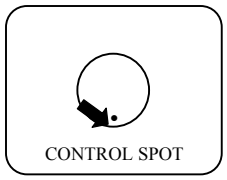

Fig. 1 NEGATIVE

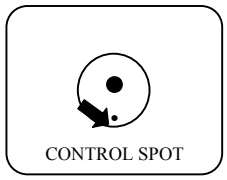

Fig. 2 POSITIVE

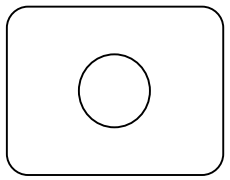

Fig. 3 INVALID

Note :

- Any sample with a distinguishable spot should be treated as POSITIVE, even if the spot is lighter than the POSITIVE CONTROL included with the kit.
- Most positive results remain easily distinguishable for several days.

PERFORMANCE OF HIVSCAN™ 1+2 (2.1)

The performance of HIVSCAN™ 1+2 (2.1) with respect to a known Anti-HIV 1 Low titer Performance Panel: PRB106, and Anti-HIV Seroconvension Panel PRB929

Sensitivity: 100%
Specificity: 100%

LIMITATIONS OF TEST

1. Strict adherence to procedures stated in Package Insert is essential. Modifications of procedure may invalidate test.
2. False positive and false negative test results can be expected with a test kit of this nature. The proportion of false positive and false negative results will depend on the sensitivity and specificity of test kit, and on the prevalence of HIV-1 and/or HIV-2 infection in the population to be screened.
3. The prevalence of HIV-1 and/or HIV-2 antibody in random donors is not known but the higher the prevalence of HIV-1 and/or HIV-2 antibody in population, the lower the proportion of false positive samples.
4. All clinical and laboratory information should be used when diagnosing a HIV-1 and/or HIV-2 infection. HIVSCAN™ 1+2 (2.1) is to be used as an aid to diagnose and should not be interpreted as diagnostic itself.

EY LABORATORIES, INC.

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Kit Manufactured in Hong Kong by :
E-Y Laboratories (H.K.) Ltd. for EY Laboratories, Inc.
(23 Mei Wan Street, Tsuen Wan, N.T., Hong Kong)

HIVSCAN™ 1+2 (2.1) KIT

for the detection of antibodies
to HIV-1 and HIV-2

INSTRUCTION MANUAL

INTRODUCTION

The **HIVSCAN™ 1+2 (2.1)** is a rapid, qualitative test for the detection of antibodies to either of the two human immunodecficiency viruses, HIV-1 or HIV-2, in human serum or plasma. This kit is intended only as an initial screening test and reactive samples should be confirmed by either in ELISA or Western Blot Test if possible.

The **HIVSCAN™ 1+2 (2.1)** assay is extremely simple to perform. All reagents and materials required for the test are provided in the kit.

PRINCIPLE OF THE TEST

In **HIVSCAN™ 1+2 (2.1)**, the proteins coated on the membrane are **a** HIV-1 recombinant that contains the C-terminus of gp120 and gp41 and a highly purified HIV-2 peptide corresponding to a region of the envelope transmembranes (gp36). Antibodies to HIV-1 and/or HIV-2 in the human sample are trapped by the immobilized antigen. The presence of bound antibodies is revealed by subsequent treatment with a proprietary. Protein A-gold conjugate which binds to the adsorbed HIV antibodies to form a red color on the membrane. Appearance of a red spot indicates the presence of HIV-1 and/or HIV-2 antibodies.

CONTENTS OF THE HIVSCAN 1+2 (2.1)

		20 Tests	100 Tests
1.	HIVSCAN™ 1+2 (2.1) Devices Ready for use.	2 x 10	20 x 5
2.	Negative Control Lyophilized normal human serum, non-reactive for Hepatitis B surface antigen, HCV antibodies as well as for HIV antibodies. Contain 0.05% thimerosal as preservative.	1 vial	1 vial
3.	Positive Control Inactivated, lyophilized normal human serum containing rabbit antibodies to HIV-1 antigens. Contain 0.05% thimerosal as preservative.	1 vial	1 vial
4.	GCP Diluent Use for reconstitution of Protein-A-Gold Reagent (GCP).	3 vials	11 vials
5.	Lyophilized, Protein-A-Gold Reagent (GCP) Lyophilized Protein A-Gold Reagent containing 0.05% Sodium Azide as preservative.	3 vials	11 vials
6.	Wash and Block Solution (W/B Solution) Use in device preparation and washing during assay, and for reconstitution of the Lyophilized Controls.	2 bottles (8ml/btl)	1 bottle (50ml/btl)
7.	Clear Solution For final wash. Use to prevent binding of non specific agents.	1 bottle (6ml/btl)	1 bottle (16ml/btl)
8.	Reagent Pipettes Provided for the transfer of Samples, Controls and Protein A-Gold Reagent.	30 pcs	115 pcs
9	1 ml Calibrated Pipettes With graduation marks. Provided for reconstitution of Lyophilized Controls.	2 pcs	2 pcs

PRECAUTIONS

1. **DO NOT** use the kit components beyond the expiration date.
2. **DO NOT** mix and use kit reagents from different kit lots.
3. **DO NOT** interchange bottle **CAPS** as this will lead to cross-contamination and may affect kit performance.
4. Avoid microbial contamination of kit reagents.
5. Use a separate pipette for each sample tested and discard it as biohazard waste.
6. **DO NOT** remove the HIVSCAN™ 1+2 (2.1) devices from their pouches until ready to be used. Re-close the pouch tightly after opening.
7. Follow the recommended standard HIVSCAN™ 1+2 (2.1) assay procedure for testing of all samples. The precision and accuracy of the results are dependent upon the use of reproducible techniques.
8. Use only the reactive CONTROL supplied with the HIVSCAN™ 1+2 (2.1). It is recommended that tests be run concurrently with the reconstituted POSITIVE and NEGATIVE CONTROL especially if the kit has not been used for several days.
9. This kit should only be used by qualified medical or laboratory personnel after adequate training, or under strict supervision.

PREPARATION OF REAGENTS

Note :

- If the kit devices and reagents have been stored in the refrigerator, allow all components to come to room temperature before use.
- Use the Calibrated Pipettes provided to remove the appropriate quantity of WASH AND BLOCK SOLUTION (W/B Solution) for reconstitution of the LYOPHILIZED CONTROLS.
- Shake the reagents well before use.

1. **Reconstitution of Negative and Positive Controls**
   Reconstitute each vial of **LYOPHILIZED CONTROLS** with 1 ml of **WASH AND BLOCK SOLUTION**. Swirl the solution well until completely dissolved before use. The reconstituted controls are stable for 3 months at 4°C and for 2 months at room temperature (25°C). The controls needs to be re-sealed with parafilm and put back to the zip-lock bag.
2. **Reconstitution of Lyophilized Protein A-Gold Reagent (GCP Reagent)**
   Reconstitute each vial of **LYOPHILIZED PROTEIN A-GOLD REAGENT** with one vial of **GCP DILUENT**. Shake well until completely dissolved before use. One vial of Protein A-Gold reagent is sufficient for 9-10 tests. The reconstituted Protein A-Gold reagent is stable for 25 days at 4°C.
3. **Wash and Block Solution (For 100 Tests Kit)**
   Each time fills 25ml W/B Solution into the dropper bottle provided, snap dropper tip into place on tip of bottle and cap.

SPECIMEN PREPARATION

The HIVSCAN™ 1+2 (2.1) test can be performed on either serum of plasma. It is recommended that fresh samples be used whenever possible. If this is not possible, samples should be stored in a refrigerator (2-8°C) before analysis. For long term storage, specimens should be frozen at -20°C (see section, "Frozen Samples").

STORAGE OF THE KIT

Unopened kit should be stored in a cool dry area.

FROZEN SAMPLES

The HIVSCAN™ 1+2 (2.1) works best when used with fresh samples that have NEVER been frozen and thawed. However, most frozen samples will work well with the assay after treatment with one of the following procedures.

I. Allow sample to thaw upright and undisturbed. Allow particulate to settle to bottom of sample container. Use clear upper portion for assay.
II. Centrifuge the sample. Carefully draw up the supernatant using a pipette, be careful not to remove and particulates. Use this supernatant as sample in the standard HIVSCAN™ 1+2 (2.1) assay procedure.
III. Filter the sample using a 0.2μm cellulose acetate (syringe) filter. Use the filtrate as the sample in the standard HIVSCAN™ 1+2 (2.1) assay procedure.

STANDARD ASSAY PROCEDURE

Note :

- Use one device per test.
- Add the WASH AND BLOCK SOLUTION directly from the dropper bottle provided.
- Deliver "free-falling drops" onto the device for all samples and reagents to ensure consistent results. Shake the reagents well before use.

To the HIVSCAN™ 1+2 (2.1) device :

1. Add 3 drops of **WASH AND BLOCK SOLUTION** and allow to soak in.
2. Add 1 drop (or 45μl) of **SAMPLE** and allow to soak in.
3. Add 3 drops of **WASH AND BLOCK SOLUTION** and allow to soak in.
4. Add 2 drops of **RECONSTITUTED PROTEIN A-GOLD REAGENT** and allow to soak in.
5. Add 3 drops of **WASH AND BLOCK SOLUTION** and allow to soak in.
6. Add 3 drops of **CLEAR SOLUTION** and allow to soak in.

For easiest interpretation, read results immediately.

Note :

- Samples that take longer than one minute to flow through the devices should first be treated according to Procedure 3 in the section on **"FROZEN SAMPLE"** before being re-tested according to the standard HIVSCAN™ 1+2 (2.1) assay procedure using a fresh device.

INTERPRETATION OF RESULTS

The serum control spot should be visible on all devices. Results are then interpreted as NEGATIVE or POSITIVE.

Device Pattern After Assay	Interpretation	Fig.
Clear membrane OR overall pink color, Serum control spot visible.	NEGATIVE	1
A distinct RED/PINK SPOT appears, Serum control spot visible.	POSITIVE for antibodies to HIV-1 and/or HIV-2	2
No spot	Invalid Result	3