人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒 说明书
(胶体金渗透法)（血清/血浆）

【产品名称】人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)

【英文名称】Rapid HIV（HIV-1/2） Test Kit

【包装规格】50人份/盒

【预期用途】本产品适用于血清、血浆样本中人类免疫缺陷病毒（HIV-1/2）抗体的定性检测。

本产品可用于人类免疫缺陷病毒感染的辅助诊断。

【检验原理】人体免疫缺陷病毒（HIV）是引起获得性免疫缺陷综合症（艾滋病）的原因。人体感染了HIV－1 和 HIV－2 后会产生相应的 HIV 抗体，因此，检测 HIV－1 或HIV－2 抗体的存在就能判断是否感染 HIV1/2 。麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)应用与 HIV－1 和 HIV－2 基因组保守区域相关的人工合成多肽，定性地检测 HIV－1 组中M 和O 型及HIV－2 的抗体。样品添加于反应区，一个含胶体金轭合物的轭合帽中产生可以溶解的指示试剂，通过显色反应能产生清晰易读的结果。在结果中出现一条水平的红色操作控制线，表明试剂及检测成分均有效并且操作正确。当胶体金轭合物与HIV 抗体轭合后，会出现一条水平的反应线；如果没有HIV 抗体，结果中就只会出现一条垂直的操作控制线。

【主要组成成份】

50人份/盒:

- 50 个检测盒
- 50 个胶体金Instant Gold™轭合帽
- 50 支小吸管
- 1 支 缓冲溶液(30 mL)
- 阳性和阴性控制包装
- *50 支预制均等的稀释缓冲溶液

(*检测冷冻样品时请向厂商提出需要要求)

【储存条件】室温(2-30℃)保存。应存放在阴凉干燥、避光、隔热和防潮的地方。避免冰冻保存。

【有效期】24个月

【样本要求】

血清或血浆样品的收集和储存:

麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)适用于检测血清或血浆样品。用抗凝血剂如EDTA、肝素、或柠檬酸提取的血浆可用于检测。样品可以在环境温度下过夜运输，但如果环境温度>35℃，样品必须放入冰柜运输。如果收到样品后不能立即使用，则必须放入冷藏柜（2－8℃）储存，最多5 天；如果样品需要等很长时间才使用，则必须放入<-20℃ 的冷冻柜冷冻储存。避免反复冰冻融解。

【检验方法】

注意事项

- 在进行下一个检测步骤前，所滴加的溶液必须全部渗透检测膜；
- 试验一旦开始，各个检测步骤必须连续进行，中间不得有中断；
- 在平坦的工作台上进行检测；
- 即时解读检测结果，否则将可能导致不准确的检测结果；
- 对产品品质有怀疑时可用厂方提供的质控品进行测试，具体操作步骤与所做的检测步骤相同。

* 适用于新鲜收集的血清/血浆样品

1. 加 3 滴 PUSH 缓冲溶液到检测盒的中央

*2. 用一次性小滴管，直接加 1 滴血清或血浆样品到检测盒里

3.将轭合帽放置在反应盒上，滴加12滴PUSH缓冲溶液到反应盒里，等缓冲溶液完全被吸收后再移开轭合帽，待所有的胶体金轭合物被膜吸收后，再滴加3滴PUSH缓冲溶液清洗反应膜,立即读取结果

备注：对于冰冻样品的检测，用刻度吸管将50μL的样品加到预制的稀释缓冲溶液瓶中，轻轻混合后，将混合液全部滴加到检测盒内，等溶液完全吸收后，继续上述步骤3。

【检验结果的解释】

怎样读取检测结果?

你大概没有感染 HIV-1 和/或 HIV-2

只在控制区（即 “C” 区）下有一条红色线出现，即表示你大概没有感染 HIV-1 或 HIV-2 。若 HIV 的病症持续，可以用另一套麦美华HIV-1/2重新检测或咨询你的医生。

你可能感染了 HIV-1 和/或 HIV-2

在检测区（即“T”区）和控制区（即“C”区）同时出现两条红线，即表示你可能感染了 HIV-1 或/和 HIV-2。 其中一条线可能比另一条线浅色，但两条线的颜色无需深浅一致。这种结果意味着你的血液中可能存在 HIV-1 和/或 HIV-2 的抗体，请尽快联络你的医生。

检测结果无效

如果没有红线出现在控制区(即“C”区)，即使有一条红线出现在检测区(即“T”区)，检测结果是无效的。同样地，如果有一条断裂的红线出现在控制区(即“C”区)，表明可能在检测过程中检测盒或检测样品出现问题，你应该用一套新的麦美华HIV-1/2来重新测试。如果上述问题持续出现，请联络MedMira(麦美华)在当地的经销商。

【检验方法的局限性】

- 严格遵守操作步骤以求正确结果；
- 检测线的强度和样品中抗体的滴定度没有必然的相互关系；
- 没有血清学检测可以绝对肯定一个样品不含低值的 HIV－1/2 抗体或检测到早期的 HIV 感染，因而，一个阴性的结果并不排除 HIV－1/2 病毒感染的可能性；
- 所有的阳性结果必须按要求到相关的确证实验室进行确证实验。

【产品性能指标】

敏感度

麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)对 HIV－1 组的 M 亚型抗体检测的敏感度被证明是100%。对10 个被确诊的 HIV－1 组 O 型的样品的敏感度也是100%。对99个被Western blot 确诊的HIV－2 样品检测时，其敏感度是100%（表1）。当2036个被Western blot 确诊的 HIV－1 阳性被检测时，麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)的总敏感度为99.93%（表2）。

表 1麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)对于检测 HIV-1 M组, O 组 和 HIV-2 的敏感度

样品 (组, clade)	样品的数量	麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)敏感度(%)
HIV-1 (M,A)	8	100
HIV-1 (M,B)	58	100
HIV-1 (M,C)	19	100
HIV-1 (M,D)	4	100
HIV-1 (M,E)	3	100
HIV-1 (M,F)	3	100
HIV-1 (M,G)	1	100
HIV-1 (O)	10	100
HIV-2	99	100

表 2 由 HIV-1 流行地域研究麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)的敏感度

国家	流行情况	样品数量	麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)敏感度(%)
加拿大	B	836	99.76
印度	C,A,B	20	100
秘鲁	B,F	20	100
坦桑尼亚	C,A,D	14	100
泰国	E,B	20	100
特立尼达	B	20	100
美国	B	1105	99.73

特异性

对15,420 个HIV－1/HIV－2 阴性样品的检测结果表明麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)的总特异性为 99.31%。

重现性

麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)的重现性为 100%，既不存在内部观测差异，也不存在批间差异。

与获FDA 批准的SUDS 产品比较

麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)与 SUDS 产品有着 100%相同的检测结果。

表 3 与获FDA 批准的SUDS 产品比较

SUBS 结果 + −	麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)结果 +	麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)结果 −	总数
	50	0	50
	0	150	150
总数	50	150	200

干扰因素的研究

用400 份的样品来研究EDTA、肝素、柠檬酸钠和过高的AST（范 围 为96-1764U/L）、ALT(136-2296U/L)、 ALP（297-550U/L）、 全胆红素（34-65μmol/L）、LD（350-600U/L）和尿酸(600-940μmol/L）对麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)的影响。 结果表明麦美华人类免疫缺陷病毒（HIV-1/2）抗体检测试剂盒(胶体金渗透法)均不受上述因素的干扰。

【注意事项】

1. 采用正确的生物安全操作法来处理样品和试剂。这些安全事项包括:

A. 戴安全手套;

B. 不可用嘴接触小吸管;

C. 处理这些材料时不可吃喝东西、使用化妆品或隐型眼镜;

D. 用合适的消毒剂如0.1%次氯酸钠清洁和消毒所有被样品和试剂玷污的地方;

E. 清除和回收所有的样品、试剂和所有其它当地法规认为是潜在的污染物质;

2. 检测盒是一次性使用盒,不可反复使用, 一旦从包装里拿出请尽快使用, 以免受潮, 影响检测结果;

3. 本品只适用于体外诊断。

【参考文献】

1. Carson, JL. et al. 1987. Rapid, easy and economical screening tests for antibodies to human immunodeficiency virus. Lancet ii:361-362.

2. Van de Perre, PD. et al. 1988. Comparison of six serological assays for human immunodeficiency virus antibody detection in developing countries. J. Clin. Microbiol. 26:552-556.

【生产企业】

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【中国地区售后服务单位】

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2014 年 2 月 24 日

medmira

Rapid HIV Test Kit

This package insert must be read carefully prior to using the product. Accuracy of test results cannot be guaranteed if there are deviations from the enclosed instructions.

PACKAGING FORMAT
- Box of 50 tests

INTENDED USE
Rapid HIV test kit can detect antibodies to HIV-1 and/or HIV-2 in serum, plasma. It can be used in blood donation, general public health, emergency, blood transfusion and remote area without proper equipment.

BIOLOGICAL PRINCIPLES OF THE TEST
Human immunodeficiency virus (HIV) causes acquired immunodeficiency syndrome (AIDS). Infection with HIV-1 and/ or HIV-2 results in the production of the corresponding HIV antibodies. Therefore, tests that detect HIV-1/HIV-2 antibodies provide the means to identify HIV infected individuals.[1,2] Rapid HIV Test Kit utilizes synthetic peptides corresponding to conserved regions of the HIV-1 and HIV-2 *env* genomes for the qualitative detection of antibodies to HIV-1 group M & O and/or HIV-2. Sample is added to the reaction zone. A conjugate cap contains the indicator reagent, producing a colorimetric reaction that can be easily visualized and interpreted. An integrated vertical red procedural control line appears to indicate that the reagent and test components are functioning properly and that the test procedure has been performed correctly. When the conjugate binds to the HIV antibodies, a horizontal test line also appears. In the absence of HIV antibodies, only the procedural control line appears.

CONTENTS
Box of 50 Tests (Serum/Plasma only)
- 50 test cartridges
- 50 conjugate caps
- 50 disposable pipettes
- 1 Buffer solution (30 mL)
- Positive and Negative control pack

50 vials of pre-aliquoted diluent buffer can be requested from the manufacturer for previously frozen serum or plasma samples.

STORAGE CONDITION AND EXPIRY DATE
The Rapid HIV Test Kit should be stored in a cool dry area protected from direct sunlight, heat and moisture. Do not freeze.
Expiry Date: 24 months

EQUIPMENT REQUIRED
No additional equipments are required.

SPECIMEN COLLECTION
For Serum/Plasma
Plasma obtained using anticoagulants such as EDTA, heparin, or sodium citrate is suitable for testing. Serum or plasma specimens may be shipped overnight at ambient temperature.
However, if the transit time is expected to exceed 24 hours and the ambient temperature is >35°C, specimens should be shipped under refrigeration. If specimens cannot be tested upon receipt, they can be stored under refrigeration (2 to 8°C) for up to 5 days. For a longer delay in testing, specimens should be stored frozen (< -20°C). Avoid multiple freeze thaw cycles.

INSTRUCTIONS

Please read the following items carefully before performing the test.
- **Read this instruction sheet completely and carefully prior to use of the Rapid HIV Test Kit. If the directions are not followed exactly, inaccurate test results may occur.**
- Do not use after the expiration date printed on the outside box or on the pouch
- Store in a dry place at 2-30°C
- Keep out of reach of children
- For *in vitro* diagnostic use only. Not to be taken internally
- Do not open the pouch until you are ready to start the test
- Dispose with care for all test kit materials after use

DIRECTIONS FOR USE
GENERAL PREPARATION
1. Remove the mylar pouch from the box.`
2. Using the notched corners, tear open the Mylar pouch (both compartments). Place all components on a clean, flat surface. Remove the cap from the Diluent Buffer vial (Red colour cap) and place onto a clean, flat surface.
3. Ensure the blue Specimen Filtration Unit is placed firmly in the well of the white plastic Test Cartridge.

TESTING PROCEDURE

- ***All solutions must be completely absorbed into the test membrane before proceeding to the next step in the testing procedure.***
- ***Once the assay has been started, all subsequent steps should be completed without interruption.***
- ***Perform the test on a flat work surface.***
- ***Read the test results immediately. Failure to do so may result in inaccurate test results.***

FOR FRESHLY COLLECTED SERUM/PLASMA
1. Add 3 drops of Buffer to the center of the test cartridge.
*2. Using a disposable pipette, add one drop of test sample. Discard pipette.
3. Place a conjugate cap on the test cartridge and add 12 drops of buffer. Remove the conjugate cap after the solution has been absorbed. Read result.

*NOTE: If the specimen is cloudy or containing particulate, pipette 50 µL of test sample into the pre aliquoted diluent buffer vial (requested from manufacturer) and mix gently. Using a disposable pipette, add the entire contents of the vial dropwise onto the test cartridge. Allow the solution to be completely absorbed. Proceed to Step 3 above.

QUALITY CONTROL
To insure assay validity, a procedural control is incorporate in the device. If there is no procedural control line under the C, and even if the line appears adjacent to the T, the test is invalid and should be repeated with a new Rapid HIV Test Kit.

HOW TO READ THE TEST RESULTS

You Probably Are Not Exposed to HIV-1 and/or HIV-2
The presence of one red line in the control region (C) means you probably are not exposed to HIV-1 and/or HIV-2. If the symptoms still persist or there is reason to be concern, repeat the procedure with another Rapid HIV Test Kit or consult your doctor.

You might be exposed to HIV-1 or HIV-2
The presence of two red lines in both the test region (T) and control region (C) means you might be exposed to HIV-1 and/or HIV-2. One line may be lighter than the other, and they do not have to match. It means that HIV-1 and/or HIV-2 antibodies are probably present in your blood. Visit your doctor as soon as possible.

Invalid Result
The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). Also, the presence of a broken line under the (C) indicates that there has been a problem, either with the test device or the specimen, during the Testing Procedure. You should repeat the procedure with a new Rapid HIV Test Kit . If the problem persists, contact your local distributor.

LIMITATIONS OF THE PROCEDURE
- The procedure must be followed as directed to obtain accurate results.
- The intensity of the test line does not necessarily correlate to the titre of antibody in the specimen.
- No serological test can provide absolute assurance that a specimen does not contain the low level of HIV- 1/-2 antibodies present at an early stage of infection.
- A negative result therefore does not exclude the possibility of exposure to or infection with HIV-1/2 viruses.
- All positive specimens must be confirmed by supplemental testing.

PERFORMANCE CHARACTERISTICS
Sensitivity
The sensitivity of the Rapid HIV Test Kit for the detection of antibodies to HIV-1 group M subtypes was determined to be 100%. The Rapid HIV Test Kit showed 100% sensitivity when 10 confirmed HIV-1 group O specimens were tested. The sensitivity of the Rapid HIV Test Kit for HIV-2 antibodies was determined to be 100% when 99 Western blot confirmed HIV-2 positive specimens were tested (Table 1). The overall sensitivity of the Rapid HIV Test Kit t was 99.93% when 2036 Western blot confirmed HIV-1 positive specimens (different clades) were tested (Table 2).

Table 1 Sensitivity of Rapid HIV Test Kit with HIV-1 group M, group O and HIV-2

Specimen (group, clade)	Number of Samples	Rapid HIV Test Kit Sensitivity (%)
HIV-1 (M,A)	8	100
HIV-1 (M,B)	58	100
HIV-1 (M,C)	19	100
HIV-1 (M,D)	4	100
HIV-1 (M,E)	3	100
HIV-1 (M,F)	3	100
HIV-1 (M,G)	1	100
HIV-1 (O)	10	100
HIV-2	99	100

Table 2 Sensitivity of Rapid HIV Test Kit with prevalent HIV-1 clades by region

Country	Prevalence	Number of Samples	Rapid HIV Test Kit Sensitivity (%)
Canada	B	836	99.76
India	C,A,B	20	100
Peru	B,F	20	100
Tanzania	C,A,D	14	100
Thailand	E,B	20	100
Trinidad	B	20	100
United States	B	1105	99.73

Specificity
The overall specificity of the Rapid HIV Test Kit was 99.31% when 15,420 HIV-1/HIV-2 negative specimens were tested.

Reproducibility
There were neither intra- or inter-observer variations nor intra- or inter-lot variations, and the reproducibility of the Rapid HIV Test Kit was found to be 100%.

Comparability with a FDA Approved Rapid HIV Test
The Rapid HIV Test Kit showed 100% concordance with the FDA approved SUDS rapid HIV test (Table 3).

Table 3 Comparative Study between Rapid HIV Test Kit and SUDS

SUDS result + -	Rapid HIV Test Kit Result +	-	Total
	50	0	50
total	0	150	150
	50	150	200

Interference Study
Interference study was performed on 400 specimens and the results indicated that EDTA, heparin sodium citrate and elevated analytes AST (range 96 – 1764 U/L), ALT (136 – 2296 U/L), ALP (297 – 550 U/L), total bilirubin (34 – 65 µmol/L), LD (350 – 600 U/L) and Uric acid (600 – 940 µmol/L) did not interfere with the test.

PRODUCT WARRANTY
MedMira Laboratories Inc. guarantees the quality of this product if stored and used as stipulated. Any component of the kit found to be defective shall be replaced free of charge upon return of the defective product. MedMira Laboratories Inc. disclaims any implied warranty of merchantability or fitness for a particular purpose, and in no event shall the MedMira Laboratories Inc. be liable for consequent damage.

LITERATURE CITED
1. Carson, JL. et al. 1987. Rapid, easy and economical screening tests for antibodies to human immunodeficiency virus. Lancet ii : 361-362.
2. Van de Perre, PD. et al. 1988. Comparison of six serological assays for human immunodeficiency virus antibody detection in developing countries. J. Clin. Microbiol. 26: 552- 556.

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