad are covered by a quality assurance system from reception of raw materials to finished product marketing.
Each batch of finished products is subjected to quality control and is only marketed if it meets the acceptance criteria.
The documentation concerning production and testing of each batch is stored by our company.

BIO-RAD

CONTENTS

1. INTENDED USE

The fast test device uses the Immunochromatography (ICT or lateral migration) technique to detect anti-HIV-1 and anti-HIV-2 antibodies in human serum, plasma, venous blood and capillary blood.

2. CLINICAL VALUE

Acquired Immunodeficiency Syndrome (AIDS) is an infectious disease of viral origin, reflected in severe cellular immunodeficiency.

Two types of virus related to the lentivirus group have been isolated in lymphocytes of patients suffering from AIDS or its prodromes. The first, named HIV-1, was isolated in France, then the United States. The second, named HIV-2, was isolated in two patients of African origin and found to be responsible for a new AIDS focus in West Africa.

3. PRINCIPLE OF THE Genie™ Fast HIV 1/2

HIV-1 gp120, gp41 and HIV-2 gp36 recombinant antigens, conjugated to colloidal gold, are adsorbed at the base of a strip of nitrocellulose membrane.

HIV-1 and HIV-2 antigens are immobilised in the test zone (T).

Anti-HIV antibodies are immobilised in the control zone (C).

When the sample is deposited at the bottom of the strip, it starts migrating by capillary diffusion, rehydrating the antigen-conjugated gold.

In the presence of anti-HIV-1 and/or HIV-2 antibodies, these will bind to the conjugated antigens to form a particular complex which will be carried by the sample migration. This particular complex will continue to migrate as far as zone (T) and will be captured by the HIV-1 and HIV-2 antigens immobilised in this zone, to produce a visible red strip in zone (T). The excess antigen-conjugated gold will continue to migrate as far as zone (C), where it will be captured and aggregated by the anti-HIV antibodies to produce a red strip in zone (C), indicating the validity of the test (proof of sample migration).

In the absence of anti-HIV-1 or anti-HIV-2 antibodies in the sample, there will be no red strip in zone (T), but the antigen-conjugated gold will continue to migrate alone as far as zone (C), where it will be captured to produce a red strip indicating the validity of the test (proof of sample migration).

See Chapter 12: Results interpretation.

4. COMPOSITION OF THE KIT

LABELLING	TYPE OF REAGENTS	PRESENTATION 72327
Device	Nitrocellulose strip, the base of which contains recombinant HIV-1 and HIV-2 antigens conjugated to gold, HIV-1 and HIV-2 antigens in zone T and anti-HIV antibodies in zone C.	25 cassettes
Diluent	Diluent (for the whole blood protocol) Preservative: Sodium azide (<0.1%)	1 vial (5 ml)
Pipettes	Plastic pipettes for depositing serum, plasma and venous blood	50 pipettes

5. PRECAUTIONS

The quality of results depends on the extent to which the following good laboratory practices are respected:

- Before use, you must wait for 30 minutes for the reagents to stabilise at the laboratory temperature, if this is different from the storage temperature.
- Use the reagents in such a way as to prevent contamination.
- Use disposable equipment by preference.
- Once the pouch is open, do not leave the cassette in the open air for more than 20 minutes before depositing the sample.
- The waiting time between the last deposit (sample or diluent) and the reading, must not exceed 30 minutes.
- Use a new distribution cone or a new disposable pipette, provided in the kit, for each sample.
- Do not change the procedure.

6. HEALTH AND SAFETY INSTRUCTIONS

All the reagents in the kit are for use in "*in vitro*" diagnosis.
Wear disposable gloves when handling reagents.
Do not pipette with your mouth.
Because no method can absolutely guarantee the absence of HIV, Hepatitis B or C virus or other infectious agents, assume that these reagents, as well as the patient samples, are potentially infectious and handle them with the usual precautions.
Consider the equipment in direct contact with the samples and reagents to be contaminated also and treat it as such.
Avoid splashing samples or the solution containing them.
Soiled surfaces will be cleaned with 10% dilute bleach.
The equipment used for cleaning must be thrown into a special contaminated waste container.

The samples, reagents of human origin and the equipment and contaminated products will be disposed of after decontamination:
- either by soaking in bleach at a final concentration of 10% sodium hypochlorite (1 volume of bleach per 10 volumes of contaminated liquid or water) for 30 minutes.
- or by autoclaving at 121°C for at least 2 hours.

Autoclaving at 121°C, for at least one hour, is the best method for deactivating HIV viruses and the hepatitis B virus.
- WARNING : DO NOT PUT SOLUTIONS CONTAINING SODIUM HYPOCHLORITE (BLEACH) INTO THE AUTOCLAVE.

Don't forget to neutralise and/or autoclave effluent solutions or any liquid containing biological samples before placing them in the sink.
Furthermore, chemicals must be handled and disposed of according to good laboratory practices.
Do not use expired reagents.
The safety data sheet is available on request.

7. MATERIAL NOT PROVIDED

Automatic or semi-automatic pipettes or multipipettes, adjustable or fixed, to measure and deposit the sample.
Lancet and pipette required for taking capillary samples.

8. REAGENTS

8.1 Cassette:

Each cassette is packaged in a sealed aluminium pouch.

8.2 Diluent for the venous or capillary blood protocol:

This diluent buffer is supplied in a dropper bottle.

8.3 Consumables:

Plastic pipettes (serum, plasma and venous blood).

9. STORAGE CONDITIONS - SHELF LIFE

The kit must be stored at +2-30°C. Every item in the Genie™ Fast HIV 1/2 kit stored at +2-30°C can be used until the expiry date noted on the box.
After opening the pouch, the cassette must be used within 20 minutes of this opening.
The bottle of diluent can be stored at +2-30°C, until the expiration date of the kit, even after its first use.

10. SAMPLE

Take a blood sample according to the usual method. The test must be performed on undiluted samples of serum, plasma, venous or capillary blood. Plasma and venous blood are collected with the following anticoagulants: EDTA-K2, Lithium Heparinate, ACD (Citrate-Dextrose).
Fibrin particles or aggregates in suspension may lead to false positive results.
Chemical treatments, heating or dilution of the blood may alter the results and give inappropriate results.
If the samples have to travel, pack them according to current regulations for transporting etiological agents.
Fresh samples can be stored at 2-8°C up to 7 days for serum and plasma and up to 3 days for whole venous blood, without interference on the negative or positive results.
Fresh serum and plasma can also be frozen and thawed up to 3 times, without interference on the negative or positive results.

Comment: DO NOT USE HYPERHEMOLYZED SERUM OR PLASMA - very pronounced hemolysis may affect test performance.
No interference has been shown in samples containing up to 100 mg/l of bilirubin or in lipemic samples containing up to 30 g/l of triolein and in hemolyzed samples containing up to 5 g/l of haemoglobin. Abnormally high albuminemia (100 g/l) can give false positive results.

11. ASSAY PROCEDURE

The procedure will be respected as follows:

11.1. Open the pouch and remove the cassette (the sample must be deposited within 20 minutes of opening the pouch).

11.2. Place the cassette on a flat, horizontal surface with the circular zone for sample deposit facing the operator.

11.3. Deposit the sample

a. **Plasma/Serum protocol:** Deposit 3 drops(*) of the sample in the circular sample zone, using the plastic pipette provided with the kit, or 80 µl using an automatic pipette.

b. **Venous Blood protocol:** Deposit 2 drops(*) of blood in the circular sample zone, using the plastic pipette provided with the kit or 80 µl of blood using an automatic pipette, then add 2 drops of diluent using the dropper bottle provided with the kit (~ 80 µl).

c. **Capillary Blood protocol:** According to the laboratory practice, use a fingerstick lancet and an appropriate plastic pipet (without anticoagulant) to collect blood by capillary action. Deposit 80 µL of capillary blood in the circular deposit zone on the device, then add 2 drops (~ 80 µL) of diluent using the dropper bottle provided with the kit.

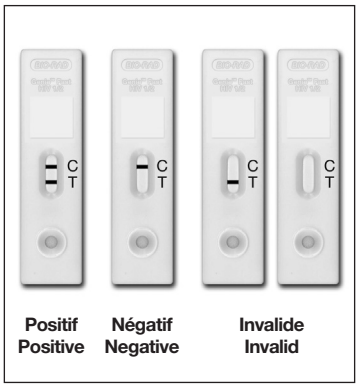
Avoid any excess sample or diluent flowing outside the circular deposit zone.

(*) the number of drops is defined according to the viscosity of the sample.

11.4. Reading

Visual reading takes place between 10 min. and 30 min. after the last deposit (sample or diluent).

12. RESULTS INTERPRETATION AND ANALYSIS



12.1 Test Validity:

The test validity can be read in the Control zone (C).

Serum/Plasma protocol: to validate the test, a red Control strip (C) must be present.

Venous and capillary blood protocol: to validate the test, a red Control strip (C) and a red circular sample deposit zone must be present.

If the validity conditions are nonconforming, the test is considered to be invalid, the cassette must be disposed of and the test repeated with a new cassette.

If red cells migrate into the Test zone (T), where they could interfere with interpreting negative or slightly positive samples, it is recommended to repeat the test.

12.2 Positive Result:

The appearance of a red strip (even of very low intensity) in the Test zone (T) after 10 to 30 minutes indicates the presence of anti-HIV-1 or HIV-2 antibodies.

You are recommended to wait for 10 minutes before reading the results (even if red strips appear quickly in the test zone), in order to confirm that the colouring is maintained, before declaring a positive result).

No positive result must be declared beyond 30 minutes.

Comment: Any red strip even observed faintly in the Test zone (T) must be considered and interpreted as a positive result.

12.3 Negative Result:

The absence of a red strip in the Test zone (T) after 30 minutes means that anti-HIV-1 or HIV-2 antibodies have not been detected.

However, this does not exclude the possibility of an early stage of HIV infection.

Comment: Never interpret beyond 30 minutes after the last deposit.

13. PERFORMANCE

The performance of Genie™ Fast HIV 1/2 has been evaluated on five different clinical sites by testing samples taken from blood donors, HIV positive patients and seroconversion panels.

13.1 Specificity studies

a) Blood donor population

- 2517 specimens from blood bank donors (1108 of serum, 708 of plasma and 701 of whole venous blood) were tested with Genie™ Fast HIV 1/2 reagent. Specificity was 99.5% (2505/2517) with a confidence interval (CI) of 95% from [99.2 to 99.7].

Donor specificity	Total number of specimens	Repeatable positives (RR)	Specificity RR (%)	CI 95 (%)
Serum (Gel, Act)	1108	5	**99.5** (1103/1108)	[98.9; 99.9]
Plasma (EK2, HeLi, ACD)	708	5	**99.3** (703/708)	[98.4; 99.8]
Whole venous blood (EK2, HeLi)	701	2	**99.7** (699/701)	[99.0; 100.0]
Total	**2517**	**12**	**99.5** (2505/2517)	**[99.2; 99.7]**

b) Population of hospitalised patients

- 1010 samples from patients not infected with HIV and taken from hospital complexes (428 of serum, 227 of plasma, 327 of whole venous blood and 28 of capillary blood paired with venous blood) were tested with Genie™ Fast HIV 1/2 reagent.
  Overall specificity was 99.5% (1005/1010), CI 95% [98.9 - 99.8%] with 99.3% (425/428) and 99.1% (225/227) for serum and plasma respectively, 100% for whole venous blood (327/327) and capillary blood (28/28).

  Comment: The whole venous blood and capillary blood from the same 28 patients gave equivalent results.

Specificity for hospitalised patients	Total number of specimens	Repeatable positives (RR)	Specificity RR (%)	CI 95 (%)
Serum (Gel)	428	3	**99.3** (425/428)	[98.0; 99.9]
Plasma (EK2, HeLi)	227	2	**99.1** (225/227)	[96.9; 99.9]
Whole venous blood (EK2, HeLi)	327	0	**100** (327/327)	[98.9; 100]
Capillary blood	28 (*)	0	**100** (28/28)	[87.7; 100.0]
Total	**1010**	**5**	**99.5** (1005/1010)	**[98.9; 99.8]**

(*) specimens of capillary blood paired with whole venous blood from 28 patients.

c) Cross reactions

- Specificity was also evaluated on samples from 200 pregnant women and 107 patients suffering from pathologies not linked to HIV infection (7 dengue, 3 filariasis; 5 bilharzia; 4 leishmaniosis; 11 lupus erythematous; 10 malaria; 10 rheumatoid factors; 9 influenza; 8 ANA (anti-nuclear factors); 10 hepatitis A; 10 hepatitis B; 10 hepatitis C; 10 HTLV). Specificity was found to be 100%, CI95% [98.2 – 100] for the pregnant women (200/200) and 97.2%, CI95% [92.0 – 100] for the other pathologies (104/107) with three repeatable positive results (2 cases of malaria and 1 case of hepatitis B).

13.2 Sensitivity studies

a) Samples of HIV-1 positive patients

- 1050 samples from patients known to be infected with HIV-1 (385 of serum, 301 of plasma, 338 of whole venous blood and 26 of capillary blood paired with venous blood) were tested with Genie™ Fast HIV 1/2 reagent.
  Sensitivity was **100%** (1050/1050), CI95 [99.7 -100%] for the four types of samples (serum, plasma, whole venous blood and capillary blood).

Comment: The whole venous blood and capillary blood from the same 26 patients gave equivalent results.

Sensitivity for HIV-1 patients	Total number of specimens	Number of reactive samples	Sensitivity (%)	CI 95 (%)
Serum (Gel)	385	385	100 (385/385)	[99.1; 100]
Plasma (EK2, HeLi)	301	301	100 (301/301)	[98.8; 100]
Whole venous blood (EK2, HeLi)	338	338	100 (338/338)	[98.9; 100]
Capillary blood	26 (*)	26	100 (26/26)	[86.3; 100]
Total	**1050**	**1050**	**100** (1050/1050)	**[99.7; 100]**

(*) specimens of capillary blood paired with whole venous blood from 26 patients.

b) Samples from HIV-2 positive patients

- 101 serums and 8 fresh plasma from patients treated or not for their HIV-2 infection, tested with the Genie™ Fast HIV 1/2 reagent were all found to be positive.
  Sensitivity was **100%** (109/109) with a confidence interval of 95% [96.7; 100].

Sensitivity for HIV-2 patients	Total number of specimens	Number of reactive samples	Sensitivity (%)	CI 95 (%)
Serum	109	109	**100** (109/109)	[96.7; 100]

c) Samples from genotyped HIV-1 positive patients

- 154 serums from patients infected by an HIV-1 strain of known genotype (see table below), tested with Genie™ Fast HIV 1/2 reagent were all found to be positive, giving a sensitivity of 100% (154/154) with a confidence interval of 95% [97.6- 100].

Genotype	Total number of specimens	Number of reactive samples
CRF01	9	9
CRF02	20	20
CRF05	1	1
CRF06	7	7
CRF08	1	1
CRF09	5	5
CRF10	1	1
CRF11	6	6
CRF12	1	1
CRF13	2	2
CRF14	6	6
CRF15	3	3
CRF19	3	3
CRF27	1	1
Subtype A	12	12
Subtype B	21	21
Subtype C	9	9
Subtype D	9	9
Subtype F	9	9
Subtype G	12	12
Subtype H	6	6
Subtype J	4	4
Subtype K	1	1
Group O	5	5
Total	**154**	**154**
Sensitivity: 100%		

b) Fresh samples from HIV-1 and HIV-2 positive patients

- 113 fresh serum (SST2 gel tubes), 216 fresh plasma (EDTA-K2/ Lithium Heparinate), 243 fresh whole venous blood (EDTA-K2/ Lithium Heparinate) and 26 fresh capillary blood samples, (taken from ≤ 1 day) from patients known to be infected with HIV-1 and 8 fresh plasma (EDTA-K2) from patients known to be infected with HIV-2 were tested with Genie™ Fast HIV 1/2 reagent. All the samples were found to be positive, giving a sensitivity of **100%** no matter what the type of sample.

Sensitivity for Fresh HIV-1 and HIV-2 positive samples (≤ 1 day)	**Total number of specimens**	**Number of reactive samples**	**Sensitivity (%)**
Serum HIV-1 (SST2 Gel)	113	113	**100** (113/113)
Plasma HIV-1 (EK2, HeLi) and HIV-2 (EK2)	216 8	224	**100** (224/224)
Whole venous blood HIV-1 (EK2, HeLi)	243	243	**100** (243/243)
Capillary blood HIV-1	26	26	**100** (26/26)
Total	606	606	100 **(606/606)**

e) Sensitivity in seroconversion panels

- 31 commercial seroconversion panels, of which 30 included 65 early seroconversion points (*), and further more 40 samples representing a per-seroconversion stage (*) were tested with Genie™ Fast HIV 1/2 reagent and a CE marked comparative rapid test.

Panels tested	**Total number of specimens**	**Number of positive samples with CE marked reference rapid test**	**Number of positive samples with Genie™ Fast HIV 1/2**
Seroconversion (31 panels)	118	80	83 (**)
Early seroconversion (30 panels)	65	30	33 (**)
Per-seroconversion	40	37	37

(*) As defined in the Common Technical Specifications (CTS)
(**) In 3 seroconversion panels, the first positive point was detected at least one point earlier on Genie™ Fast HIV 1/2 and in 1 seroconversion panel, the first positive point was detected one point later than with the reference rapid test.

f) Hook effect

- No hook effect was observed with the Genie™ Fast HIV 1/2 reagent with a series of dilutions of samples strongly positive in HIV-1 and HIV-2 antibodies.

13.3 Reproducibility studies

a) Inter-assay reproducibility

- The inter-assay reproducibility study was performed with 7 different samples of serum (1 HIV-negative, 3 weak, moderate and strong HIV-1, 3 weak, moderate and strong HIV-2, and 5 different samples of whole venous blood (1 HIV-negative, 2 weak and strong HIV-1, 2 weak and strong HIV-2.
  The analysis of samples using Genie™ Fast HIV 1/2 reagent was performed twice a day for 5 days (10 replicates) for the serum or once a day in triplicate for 3 days (9 replicates) for whole venous blood.
  For all the samples tested, both negative and positive, no discordance was found between replicates.

b) Inter-operator reproducibility

- The study of inter-operator reproducibility was performed with 5 samples of whole venous blood (1 HIV-negative, 2 weak and moderate HIV-1, 2 weak and moderate HIV-2) tested in triplicate by three different operators on two batches of reagent.
  For all the samples tested, both negative and positive, no discordance was found between the three operators.

c) Inter-batch reproducibility

- The inter-batch reproducibility study was performed on three batches, with 5 samples of whole venous blood (1 HIV-negative, 2 weak and moderate HIV-1, 2 weak and moderate HIV-2) and 7 plasma samples (1 HIV-negative, 2 weak and moderate HIV-1, 4 weak, moderate and strong HIV-2) tested in triplicate on each of the three batches.
  For all the samples tested, both negative and positive, no discordance was found between the three batches.

14. TEST LIMITS

It is recommended to retest any sample initially found to be positive, in accordance with the criteria described in chapter 12.
Any sample found to be reproducibly positive must be confirmed using an appropriate method (Western-Blot or equivalent) to prove the presence of anti-HIV antibodies.

A negative result means that the sample tested does not contain anti-HIV antibodies detectable by the Genie™ Fast HIV 1/2 test.
Such a result does not exclude the possibility of HIV-1 or HIV-2 infection. Indeed low levels of antibodies may not be detected if the infection was recent.
The variability of HIV-1 (group M, group O) and HIV-2 means that false negative reactions cannot be excluded.
No known method can guarantee that the HIV virus is absent.
See also the limits linked to samples, described in paragraph 10.

15. BIBLIOGRAPHY

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(GB) - CE marking (European directive 98/79/CE on *in vitro* diagnostic medical devices)
(FR) - Marquage CE (Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro*)
(ES) - Marcado CE (Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico *in vitro*)
(IT) - Marchiatura CE (Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici *in vitro*)
(DE) - CE Konformitätskennzeichnung (Europäische Richtlinie 98/79/EG über *In-vitro*-Diagnostika)
(PT) - Marcação CE (Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico *in vitro*)
(SE) - CE-märkning (Europeiskt direktiv 98/79/EG om medicintekniska produkter för *in vitro*-diagnostik)
(DK) - CE-mærkningen (Europa direktiv 98/79/EF om medicinsk udstyr til *in vitro*-diagnostik)
(GR) - Χαρακτηρισμος CE (ευρωπαικη οδηγια 98/79/CE περι *in vitro* διαγνωστικες ιατρικες συσκευες)
(PL) - CE oznaczenie (Dyrektywa unijna 98/79/CE dotycząca produktów medycznych do badań *in vitro*)
(LT) - CE ženklas (Europos sąjungos direktyva 98/79/CE dėl *in vitro* diagnostikos medicinos prietaisų)
(HU) - CE jelzés (98/79/CE Európai Irányelv az *in vitro* orvosi diagnosztikai eszközökről)
(EE) - CE märgistus (Euroopa direktiiv 98/79/CE *in vitro* diagnostikameditsiiniseadmete kohta)
(SK) - CE označenie o zhode (Európska direktíva 98/79/CE pre *in vitro* diagnostické zdravotnícke postupy)
(CZ) - CE značka (Evropská direktiva 98/79/CE o diagnostických zdravotnických prostředcích *in vitro*)
(NO) - CE-merking (EU-direktiv 98/79/CE om medisinsk utstyr til *in vitro*-diagnostikk)
(RO) - Marca CE (Directiva europeana 98/79/CE pentru dispozitive medicale de diagnostic *in vitro*)
(BG) - CE маркировка (Европейска директива 98/79/CE за *ин витро* диагностичните медицински изделия)

IVD

(GB) - For *in vitro* diagnostic use
(FR) - Pour diagnostic *in vitro*
(ES) - Para diagnóstico *in vitro*
(IT) - Per uso diagnostico *in vitro*
(DE) - *In-vitro*-Diagnostikum
(PT) - Para uso em diagnóstico *in vitro*
(SE) - *In vitro*-diagnostik
(DK) - *In vitro* diagnose
(GR) - Για *in vitro* διαγνωστικη χρηση
(PL) - Do stosowania *in vitro*
(LT) - *in vitro* diagnostikai
(HU) - Csak *in vitro* diagnosztikai alkalmazásra
(EE) - *In vitro* diagnostiliseks kasutamiseks
(SK) - Na diagnostiku *in vitro*
(CZ) - Pro diagnostiku *in vitro*
(NO) - Til *in vitro*-diagnostikk
(RO) - Pentru diagnostic *in vitro*
(BG) - За *ин витро* диагностика

REF

(GB) - Catalogue number
(FR) - Référence catalogue
(ES) - Número de catálogo
(IT) - Numero di catalogo
(DE) - Bestellnummer
(PT) - Número de catálogo
(SE) - Katalognummer
(DK) - Katalognummer
(GR) - Αριθμος καταλογου
(PL) - Numer katalogu
(LT) - Katalogo numeris
(HU) - Cikkszám
(EE) - Katalooginumber
(SK) - Katalógové číslo
(CZ) - Katalogové číslo
(NO) - Katalognummer
(RO) - Număr de catalog
(BG) - Каталожен номер

(GB) - Manufacturer
(FR) - Fabricant
(ES) - Fabricante
(IT) - Produttore
(DE) - Hersteller
(PT) - Fabricante
(SE) - Tillverkad av
(DK) - Fremstillet af
(GR) - Κατασκευαστης
(PL) - Producent
(LT) - Gamintojas
(HU) - Gyártó
(EE) - Tootja
(SK) - Výrobca
(CZ) - Výrobce
(NO) - Produsent
(RO) - Producător
(BG) - Производител

EC REP

(GB) - Authorised Representative
(FR) - Représentant agréé
(ES) - Representante autorizado
(IT) - Distributore autorizzato
(DE) - Bevollmächtigter
(PT) - Representante Autorizado
(SE) - Auktoriserad representant
(DK) - Autoriseret repræsentant
(GR) - Εξουσιοδοτημενος αντιπροσωπος
(PL) - Upoważniony Przedstawiciel
(LT) - Įgaliotasis atstovas
(HU) - Meghatalmazott Képviselő
(EE) - Volitatud esindaja
(SK) - Autorizovaný zástupca
(CZ) - Zplnomocněný zástupce
(NO) - Autorisert representant
(RO) - Reprezentant autorizat
(BG) - Упълномощен представител

LOT

(GB) - Batch code
(FR) - Code du lot
(ES) - Código de lote
(IT) - Codice del lotto
(DE) - Chargen-Bezeichnung
(PT) - Código do lote
(SE) - Batchnr
(DK) - Batchkoden
(GR) - Κωδικας παρτιδας
(PL) - Numer serii
(LT) - Serijos numeris
(HU) - Gyártási szám
(EE) - Partii kood
(SK) - Číslo šarže
(CZ) - Číslo šarže
(NO) - Partikode
(RO) - Număr de lot
(BG) - Партиден номер

(GB) - Expiry date YYYY/MM/DD
(FR) - Date de peremption AAAA/MM/JJ
(ES) - Estable hasta AAAA/MM/DD
(IT) - Da utilizzare prima del AAAA/MM/GG
(DE) - Verwendbar bis JJJJ/MM/TT
(PT) - Data de expiração AAAA/MM/DD
(SE) - Utgångsdatum ÅÅÅÅ/MM/DD
(DK) - Anvendes før ÅÅÅÅ/MM/DD
(GR) - Ημερομηνια ληξης YYYY/MM/DD
(PL) - Data ważności YYYY/MM/DD
(LT) - Galioja iki YYYY/MM/DD
(HU) - Szavatossági idő ÉÉÉÉ/HH/NN
(EE) - Aegumistähtaeg AAAA/KK/PP
(SK) - Použiteľné do RRRR/MM/DD
(CZ) - Datum exspirace RRRR/MM/DD
(NO) - Utløpsdato ÅÅÅÅ/MM/DD
(RO) - Data expirarii AAAA/LL/ZZ
(BG) - Срок на годност година/месец/ден

(GB) - Storage temperature limitation
(FR) - Limites de températures de stockage
(ES) - Temperatura límite
(IT) - Limiti di temperatura di conservazione
(DE) - Lagertemperatur
(PT) - Limites de temperatura de armazenamento
(SE) - Temperaturbegränsning
(DK) - Temperaturbegrænsning
(GR) - Περιορισμος θερμοκρασιας αποθηκευσης
(PL) - Temperatura przechowywania
(LT) - Saugojimo temperatūriniai apribojimai
(HU) - Tárolási hőmérsékleti határok
(EE) - Piirangud säilitustemperatuurile
(SK) - Skladovacia teplota od do
(CZ) - Teplotní rozmezí od do
(NO) - Oppbevaringstemperatur
(RO) - Limitele de temperatură la stocare
(BG) - Температурни граници на съхранение

(GB) - Consult Instruction for use
(FR) - Consulter le mode d'emploi
(ES) - Consulte las instrucciones de uso
(IT) - Consultare le istruzioni per uso
(DE) - Siehe Gebrauchsanweisung
(PT) - Consulte o folheto informativo
(SE) - Se bruksanvisningen
(DK) - Se instruktion før brug
(GR) - Συμβουλευθειτε τις οδηγιες χρησης
(PL) - Sprawdź instrukcję
(LT) - Ieškokite informacijos vartojimo instrukcijoje
(HU) - Olvassa el a használati utasítást
(EE) - Kasutamisel vaata instruktsiooni
(SK) - Katalógové číslo
(CZ) - Viz návod k použití
(NO) - Se bruksanvisninger
(RO) - Consultati prospectul de utilizare
(BG) - Виж инструкцията за употреба

(GB) • This product contains human or animal components. Handle with care.
(FR) • Ce produit contient des composants d'origine biologique humaine ou animale. Manipuler avec précaution.
(ES) • Este producto contiene componentes humanos o animales. Manejar con cuidado.
(IT) • Questo prodotto contiene componenti umane o animali. Maneggiare con cura.
(DE) • Dieses Produkt enthält Bestandteile menschlichen oder tierischen Ursprungs. Vorsichtig handhaben.
(PT) • Este medicamento contém componentes de origem humana ou animal. Manuseie com cuidado.
(SE) • Denna produkt innehåller beståndsdelar från människa eller djur. Hantera produkten varsamt.
(DK) • Dette produkt indeholder humane og animalske komponenter. Skal behandles med forsigtighed.
(GR) • Αυτό το προϊόν περιέχει ανθρώπινα ή ζωικά στοιχεία. Χειριστείτε το με προσοχή.
(PL) • Niniejszy produkt zawiera składniki pochodzenia ludzkiego lub zwierzęcego. Należy obchodzić się z nim ostrożnie.
(LT) • Šiame produkte yra žmogiškosios arba gyvūninės kilmės sudėtinių dalių. Elgtis atsargiai.
(HU) • A készítmény emberi vagy állati eredetű összetevőket tartalmaz. Óvatosan kezelendő.
(EE) • Käesolev toode sisaldab inim-või loomseid komponente. Käsitseda ettevaatlikult.
(SK) • Tento výrobok obsahuje ľudské alebo zvieracie zložky. Narábajte s ním opatrne.
(CZ) • Tento výrobek obsahuje lidské nebo zvířecí komponenty. Zacházejte s ním opatrně.
(RO) • Acest produs conține materiale de origine umană sau animală. Manevrați-l cu grijă.
(BG) • Този продукт съдържа човешки или животински компоненти. Бъдете внимателни при работа с него.
(LV) • Šis produkts satur cilvēkiem vai dzīvniekiem paredzētas sastāvdaļas. Apieties uzmanīgi.
(MT) • Dan il-prodott fih komponenti umani jew tal-annimali. Uża b'attenzjoni.
(NL) • Dit product bevat menselijke of dierlijke bestanddelen. Breekbaar.
(SI) • Izdelek vsebuje človeške ali živalske sestavine. Rokujte previdno.
(FI) • Tässä tuotteessa on ihmisestä tai eläimistä peräisin olevia osia. Käsittele varovasti.

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