BIO-RAD

SFD HIV 1/2 PA

100 (20 × 5) tests 71110

PASSIVE PARTICLE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND/OR HIV-2 IN HUMAN SERUM OR PLASMA

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.

TABLE OF CONTENTS

1. INTENDED USE

SFD HIV 1/2 PA is intended to serve as a tool for the detection of antibodies to HIV-1 and/or HIV-2 and as an aid in the diagnosis of infection by HIV-1 and/or HIV-2. The test is ideally suited for screening of blood donors and high risk populations. The test may be performed on either plasma or serum specimens.

2. ASSAY PRINCIPLE

SFD HIV 1/2 PA is an "*in vitro*" diagnostic test for the detection of antibodies to HIV-1 and/or HIV-2 which is manufactured using gelatin particle, sensitized with recombinant HIV-1 antigens (HIV-1/gp 41 and HIV-1/p 24) and HIV-2 antigen (HIV-2/gp 36). The SFD HIV 1/2 PA (particle agglutination) test is based on the principle that sensitized particles are agglutinated by the presence of antibodies to HIV-1 and/or HIV-2 in human serum/plasma.

3. CONTENTS OF THE SFD HIV 1/2 PA KIT

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

The kit contains enough reagents to perform 100 qualitative tests. Each kit contains the following reagents and accessories :

	Reagents				
Maximum Assays	Reconstituting Solution (Liquid) (A)	Sample Diluent (Liquid) (B)	Sensitized Particles (Lyophilized) (C)	Control Particles (Lyophilized) (D)	Positive Control (Liquid) (E)
Screening 100 (20 × 5)	10 ml × 1 vial	20 ml × 1 vial	0.6 ml* × 5 vials	1.0 ml* × 5 vials	0.5 ml × 1 vial

* After reconstitution (to reconstitute with the indicated volume = * of A solution)

Accessories : Droppers : 2 pieces (25 µl)

A. Reconstituting Solution (Liquid) - For use in the reconstitution of Sensitized Particles and Control Particles. This reagent contains 0.1 % (w/v) of sodium azide as preservative.

B. Sample Diluent (Liquid) - For use in diluting test specimens. This reagent contains 0.1 % (w/v) of sodium azide as preservative.

C. Sensitized Particles (Lyophilized) -Lyophilized preparation of gelatin particles sensitized with recombinant HIV-1 antigens (gp 41 and p 24) and HIV-2 antigen (gp 36), reconstituted by adding the prescribed quantity of Reconstituting Solution (as shown on the above table). The reconstituted reagent contains 1 % of gelatin particles sensitized with recombinant HIV-1/2 antigens and 0.1 % (w/v) of sodium azide as preservative.

D. Control Particles (Lyophilized) - Reconstituted by adding prescribed quantity of Reconstituting Solution (as shown on the above table). Reconstituted particles contains 1 % of gelatin particles sensitized with *E. coli* extract and 0.1 % (w/v) of sodium azide as preservative.

E. Positive Control (Liquid) - Liquid preparation containing HIV-1 mouse monoclonal antibodies and HIV-2 mouse monoclonal antibodies. The control gives a 1:128 (± 1 dilution) antibody titer at the final dilution when tested according to the Positive Control Test Procedure (see Table 3). This reagent contains 0.1 % (w/v) of sodium azide as preservative.

The 2 droppers (25 µl) included in the kit are designed for the sole purpose of dispensing the reconstituted Sensitized Particles or Control Particles.

All reagents contain normal rabbit serum.

4. MATERIAL REQUIRED BUT NOT PROVIDED

- Distilled water
- Sodium hypochlorite (household bleach) and sodium bicarbonate
- Disposable gloves
- Microplates with round bottom wells ("U" shaped - FASTEC type)
- Micropipettes with tips able to dispense 25 µl for dispensing and diluting specimens
- Volumetric pipettes able to dispense 1.0 ml and 5.0 ml for particles reconstitution
- Plate mixer (optional): Automatic vibratory shaker (not a rotating mixer) to mix contents thoroughly

- Plate viewer -(optional): For reading
- Container for biohazardous waste

N.B: Only high quality, rigid, "U" shaped microplates, (such as Fujirebio FASTEC plates), should be used for the assay. The use of flexible plates is not recommended as their surface is not smooth and can adversely affect the test results.

Reuse of microplates is not recommended. However, if microplates are to be reused, it is critical that special care be taken when cleaning the microplate before reusing it, otherwise the reaction may be adversely affected. Be sure not to leave any disinfectant or detergent residues on the plate.

5. PRECAUTIONS

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

- Do not use expired reagents.
- Do not mix reagents from different lots within a given test run.
- Before use, it is required to wait 30 minutes to allow the reagents stabilizing at room temperature (15-30°C).
- Carefully reconstitute reagents avoiding any contamination.
- Use glassware thoroughly washed and rinsed with distilled water or preferably, disposable material.
- Use a new dispensing tip for each sample.
- Check pipettes for accuracy and precision and if the instruments being used are correctly working.
- Do not change the assay procedure.

6. HEALTH AND SAFETY INSTRUCTION

- All the kit reagents are intended to "*in vitro*" diagnostic use.
- Wear disposable gloves when handling reagents and samples and thoroughly wash your hands after handling them.
- Do not pipette by mouth.
- Because no known test method can offer complete assurance that the HIV, Hepatitis B or C virus or other infectious agents are absent, consider patient samples, as potentially infectious and handle them carefully.

- Any equipment directly in contact with samples should be considered as contaminated products and treated accordingly.
- Avoid spilling samples or solutions containing samples.
- Contaminated surfaces should be cleaned 10 % diluted bleach. If the contaminating fluid is an acid, the contaminated surfaces should be first neutralized with sodium bicarbonate, then cleaned with bleach, and dried with absorbent paper. The material used for cleaning should be discarded into a biohazardous waste container.
- Samples, as well as contaminated material and products should be discarded after decontamination:
  - either by soaking into bleach at a final concentration of 5 % sodium hypochlorite (1 volume of bleach per 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 HIV and HBV.

  CAUTION : DO NOT PLACE SOLUTIONS CONTAINING SODIUM HYPOCHLORITE IN THE AUTOCLAVE
- Do not forget to neutralize and/or autoclave the wash waste solutions or any fluid containing biological samples before discarding them into the sink.
- The Material Safety Data Sheet is available upon request.
- Chemicals should be handled and discarded in accordance with Good Laboratory Practices.
- Some reagents contain sodium azide as a preservative. Sodium azide may form copper or lead azides in laboratory plumbing. Such azides are explosive. To prevent azide built-up, flush the pipes with a large amount of water if solutions containing azide are discarded into the sink after inactivation.

7. RECONSTITUTION OF REAGENTS

Note: Before use, allow reagents to reach room temperature (15-30°C).

a) Reagents ready to use :

Reagent A : Reconstituting Solution
Reagent B : Sample Diluent
Reagent E : Positive Control

b) Regents to reconstitute:

Reagent C : Sensitized particles
To reconstitute with the following volume of reconstituting solution (Reagent A) :
- 0.6 ml for the 100 tests kit

Reagent D : Control particles
To reconstitute with the following volume of reconstitution solution (Reagent A):
- 1 ml for the 100 tests kit

N.B : THE SUSPENSION OF SENSITIZED PARTICLES AND OF CONTROL PARTICLES MUST BE HOMOGENEIZED BY GENTLY SHAKING AND INVERTING JUST BEFORE DISTRIBUTION.

8. VALIDITY - STORAGE

Store the kit at +2-10°C. Once opened, all the kit reagents may be stored at +2-10°C until the expiration date stated on the box except for specific instructions:
R(C) and R(D) : Ideally lyophilized reagents contained in the kit should be used within the same day of reconstitution. However, they will remain stable for 14 days after reconstitution under the proper storage conditions (+2-10°C) and the test procedures mentioned in the package insert.

9. SAMPLE PREPARATION

Collect a blood sample according to the current practices.
The tests should be performed with undiluted serum or plasma samples (collected as EDTA, heparin, citrate based anticoagulants).
Extract the serum or plasma from the clot or red cells as soon as possible in order to avoid hemolysis. Extensive hemolysis may affect test performance. Samples with aggregates should be clarified by centrifugation prior testing. Suspended fibrin particles or aggregates may yield falsely positive results.
The samples can be stored at +2-8°C if the test is performed within 7 days or they may be deep-frozen at -20°C.
Avoid repeated freezing and thawing.
If the samples have to be shipped, they should be packaged in accordance with the regulations effective for the transport of etiological agents.
Inactivation of serum specimens may be performed using standard inactivation, 56°C for 30 minutes.

DO NOT USE CONTAMINATED, HYPERLIPEMIC OR HYPERHEMOLYZED SERUM OR PLASMA SAMPLES.

Note: No interference has been observed of concentration of bilirubin up to 21.5 mg/dl, of hemoglobin up to 560 mg/dl and for chylomicron turbidity up to 2300.

10. ASSAY PROCEDURE

Preliminary remarks:

1. Specimens that are found positive with SFD HIV 1/2 PA qualitative test should be re-tested in duplicate. If either or both repeated tests are positive or indeterminate, then the specimens should be tested using the semi-quantitative procedure.
2. When performing the semi-quantitative procedure, it is not unusual to see specimens with titers well beyond well # 12. Additional dilution of these specimens may be necessary, prior to dispensing them into the microplate, for end-point determinations in the semi-quantitative test.
3. It is recommended to perform a reagent control test for qualitative and semi-quantitative tests (as shown in the table 1).

Table 1 – Operating mode for reagent control test

Well N°	1	2
Sample diluent (µl)	25	25
Control Particles (µl)	25	
Sensitized Particles (µl)		25
Mix using plate mixer (automatic vibratory shaker), cover the plate and incubate for 2 hours		
Interpretation		

Qualitative Assay Method (Table 2)

a. Using a micropipette, place 75 µl (3 drops of 25 µl) of Sample Diluent in well # 1 of a microplate and 25 µl each (1 drop of 25 µl) into wells # 2 and # 3.

b. Using a micropipette, add 25 µl of serum/plasma specimen into well # 1. Mix the contents of well # 1 by filling and discharging the micropipette 5 or 6 times. Then, using a micropipette, transfer 25 µl of the diluted solution from well # 1 into well # 2. Mix the contents of well # 2 in the same manner as described above and transfer 25 µl into well # 3. Following the same procedure, mix the contents of well # 3 and then discard 25 µl of solution remaining in the pipette after mixing.

c. Using the one of the droppers supplied in the kit, place 25 µl (1 drop) of reconstituted Control Particles into well #2. Using the other dropper, place 25 µl (1 drop) of reconstituted Sensitized particles into well # 3.

d. Mix the contents of the wells thoroughly using a plate mixer (automatic vibratory shaker), or if no mixer is available, by tapping each of the four corners of the plate sharply with your finger 5 to 6 times. Cover the plate and place it on a vibration-free surface. Allow it to stand at room temperature (15-30°C) for 2 hours before reading the patterns.

Table 2 – Qualitative Test Procedure

Well N°	1	2	3
Sample Diluent (µl) Specimen (µl)	75 25	25 25	25 25 → Discard
Specimen Dilution	1:4	1:8	1:16
Control Particles (µl)		25	
Sensitized Particles (µl)			25
Final Dilution		1:16	1:32
Mix using plate mixer (automatic vibratory shaker), cover the plate and incubate for 2 hours			
Interpretation			

Semi-quantitative Assay Method (Table 3)

It is recommended that specimens showing repeated positive reactions in the Qualitative Assay be retested in the Semi-quantitative Assay for accurate interpretation.

a. Using micropipette, place 75 µl (3 drops of 25 µl) of Sample Diluent in well # 1 of a microplate and 25 µl (1 drop of 25 µl) in wells # 2 through # 12.

b. Using a micropipette, add 25 µl of serum/plasma specimen into well # 1. Mix the contents of well # 1 by filling and discharging the micropipette 5 or 6 times. Then, using the micropipette, transfer 25 µl of the diluted solution from well # 1 into well # 2 and mix the contents, as above. In order to make a two-fold dilution, repeat the same mixing and transferring procedure for the rest of the wells, from well # 3 to well #12, as shown in Table 3.

   To insure accuracy, the positive control should be run in parallel with the specimens that are being tested, and results for the positive control should be 1:128, plus or minus one dilution.

c. Using one of the droppers supplied in the kit, place 25 µl (1 drop) of reconstituted Control Particles into well # 2. Using the other dropper, place 25 µl (1 drop) of Sensitized Particles in each well, starting from well # 3 through well # 12.

d. Mix the contents of the wells thoroughly with a plate mixer (automatic vibratory shaker), or if no mixer is available, by tapping each of the four corners of the plate sharply with your finger 5 to 6 times. Cover the plate and place it on a vibration-free surface. Allow it to stand at room temperature (15-30°C) for 2 hours before reading the patterns.

Table 3 – Semi-quantitative Assay

Well N°	1	2	3	4	5	6	7	8	9	10	11	12
Sample diluent (µl) Specimen or Positive Control (µl)	75 25	25 25	25 25	25 25	25 25	25 25	25 25	25 25	25 25	25 25	25 25	25 25 → discard
Specimen Dilution	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048	1:4096	1:8192
Control Particles (µl)		25										
Sensitized Particles (µl)			25	25	25	25	25	25	25	25	25	25
Final Dilution		1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048	1:4096	1:8192	1:16384
Continue sample dilution from wells 2 – 12												
Mix using plate mixer (automatic vibratory shaker), cover the plate and incubate for 2 hours												
Interpretation												

11. VALIDATION AND INTERPRETATION OF RESULTS

Validation of tests:

a. For semi-quantitative and qualitative test confirm that the reaction of each specimen and Control Particles (1:16 final dilution) is negative (-).

b. With the reagent control test, the mixture of Sample Diluent, both with reconstituted Sensitized Particles and Control Particles, should give no reaction (-) on any run of tests (Reagent Control).

c. For semi-quantitative test, confirm that the titer of Positive Control is 1:128 (± 1 dilution) at final dilution according to test procedures outlined in Table 3.

Reading and interpretation of agglutinations:

The agglutinations can be interpreted visually or by carefully placing the microplate on an optional plate viewer with indirect lighting), and comparing the agglutination patterns with those of Reagent Control. Refer to the criteria shown in Table 4 to interpret the results.

Table 4 – Reading and interpretation of agglutinations

Setting of Particles Patterns	Reading	Interpretation
Particles are concentrated in the shape of a button in the center of the well. There is a smooth round outer margin.	(-)	Negative
Particles are concentrated in the shape of a compact ring with a smooth round outer margin.	(±)	Indeterminate (see note below)
Particles form a large ring with a rough multiform outer margin. Peripheral agglutination occurs.	(+)	Positive
Firmly agglutinated particles spread out covering the bottom of the well uniformly	(++)	

Note: Specimens that show indeterminate results (±) should be re-tested following Test procedures listed in Table 3 (Semi-quantitative Assay Method). Repeat indeterminate (±) or reactive results should be confirmed by other methods to ensure accurate interpretation. Refer to "14. LIMITS OF THE

TEST" mentioned below for further details.

Criteria for interpretation:

A specimen showing negative reaction with Control Particles (final dilution 1:16) but showing agglutination with Sensitized particles (final specimen dilution 1:32 or more) is regarded as showing a positive reaction to HIV. Specimens showing positive reaction with the Control particles and negative reaction with the Sensitized Particles are considered as showing a negative reaction to HIV.

The work sheet supplied separately shall be used for interpreting the results. Please contact the supplier of this test to obtain the work sheet.

Table 5 – Interpretation Criteria

Control particles	Sensitized Particles	Assessment
-	+	Positive
-	-	Negative
+	-	Negative
+	+	Indeterminate
After Absorption using Control Particles*		
-	+	Positive
-	-	Negative

* Some specimens may require 2 absorptions

12. ABSORPTION PROCEDURE

If a specimen causes agglutination (± or positive) with both Control and Sensitized particles, it should be re-tested as follows :

a. Place 0.35 ml of reconstituted Control Particles into a small test tube.

b. Add 50 µl of specimen to the test tube and mix thoroughly using a vortex mixer. Incubate at room temperature (15-30°C) for at least 20 minutes.

c. Centrifuge for 5 minutes at 2000 r.p.m. Then take 50 µl of the supernatant (absorbed 1:8 specimen dilution) and carefully place it into well # 2 (refer to Table 3).

d. Add 25 µl of Sample Diluent to well # 3 and all other wells through # 12. Then transfer 25 µl of absorbed specimen from well # 2 into well # 3 and mix well according to the instructions described in the semi-quantitative assay. Repeat the same procedure for wells # 3 through to obtain a 2-fold dilution (refer to Table 3).

13. PERFORMANCES

Sensitivity

Sensitivity studies for SFD HIV1/2 PA kit have been performed on documented samples of patients infected with HIV.
The detection of confirmed HIV positive samples has been evaluated on:

- 486 HIV-1 group M samples, with 134 serotyped samples (A, B, C, D, E, F, G subtypes). Sensitivity was 100% on these samples.
- 24 HIV-1 group O samples. All have been found positive.
- 173 HIV-2 samples. All have been found positive.

The early detection has been evaluated on :

- SFTS (French society of Blood Bank) seroconversions and commercial (BBI, NABI) panels have been tested. Results are almost equivalent with some EIA tests recognized having the best antibody sensitivity.
- SFTS panel: Ten out of 11 samples of "per-seroconversion" were found positive with SFD HIV 1/2 PA.
- 31 commercial panels have been tested with SFD HIV1/2 PA. The following table shows the 1st detected sample of each panel.

Panel	1st detected sample	Panel	1st detected sample	Panel	1st detected sample
BBI S	2	BBI AH	2	NABI 211	C
BBI T	2	BBI AI	2	NABI 241	D
BBI U	2	BBI AJ	7	NABI 251	F
BBI W	10	BBI AK	6	NABI 261	D
BBI X	6	BBI AL	6	NABI 271	C
BBI Y	5	BBI AM	3		
BBI Z	5	BBI AS	6		
BBI AB	3	BBI AT	5		
BBI AC	2	BBI AW	2		
BBI AD	6	BBI AY	5		
BBI AE	3	BBI BA	6		
BBI AF	6	BBI BB	4		
BBI AG	4	BBI BD	7		

Specificity

Specificity on 5041 unselected blood donors was 99.74%.
418 samples positive for other markers (HTLV-1, HSV, VZV) or from pregnant women and patients with rheumatoid arthritis were tested. Only one sample was reactive. Consequently, the specificity on this population was 99.76%.

Accuracy

Intra assay accuracy study has been conducted on 3 HIV-1 positive samples (P-1, 2, 3) that have been tested 5 consecutive times with 3 different lots according to the test procedures. All results were found to be within one well (one doubling dilution) variation.

	Lot 1-930126			Lot 2-930408			Lot 3-930422		
Sample	P-1	P-2	P-3	P-1	P-2	P-3	P-1	P-2	P-3
1	1 :1024	1 :256	1 :64	1 :2048	1 :512	1 :128	1 :1024	1 :256	1 :64
2	1 :1024	1 :256	1 :64	1 :2048	1 :512	1 :128	1 :1024	1 :256	1 :64
3	1 :1024	1 :256	1 :64	1 :2048	1 :512	1 :128	1 :1024	1 :128	1 :64
4	1 :1024	1 :256	1 :64	1 :2048	1 :512	1 :128	1 :1024	1 :256	1 :64
5	1 :1024	1 :256	1 :128	1 :2048	1 :512	1 :128	1 :1024	1 :256	1 :64
Mean	1 :1024	1 :256	1 :64	1 :2048	1 :512	1 :128	1 :1024	1 :256	1 :64
Variation	+/- 0 dil	+/- 0 dil	+1 dil	+/- 0 dil	+/- 0 dil	+/- 0 dil	+/- 0 dil	- 1 dil	+/- 0 dil

Inter assay accuracy study has been conducted on 10 HIV-1 or HIV-2 positive samples that have been tested by 3 different operators according to the test procedures. All the results were found to be within one well (one doubling dilution) variation.

	A	B	C	Mode	Variation
Sample 1	1 :1024	1 :1024	1 :1024	1 :1024	+/- 0 dil
Sample 2	1 :256	1 :256	1 :256	1 :256	+/- 0 dil
Sample 3	1 :256	1 :256	1 :256	1 :256	+/- 0 dil
Sample 4	1 :64	1 :64	1 :32	1 :64	- 1 dil
Sample 5	1 :32	1 :32	1 :32	1 :32	+/- 0 dil
Sample 6	1 :2048	1 :2048	1 :2048	1 :2048	+/- 0 dil
Sample 7	1 :512	1 :512	1 :256	1 :512	- 1 dil
Sample 8	1 :512	1 :512	1 :512	1 :512	+/- 0 dil
Sample 9	1 :128	1 :128	1 :128	1 :128	+/- 0 dil
Sample 10	1 :128	1 :128	1 :128	1 :128	+/- 0 dil

14. LIMITS OF THE TEST

This kit is designed for the sole purpose of detecting HIV related antibodies in serum/plasma specimens. It does not, however, detect HIV directly.

Consequently:

- Even if test is negative, that indicates that the tested sample does not contain antibodies against HIV, it does not exclude the possibility to an exposure to an infection with HIV. Clinical

symptoms and other information should be used in the clinical diagnosis.

- Therefore, a positive or negative test result does not indicate a conclusive HIV infection diagnosis, or lack thereof. A comprehensive assessment of the patient's condition should comprise the careful analysis of the patient's clinical symptoms and the interpretation of the results of available tests for the disease.
- In making a clinical diagnosis, specimens showing positive results with SFD HIV 1/2 PA should be re-tested at different time intervals and the results compared. When it is possible, confirmation tests must be performed on every samples that are positive with the semi-quantitative test.
- Vibrations (such as caused by the centrifugal machine) may affect the quality of the results.
- The prozone phenomenon may rarely occur in the strongly positive samples and has not been observed during the evaluations.
- Using microplates other that "U" shaped microplates may affect the quality of the results even prevent the agglutination.

15. BIBLIOGRAPHY

- BARRE-SINOUSSI F., CHERMANN J.C., REY F. et al.
  Isolation of a T. lymphotropic retrovirus from a patient at risk for acquired immunodeficiency syndrome (AIDS) . Science, 1983, **220**, 868-871
- ALIZON M., SONIGO P., BARRE-SINOUSSI F. et al.
  Molecular cloning of lymphadenopathy associated virus. Nature, 1984, **312**, 757-760
- CLAVEL F., GUYADER M., GUETARD D. et al.
  Molecular cloning and polymorphism of the human immune deficiency virus type 2. Nature, 1986, **324**, 691-695
- McKEATING J.A., WILLEY R.L.
  Structure and function of the HIV envelope. AIDS, 1989, **3**, S35-S41
- ZAAUER H.L., EXEL-OEHLERS P.V., KRAAUEVELD T. et al.
  Early detection of antibodies to HIV1 by third-generation assays. Lancet, 1992, **340**, 770-772

- CONSTANTINE N.T., VAN DER GROEN G., BELSEY E.M. et al.
  Sensitivity of HIV antibody assays determined by seroconversion panels. AIDS, 1994, **8**, 1715-1720
- WASI C. et al.
  Evaluation of two screening tests for anti-HIV : ELISA versus particle agglutination. Virus Information Exchange Newsletter, 1988, **5**, 92
- Sng E.H. et al.
  Comparative evaluation of a particle agglutination test for human immunodeficiency virus antibody, Genitourin Med, 1988, **64**, 266-269
- OHYA K. et al.
  Screening of blood donors for antibody to human immunodeficiency virus type I by sensitive particle agglutination assay. Vox Sang, 1988, **55**, 148-151
- SEKIGUCHI S. et al.
  An automated screening test for antibodies to human immunodeficiency virus 1. Transfusion, 1988, **28**, 581-585
- YOSHIDA T. et al.
  Evaluation of passive particle agglutination test for antibody to human immunodeficiency virus. J Clin Microbiol, 1987, **25**, 1433-1437
- SPIELBERG F. et al.
  Field testing and comparative evaluation of rapid, visually read screening assays for antibody to human immunodeficiency virus. Lancet, 1989, **i**, Mar.18, 580-584
- HEALY D.S. et al.
  Detection of anti-HIV immunoglobulin M by particle agglutination following acute HIV infection. AIDS 1989, **3**, 301-304
- HENDLER H. et al.
  Estudio comparativo de las technicas de aglutinacion de particulas (AP) enzimoinmunoenzay o (EIE) en la deteccion de anticuerpos anti-virus de immunodeficiencia humana tipo 1 (VIHA) en donantes de sangre. Revista Argentina de Transfusion, 1989, **XV**, 165-168.

- CE marking (European directive 98/79/CE on *in vitro* diagnostic medical devices)
- Marquage CE (Directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro*)
- Marcodo CE (Directiva europea 98/79/CE sobre productos sanitarios para diagnóstico *in vitro*)
- EG Markierung (Europäische Richtlinie 98/79/EG über *In vitro*-Diagnostika)
- Marchiatura CE (Direttiva europea 98/79/CE relativa ai dispositivi medico-diagnostici in vitro)
- Marcação CE (Directiva europeia 98/79/CE relativa aos dispositivos médicos de diagnóstico *in vitro*)
- CE-märkning (Europa direktiv 98/79/EG om medicintekniska produkter lör *in vitro*-diagnostik)
- CE-mærkningen (Europa direktiv 98/79/EF om medicinsk udstyr til *in vitro*-diagnostik)

IVD
- For *in vitro* diagnostic use
- Pour diagnostic *in vitro*
- Para diagnóstico *in vitro*
- *In vitro*-Diagnostikum
- Per uso diagnostico *in vitro*
- Para uso em diagnóstico *in vitro*
- *In vitro* diagnostik
- *In vitro* diagnose

REF
- Catalogue number
- Référence catalogue
- Número de catálogo
- Bestellnummer
- Numero di catalogo
- Número de catálogo
- Katalognummer
- Katalognummer

- Manufacturer
- Fabricant
- Fabricante
- Hersteller
- Produttore
- Fabricante
- Tillverkad av
- Fremstillet af

EC REP
- Authorised Representative
- Représentant agréé
- Representante autorizado
- Bevollmächtigter
- Distributore autorizzato
- Representante Autorizado
- Auktoriserad representant
- Autoriseret repræsentant

LOT
- Batch code
- Code du lot
- Código de lote
- Chargen-Bezeichnung
- Codice del lotto
- Código do lote
- Batch nr.
- Batchkoden

- Expiry date YYYY/MM/DD
- Date de péremption AAAA/MM/JJ
- Estable hasta AAAA/MM/DD
- Vervvendbar bis JJJJ/MM/TT
- Da utilizzare prima del AAAA/MM/GG
- Data de expiração AAAA/MM/DD
- Utgångsdatum År/Månad/Dag
- Anvendes før ÅÅÅÅ/MM/DD

- Storage temperature limitation
- Limites de températures de stockage
- Temperatura limite
- Lagerungstemperatur
- Limiti di temperatura di conservazione
- Limites de temperatura de armazenamento
- Temperaturbegränsning
- Temperaturbegrænsning

- Consult Instruction for use
- Consulter le mode d'emploi
- Consulte la instrucción para el uso
- Siehe Gebruchsanweisung
- Consultare le istruzioni per uso
- Consulte o folheto Informativo
- Se instruktionsanvisning vid användning
- Se instruktion før brug

FUJIREBIO Inc.
FR Bldg., 62-5 Nihonbashi-Hamacho 2-chome,
Chuo-ku, Tokyo 103-0007,
Japan
Tel. : +81 3 5695 9200
Fax : +81 3 5695 9230

EC REP

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 0123

code : MZ03T
05/2009