



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) (全血)

【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】1人份/盒; 30人份/盒

【预期用途】本产品适用于全血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征 (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, 一个含胶体金颗粒的胶合鞘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。当胶体金颗粒与 HIV 抗体结合后, 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】

1人份/盒: 1个聚酯薄膜袋内含有

- 1个安置有蓝色过滤帽 (蓝色小帽) 的检测盒 (仅为全血检测时配置)
- 1个显色用的胶体金 Instant Gold™ (绿色小帽)
- 1支一次性的小吸管
- 1瓶 缓冲溶液 (白色瓶盖)
- 1瓶稀释用的缓冲液 (粉红色瓶盖)

30人份/盒: 30个聚酯薄膜袋, 每个内有

- 1个安置有蓝色过滤帽 (蓝色小帽) 的检测盒 (仅为全血检测时配置)
- 1个显色用的胶体金 Instant Gold™ (绿色小帽)
- 1支一次性的小吸管
- 1瓶 缓冲溶液 (白色瓶盖)
- 1瓶稀释用的缓冲液 (粉红色瓶盖)

【储存条件及有效期】室温(2-30°C)保存, 有效期24个月。
应存放在阴凉干燥、避光、隔热和防潮的地方。避免冰冻保存。

【样本要求】

全血样品采集:

1. 先用酒精棉消毒手指, 待手指上的酒精完全干透;
2. 拉开刺血针的白色塑料顶端, 将针头放在已消毒的手指部位, 按压刺血针手柄使针头刺入手指皮肤后, 并轻轻挤压刺破部位;
3. 挤压小吸管的顶部, 并将吸管口放在血滴中间, 慢慢打开小吸管的顶部将血滴吸入小吸管内, 将小吸管内的血液滴到稀释缓冲液小瓶中(粉红色瓶盖), 在血滴和溶液完全混和后, 即可开始检测。

【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家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。

* 新鲜收集的全血样品

1. 把6滴缓冲溶液(白色瓶盖)滴在过滤帽中间, 等溶液完全渗透后, 将混和了血滴的稀释缓冲液 (粉红色瓶盖)全部倒入蓝色过滤帽中。在进入下一步操作程序前, 必须确定蓝色过滤帽里的溶液已完全渗透到下面的检测膜;

2. 将蓝色的过滤帽从检测盒上移开, 将InstantGold™显色帽(绿色小帽)轻轻放置在检测盒的中部, 把12滴的缓冲溶液 (白色瓶盖)滴到Instant Gold™ 显色帽的中部
3. 待帽中缓冲溶液完全渗透后, 将Instant Gold™ 帽子移开, 读取结果

【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, 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或检测样品出现问题, 你应该用一套新的麦美华HIV-1/2重新测试。如果上述问题持续出现, 请联系 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诊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		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方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、使用化妆品或隐形眼镜;
 - 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沾污的地方;
 - 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, J.L. et al. 1987. Rapid, easy and economical screening tests for antibodies to human immunodeficiency virus. Lancet ii:361-362.
2. Van de Perre, P.D. 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】

MedMira Laboratories Inc.
加拿大麦美华公司
155 Chain Lake Drive, Suite 1
Halifax, Nova Scotia, Canada
B3S 1B3
Telephone: 902 450 1588
Fax: 902 450 1580
www.medmira.com (English/英文)
www.medmira.cn (Chinese/中文)

【中国地区售后服务单位】

【医疗器械注册证书编号】

国食药监械(进)字2014第3401076号

【产品标准编号】

YZB/CAN 0594-2014

【说明书批准及修改日期】

2014年2月24日

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

- Single test
- Box of 30 tests

INTENDED USE

Rapid HIV test kit can detect antibodies to HIV-1 and/or HIV-2 in whole blood. It can be used in blood donation, general public health, emergency, blood transfusion and remote areas 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

Single test

- 1 Mylar Pouch
- 1 test cartridge with attached Blue colour Specimen Filtration Unit (For Whole Blood Test)
- 1 Instant Gold™ Cap (Green colour)
- 1 disposable pipette
- 1 Universal Buffer dropper bottle (White colour Cap)
- 1 vial of Diluent Buffer Solution (Pink colour Cap)

Box of 30 tests

- 30 Mylar Pouches containing:
 - 1 test cartridge with attached Blue colour Specimen Filtration Unit (For Whole Blood Test)
 - 1 Instant Gold™ Cap (Green colour)
 - 1 disposable pipette
 - 1 Universal Buffer dropper bottle (White colour Cap)
 - 1 vial of Diluent Buffer Solution (Pink colour Cap)

Note: Each test provides one set of lancet and alcohol swab

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, store at room temperature 2-30 °C
Expiry Date: 24 months

EQUIPMENT REQUIRED

No additional equipments are required.

SPECIMEN COLLECTION

For Whole Blood

- Using the alcohol swab provided, clean your Index finger. Allow the finger to dry thoroughly.
- Pull the white plastic tip off the lancet and place it against your clean site of your Index finger. Puncture the skin by pressing the handle all the way. Hold the finger downward and apply gentle pressure beside the point of puncture.
- Squeeze the outside of the disposable pipette and place it in the center of the blood drop. Slowly release channel of the pipette. Apply **one (1)** drop of blood into the uncapped Diluent Buffer vial (Pink colour cap). Gently mix by tapping the bottom of the vial. Immediately begin the **TESTING PROCEDURE**.

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 Mylar 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 Mylar pouch until you are ready to start the test
- Dispose with care for all test kit materials after use

DIRECTIONS FOR USE

GENERAL PREPARATION

- Remove the Mylar pouch from the box.
- Using the notched corners, tear open the Mylar pouch. Place all components on a clean, flat surface.
- 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 WHOLE BLOOD SPECIMEN

- Apply six (6) drops from the MedMira Universal Buffer vial (White colour cap) to the center of the Blue Specimen Filtration Unit. Allow the buffer to absorb completely. Pour the entire contents of the Diluent Buffer vial (Pink Colour cap) into the center of the blue Specimen Filtration Unit. Ensure that the solution has completely absorbed into the blue Specimen Filtration Unit before proceeding to the next step.
- Remove the blue Specimen Filtration Unit by gently twisting the handle in a circular and upwards motion. Place the instant Gold™ Cap (Green colour) loosely into the well of the test cartridge. Apply **twelve (12)** drops of MedMira Universal Buffer to the center of the Instant Gold™ Cap.
- Allow the buffer to absorb completely. Remove the Instant Gold™ Cap and **Read Result**.

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 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
-	0	150	150
total	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

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

MedMira Laboratories Inc. Distributor
Suite 1, 155 Chain Lake Drive
Halifax, Nova Scotia. B3S 1B3
Canada
Telephone: +1-902-450-1588
Fax: +1-902-450-1580
Email: sales@medmira.com
www.medmira.com
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