Genscreen™ HIV-1 Ag Confirmatory Assay

25 tests 71121

FOR CONFIRMATORY NEUTRALIZATION OF Genscreen™ HIV-1 ANTIGEN ASSAY REACTIVE SPECIMENS

IVD For *In Vitro* Diagnostic Use

Manufacturer Quality Control

All manufactured and commercialised reagents are under complete quality system starting from reception of raw material to the final commercialisation of the product. Each lot is submitted to a quality control and only is released on the market when conforming to the acceptance criteria. The records relating to production and control of each single lot are kept within our company.

BIO-RAD

CONTENTS

1 - INTENDED USE

Specimens repeatedly reactive in the Genscreen™ HIV-1 Ag Assay must be tested to confirm the presence of HIV-1 p24 antigen. Neutralization of the viral antigen by anti-HIV antibody is an accepted method of confirmation (1-4). The presence of p24 antigen in the sample is indicated by a loss of HIV-1 antigen reactivity compared to a non-neutralized sample from the same specimen.

Genscreen™ HIV-1 Ag Confirmatory Assay is intended for the confirmation of HIV-1 p24 antigen in serum, plasma or cell culture supernatant specimens found to be repeatedly reactive in the Genscreen™ HIV-1 Ag Assay.

2 - PRINCIPLE OF THE Genscreen™ HIV-1 Ag Confirmatory Assay

The repeatedly reactive specimen is incubated with HIV-1 Antigen Confirmatory Reagent [Antibody to HIV Antigen (Human)]. If HIV-1 antigen is present in the specimen, it will be neutralized by the HIV-1 Antigen Confirmatory Reagent. The treated specimen is re-assayed using the Genscreen™ HIV-1 Ag Assay. The neutralized HIV-1 antigen is prevented from binding to the HIV-1 antibody-coated microwells, which results in a reduction of optical density. A non-neutralized control of the specimen [treated with HIV-1 Antigen Negative control (Human) in place of HIV-1 Antigen Confirmatory Reagent] is tested in parallel to the neutralized specimen for comparison of optical density. Genscreen™ HIV-1 Ag Assay repeatedly reactive specimens are confirmed positive by the Genscreen™ HIV-1 Ag Confirmatory Assay if the reduction in optical density of the neutralized specimen is greater than or equal to 50% of the non-neutralized sample and the non-neutralized specimen signal is greater than the assay cutoff.

3 - CONTENTS OF THE Genscreen™ HIV-1 Ag Confirmatory Assay

LABEL		NATURE OF THE REAGENTS	PRESENTATION
RA	**HIV-1 Ag Confirmatory Reagent**	HIV-1 Ag Confirmatory Reagent Human serum containing antibody to HIV-1 0.005% Gentamicin sulfate Preservative: ProClin™ 300 (0.5%)	1 vial 1.3 ml
C0	**Negative Control**	Negative Control Human serum non-reactive for HIV-1 Ag, HBsAg, antibody to HIV-1, HIV-2, HCV, and HTLV-I 0.005% Gentamicin sulfate Preservative: ProClin™ 300 (0.5%)	1 vial 12 ml

4 - MATERIAL REQUIRED BUT NOT PROVIDED

Refer to the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) test instructions.

5 - HEALTH AND SAFETY INSTRUCTIONS

All the reagents included in the kit are intended for *«in vitro»* diagnostic use.

- The HIV-1 Antigen Confirmatory Reagent has been tested and found non-reactive for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C Virus (HCV Ab), and antibodies to human T-cell lymphotropic viruses (HTLV-I Ab). The Confirmatory Reagent has also been heat-treated to inactivate viruses.

- Human source material used in the preparation of the negative control was tested and found non reactive for HIV-1 antigen, anti-HIV1 and anti-HIV2 antibodies, hepatitis B antigen (HB Ag), anti-HCV antibodies, anti HTLV 1/HTLV 2 antibodies and anti HIV1/HIV2.
- Because no known test method can offer complete assurance that the HIV, Hepatitis B or C virus or other infectious agents are absent, consider these reagents, as well as patient samples, as potentially infectious and handle them carefully.
- The Safety Data Sheet is available upon request.
- Some reagents contain 0.5% ProClin™ 300.

  ProClin™ 300 0.5% : Irritant.

Xi-Irritant

R43 : May cause sensitisation by skin contact
S28-37 : After contact with skin, wash immediatly with plenty of soap and water. Wear suitable gloves.

- Samples and reagent of human origin, as well as, contaminated material and products must be discarded after decontamination :
  - either by immersion in bleach at a final concentration of 5% of sodium hypochlorite (1 volume of bleach for 10 volumes of contaminated fluid or water) for 30 minutes
  - or by autoclaving at 121°C for 2 hours minimum. Autoclaving is the best method to inactivate the HIV and the HBV viruses.
  - DO NOT PLACE SOLUTIONS CONTAINING SODIUM HYPOCHLORITE IN THE AUTOCLAVE.
- Refer to the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) test instructions.

6 - PRECAUTIONS

The reliability of results depends on correct observance of the following Good Laboratory Practices :

- Do not use expired reagents.
- Do not change the assay procedure.
- Before use, it is required to wait 30 minutes to allow the reagents stabilizing at room temperature (18-30°C).
- Refer to the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) for other instructions.

7 - SPECIMENS

Collect a blood sample according to the current practices.
Serum, plasma, or cell culture samples may be used. The following anticoagulants have been evaluated and found to be acceptable : EDTA, heparin, sodium citrate.
Refer to the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) for other instructions.

8 - PREPARATION OF REAGENTS – STORAGE CONDITION - SHELF LIFE

The reagents of the Genscreen™ HIV-1 Ag Confirmatory Assay are all ready to use.
Store the kit at 2-8°C. Bring all reagents to room temperature (18-30°C) before use.
Each reagent contained in the Genscreen™ HIV-1 Ag Confirmatory Assay can be used after a first opening until the expiry date mentioned on the package.

9 - ASSAY PROCEDURE

The expected run time for this procedure is approximately 4 hours. Each run of this assay must proceed to completion without interruption after it has been started.

CAUTION ! *Specimens found to be repeatedly reactive by the Genscreen™ HIV-1 Ag Assay using the 37°C procedure should be confirmed with Genscreen™ HIV-1 Ag Confirmatory Assay using the 37°C procedure. Specimens found to be repeatedly reactive by the Genscreen™ HIV-1 Ag Assay using the 40°C procedure should be confirmed with Genscreen™ HIV-1 Ag Confirmatory Assay using the 40°C procedure*.

Strictly follow the proposed procedure.

Use the negative control and the positive control for each series to validate the test results. Apply the following Good Laboratory Practice :

1. Carefully establish the sample distribution and identification plan
2. Prepare the dilute washing solution
3. Take the carrier tray and the strips (R1) out of the protective pouch
4. Neutralization Procedure :
   a. For each specimen, label 1 plastic test tube "A" (neutralized) and 1 plastic test tube "B" (non-neutralized control). Pipette 150 µl of repeatedly reactive specimen into each tube.
   b. For HIV-1 Antigen Positive Control, label 2 plastic test tubes "A" (neutralized) and 2 plastic test tubes "B" (non-neutralized). Pipette 150 µl of HIV-1 Antigen Positive Control (C1) into each tube.
   c. For HIV-1 Antigen Negative Control, label 3 plastic test tubes "B" (non-neutralized). Pipette 150 µl of HIV-1 Antigen Negative Control (C0) into each tube.
   d. To each tube labeled "A" (neutralized) add 25 µl of HIV-1 Antigen Confirmatory Reagent.
   e. To each tube labeled "B" (non-neutralized) add 25 µl of HIV-1 Antigen Negative Control (C0).
   f. Mix each tube by gentle vortex mixing or tapping. Avoid excessive foaming.
   g. Incubate the tubes for 15-30 minutes at room temperature (18-30°C) to allow the neutralization reaction to proceed.
5. Add directly without preliminary wash of the plate, successively (suggestion of the distribution of the plate) :
   5.1 50 µl of Specimen Diluent to each well.
   5.2 150 µl of negative control (C0) in wells A1, B1, C1
   150 µl of neutralized positive control (C1) in wells D1, E1
   150 µl of non-neutralized positive control (C1) in wells F1, G1
   150 µl of treated specimen in H1, etc…

Four positive controls, two neutralized and two non-neutralized, and three negative controls should be assayed on each plate or partial plate of specimens.

Make sure that the specimen diluent was thoroughly mixed to the samples (or control). When properly mixed, the contents of each well are a uniform color

N.B : The sample distribution can be visually controlled at this step of the manipulation : after adding the sample, the diluent turns from green to blue to assure that the sample or control has been added to the well. (Refer to section 11 for automatic verification - SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE PIPETTING).

6. If possible cover the microplate with adhesive film. Press firmly all over the plate to ensure adequate tightness.
7. Incubate the plate for 60 ± 5 minutes at 37 ± 1°C or 40 ± 1°C using a dry-heat static incubator.
8. Remove the adhesive film. Aspirate the contents of all wells into a container for biohazardous waste (containing sodium hypochlorite). Add into each well a minimum of 0.370 ml of washing solution. Respect a soak time for 20 to 60 seconds. Aspirate again. Repeat this procedure 4 times (i.e. a total of a minimum of 5 washes). The residual volume must be lower than 10 µl (if necessary, dry the plate by turning it upside down on absorbent paper).

   If an automatic washer is used, follow the same procedure.
9. Quickly distribute 100 µl of the Working Conjugate Solution 1 into all wells.
   The conjugate must be shaken gently before use.
   NB : The distribution of the Working Conjugate Solution 1 which is coloured yellow can be visually controlled at this step of the manipulation.
10. If possible cover the microplate with adhesive film. Press firmly all over the plate to ensure adequate tightness. Incubate the plate for 30 ± 5 minutes at 37 ± 1°C or 40 ± 1°C using a dry-heat static incubator.
11. Remove the adhesive film. Empty all wells by aspiration and wadh a minimum of 5 times as described above. If an automatic washer is used, follow the same procedure.
12. Quickly distribute 100 µl of the Working Conjugate Solution 2 into all wells.
    The conjugate must be shaken gently before use.
    NB : The distribution of the Working Conjugate Solution 2 which is coloured green can be visually controlled at this step of the manipulation.
13. If possible cover the microplate with adhesive film. Incubate the plate for 30 ± 5 minutes at 37 ± 1°C or 40 ± 1°C using a dry-heat static incubator.
14. Remove the adhesive film, empty all wells by aspiration and wash a minimum of 5 times as described above. The residual volume must be lower than 10 µl (if necessary, dry the strips by turning them upside down on absorbent paper.)
15. Quickly dispense into each well 100 µl of prepared development solution (R8+R9), freshly prepared before use. Allow the reaction to develop in the dark for 30 ± 5 minutes at room temperature (18 - 30°C). Do not use adhesive film during this incubation.
    N.B.: The distribution of the development solution, which is coloured pink, can be visually controlled at this step of the manipulation : There is a clear difference of colouration between empty well and well containing the pink substrate solution. (refer to section 11 for automatic verification, SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING).
16. Add 100 µl stopping solution (R10) by using the same sequence and rate of distribution as for the substrate solution. Homogenize the reaction mixture.
    N.B.: The distribution of the stopping solution, which is not coloured, can be visually controlled at this step of the manipulation. After the addition of the stopping solution the pink colouration of the substrate disappears (for the negative samples) or turns from blue to yellow (for the positive samples).
17. Carefully wipe the plate bottom. **At least 4 minutes after stopping solution addition** and within 30 minutes of stopping the reaction, read the optical density at 450/620-700 nm using a plate reader.
18. Check all results for agreement between the reading and the plate and sample distribution and identification plan.

10 - CALCULATION AND INTERPRETATION OF THE RESULTS

Confirmation of the presence of HIV-1 antigen is determined by comparing the absorbance value (abs) of the neutralized samples to the absorbance value (abs) of the non-neutralized samples. This comparison is expressed as% reduction.

1) Validation of negative and positive controls

See the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) test instructions.
One Negative Control may be discarded if it is outside of the acceptable validation range described in the Genscreen™ HIV-1 Ag Assay package insert. No Positive Control may be discarded.

2) Calculation of the mean absorbance (Xabs)

Determine the mean absorbance for the Negative and Positive Controls (both neutralized and non-neutralized), by dividing the sum of their absorbance values by the number of acceptable controls.
Follow the criteria in the Calculate the mean absorbance section of the Genscreen™ HIV-1 Ag Assay package insert to calculate the mean absorbance values.

3) Calculate the% reduction

The% reduction for all controls and samples is determined by applying the following equation :

$$\% \text{ reduction} = 100 \times \frac{\text{abs non-neutralized sample - abs neutralized sample}}{\text{abs non-neutralized sample - Xabs Negative control}}$$

Example

Sample	Mean Absorbance
HIV Antigen Neg. Control, Non-neutralized	0.045
HIV Antigen Pos. Control, Non-neutralized	1.020
HIV Antigen Pos. Control, Neutralized	0.040

% reduction of HIV Antigen Positive Control Xabs (PCX) =

$$100 \times \frac{1.020 - 0.040}{1.020 - 0.045} = \frac{0.980}{0.975} = 100.5\% \text{ reduction}$$

4) Validation of the run

A run is valid if the following criteria are met :

- The absorbance value of each Negative Control (and cell culture medium control, if applicable) is greater than 0.000 AU and less than or equal to 0.100 AU. One Negative Control value may be discarded. If two or more Negative Controls are out of limit, the run must be repeated.
- The mean absorbance value of the Positive Control (PCX) is greater than or equal to 0.500 AU and the individual absorbance values are within range of 0.65 to 1.35 times the PCX. No Positive Control values may be discarded.
- The% reduction of each neutralized HIV Antigen Positive Control is ≥ 50%.

5) Interpretation of the results

A specimen is considered to be positive for HIV-1 antigen if the following criteria are met :

- The specimen is repeatedly reactive by the Genscreen™ HIV-1 Ag Assay.
- The absorbance value of the non-neutralized specimen is greater than or equal to the calculated cutoff value.
- The% reduction of the specimen abs is ≥ 50%.

NOTE : If the absorbance value of patient samples is greater than the upper linearity limits of the reader, use the upper cutoff (2.999 for the Bio-Rad Laboratories reader) as the absorbance value for the following calculations.

1. Calculate the cutoff value by adding a constant factor (0.050) to the negative control mean.
2. Determine the% reduction of each specimen abs using the equation in the Quality Control section.

An example of values obtained from an assay run and the interpretation are as follows :

Sample	Absorbance values	Mean
Neg. Control, Non-neutralized	0.041 0.050 0.045	0.045
Pos. Control, Non-neutralized	1.032 1.008	1.020
Pos. Control, Neutralized	0.037 0.043	0.040
Specimen, Non-neutralized	0.858	
Specimen, Neutralized	0.041	

Example cutoff : 0.045 + 0.050 = 0.095

$$\textbf{\% reduction of HIV-1 Antigen PCX =}\ 100 \times \frac{1.020 - 0.040}{1.020 - 0.045} = \frac{0.980}{0.975} = 100.5\%\ \text{reduction}$$

$$\textbf{\% reduction of specimen abs =}\ 100 \times \frac{0.858 - 0.041}{0.858 - 0.045} = \frac{0.817}{0.813} = 100.5\%\ \text{reduction}$$

NOTE : *In some instances, high titer HIV-1 antigen specimens will not show a ≥ 50% reduction in signal by the addition of HIV-1 Antigen Confirmatory Reagent. Therefore, highly reactive specimens (absorbance ≥ 2.000) should be diluted, e.g., 1:4 or 1:8, in HIV-1 Antigen Negative Control and assayed once again by the Genscreen™ HIV-1 Ag Confirmatory Assay. If the% reduction is still not ≥ 50% for the diluted specimen and the diluted specimen is still highly reactive, redilute the first dilution 1:16 or greater in HIV-1 Antigen Negative Control, and assay again by the Genscreen™ HIV-1 Ag Confirmatory Assay.*

11 - SPECTROPHOTOMETRIC VERIFICATION OF SAMPLE AND REAGENT PIPETTING

Refer to the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) test instructions.

12 - PERFORMANCES

Specificity

A total of 2063 fresh serum (941) and plasma (1122) samples from a blood donor population were tested with the Genscreen™ HIV-1 Ag Assay. All of the samples were negative based on previous results of HIV Ab screening and detection of HIV antigen. This specificity study was performed at the two incubation temperatures indicated in the package insert protocol. The two samples found to be repeatedly false positive were not neutralized by the confirmatory test.

Sensitivity

A sensitivity study was conducted with 78 samples (SFTS panel 96 positives and positive patients with different stages of HIV-1 infection) found repeatedly reactive with the Genscreen™ HIV-1 Ag Assay. 76 samples repeatedly reactive with the Genscreen™ HIV-1 Ag Assay were all confirmed with the Genscreen™ HIV-1 Ag Confirmatory Assay. Two patient samples, nonreactive with another EIA test, were not confirmed with the neutralization test.

55 cell culture supernatants including different groups and subtypes of Ag HIV1 (A, B, C, D, E, F, G, H, J, N et O) were neutralized.

17 seroconversions panels were studied. The reactive samples with the Genscreen™ HIV-1 Ag Assay were all confirmed with the Genscreen™ HIV-1 Ag Confirmatory Assay.

Study of the Hook Effect

Elevated concentrations of HIV-1 antigen were tested in order to verify the absence of a hook effect with the Genscreen™ HIV-1 Ag Assay. HIV-1 viral lysate was diluted with positive control diluent to obtain concentrations from 2 µg/ml to 0.2 pg/ml. All samples with concentrations < 20 ng/ml are neutralized. At values higher than this, the samples should be diluted for the neutralization to be effective.

13 - LIMITS OF THE TEST

- The Genscreen™ HIV-1 Ag Assay Procedure and HIV-1 Ag Confirmatory Assay Procedure package insert recommendations must be followed when testing serum, plasma, or cell culture specimens for confirmation of the presence of HIV-1 antigen. The user of the kit is advised to read the package insert carefully prior to conducting the test. In particular, the test procedure must be carefully followed for specimen and reagent pipetting, plate washing, and timing of incubation steps.
- Negative results can occur if the quantity of marker present in the sample is too low for the detection limits of the assay, or if the marker which is detected is not present during the stage of disease in which a sample is collected.
- Failure to add specimen or reagent as instructed in the procedure could result in a falsely negative test. Repeat testing should be considered where there is clinical suspicion of infection or procedural error.
- A patient sample absorbance value of less than 0.000 AU indicates a procedural or instrument error and must be repeated.
- Refer to the relevant section of the Genscreen™ HIV-1 Ag Assay (code 71120) test instructions for other limits.

14 - REFERENCES

1. Casey JM, Kim Y, Andersen PR, et al: Human T-cell lymphotropic virus type III: immunologic characterization and primary structure analysis of the major internal protein, p24. J Virology 55:417-423,1985.
2. Ritter J, Escaich S, Trepo C, et al: HIV antigen detection in antibody negative sera. Abstract 1627, IV International Conference on AIDS, 1988.
3. Veronese FD, Sarngadharan MG, Rahman R, et al: Monoclonal antibodies specific for p24, the major core protein of human T-cell Leukemia virus type III. Natl Acad Sci USA, 82:5199-5202,1985.
4. Schaeffler B, Flesher A, Shriver K, Tam MR: Monoclonal antibody detection of p25 HIV antigen in the serum and CSF of patients within the AIDS spectrum. Abstract 7759, IV International Conference on AIDS, 1988.
5. Resnick L, Veren K, Salahuddin SZ, et al: Stability and inactivation of HTLV-III/LAV under clinical laboratory environments. JAMA 255:1887-1891,1986.
6. Sarngadharan MG, Markham PD: The role of human T-Lymphotropic retroviruses in leukemia and AIDS, in Wormser GP (ed.): AIDS and Other Manifestations of HIV Infection. New Jersey, Noyes Publications 1987, pp 218- 220.
7. Bond WW, Favero MS, Petersen NJ, et al: Inactivation of Hepatitis B virus by intermediate-to-high level disinfectant chemicals. J Clin Micro 18:535-538,1983.

CE

(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) - leškokite 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

Bio-Rad
3, bd Raymond Poincaré
92430 Marnes-la-Coquette - France
Tél.: +33 1 47 95 60 00
Fax.: +33 1 47 41 91 33

CE 0459

01/2009
Code: 883570