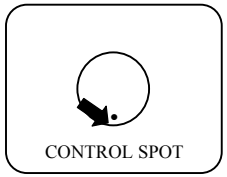

Fig. 1 NEGATIVE

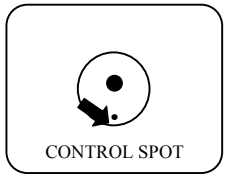

Fig. 2 POSITIVE

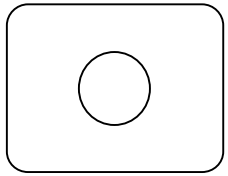

Fig. 3 INVALID

Note :

- Any sample with a distinguishable spot, even if reactivity is less than the Weak Reactive Control, should be treated as POSITIVE. All positive samples should be confirmed by a supplemental assay such as an immunoblot assay.

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 HCV infection in the population to be screened.
3. The prevalence of HCV antibody in random donors is not known but the higher the prevalence of HCV antibody in population, the lower the proportion of false positive samples.
4. All clinical and laboratory information should be used when diagnosing a HCV infection. HCVSCAN is to be used as an aid to diagnose and should not be interpreted as diagnostic itself.

EY LABORATORIES, INC.

P.O. Box 1787, 107 N. Amphlett Blvd., San Mateo, CA 94401, U.S.A.
Tel : (650) 342-3296 Outside CA : (800) 821-0044 Fax : (650) 342-2648

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)

HCVSCAN

for the detection of antibodies
to the Hepatitis C Virus in human serum or plasma

INSTRUCTION MANUAL

INTRODUCTION

The HCVSCAN KIT is a rapid, simple qualitative test for the detection of antibodies to Hepatitis C Virus, in human serum or plasma. This it is intended only as an initial screening test.

The HCVSCAN assay is fast and simple to perform. All reagents and materials required for the test are provided in the kit.

PRINCIPLE OF THE TEST

A capture antigen is immobilized on the device membrane. Antibodies to HCVSCAN 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 HCV antibodies to form a red color on the membrane. Appearance of a red spot indicates the presence of HCV antibodies.

CONTENTS OF THE HCVSCAN

		20 Tests	100 Tests
1.	HCVSCAN Devices	20 x 1	20 x 5
2.	Non-Reactive Control Lyophilized normal human serum, non-reactive for HBsAg, HIV antibodies as well as for HCV antibodies.	1 vial	1 vial
3.	Weak Reactive Control Lyophilized, inactive normal human serum with low titered antibodies to HCV	1 vial	1 vial
4.	Strong Reactive Control Lyophilized, inactive normal human serum with high titered antibodies to HCV	1 vial	1 vial
5.	Gold Conjugate (GCP) Lyophilized Protein A-Gold Conjugate containing 0.05% Sodium Azide as preservative.	3 vials	12 vials
6.	Diluent Each vial contains 1ml of purified water. For reconstitation of the GCP and controls	6 tubes	15 tubes
7.	Blocking Buffer * Phosphate buffered saline containing heat treated normal goat serum.	1 bottle	1 bottle

8.	Wash Buffer 1 * Phosphate buffered saline containing heat treated normal goat serum.	1 bottle	1 bottle
9.	Wash Buffer 2 ** Phosphate buffered saline containing Tween 20.	1 bottle	1 bottle
10.	Stop Solution *** Saline buffer.	1 bottle	1 bottle
11.	Sample Pipettes Provided for the transfer of samples.	20 pcs	100 pcs
12.	Reagent Pipettes Provided for the transfer of Protein A-Gold Reagent.	3 pcs	12 pcs

* Contains 0.1% sodium azide and 0.05% Thimersal as preservative.
** Contains 0.1% sodium azide as preservative.
*** Contains 0.001% sodium azide as preservative.

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 HCVSCAN devices from their pouches until ready to be used. Re-close the pouch tightly after opening.
7. Follow the recommended standard HCVSCAN assay procedure for testing of all samples. The precision and accuracy of the results are dependent upon the use of reproducible techniques.
8. 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.
- Shake the reagents well before use.

1. Controls
   To each vial of lyophilized control empty the contents of 1 tube of Diluent completely into the lyophilized control vial. Swirl the reconstituted control well and allow to sit at room temperature for at least 10 minutes before use. The controls are stable for at least 6 months at 4°C and for 1 month at room temperature after reconstitution.
2. Reconstitution of Lyophilized Protein A-Gold Conjugate (GCP Reagent)
   Reconstitute each vial of LYOPHILIZED CONJUGATE with 1 tube of DILUENT prior to use. Swirl well until completely dissolved and allow to sit at room temperature for at least 10 minutes before use. One vial of Protein A-Gold Reagent is sufficient for 9 tests. The reconstituted GCP conjugate is stable for 1 month at 2-8°C and for 5 days at room temperature.

SPECIMEN PREPARATION

The HCVSCAN 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").

FROZEN SAMPLES

The HCVSCAN works best when used with fresh samples that have NEVER been frozen and thawed. With frozen samples, best results are obtained after the removal of particulates from the sample by centrifugation. If a centrifuge is not available, most frozen samples perform adequately when one of following procedures is used :

I. Allow sample to thaw, then mix gently. Allow sample to stand in a rack or container and let lumps, particulates, etc. settle to bottom. Use clear part of sample for testing.
II. Filter sample with a 0.2µm or 0.45µm cellulose acetate filter. Use filtered sample for testing. If quantity of sample is limited, mix 1 drop of sample with 3 drops of BLOCKING BUFFER. Add 4 drops of the diluted sample in the standard assay procedure.

STANDARD ASSAY PROCEDURE

Note :

- Use one device per test.
- Deliver "free-falling drops" onto the device for all samples and reagents to ensure consistent results. Shake the reagents well before use.

To the HCVSCAN device :

1. Add 2 drops of BLOCKING BUFFER to the device and allow to soak in.
2. Add 1 drop (or 45µl) of undiluted SAMPLE and allow to soak in.
3. Add 2 drops of WASH BUFFER 1 and allow to soak in.
4. Add 2 drops of RECONSTITUTED GCP CONJUGATE and allow to soak in.
5. Add 2 drops of WASH BUFFER 2 and allow to soak in.
6. Add 2 drops of STOP SOLUTION and allow to soak in.
   Read results immediately for easiest interpretation.

Note :

- Samples which take longer than one minute to flow through the devices should be treated according to II. in the "FROZEN SAMPLE" section.

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 light pink color with serum CONTROL SPOT.	NEGATIVE	1
Distinct RED/PINK SPOT in center of device with serum CONTROL SPOT.	POSITIVE	2
Overall PINK/RED color OR small CONTROL SPOT absent.	INVALID	3