DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on MP Diagnostics products and packaging. These symbols are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the British and European Standard BS EN 980: 2003.

Use by

SYNONYM for this:

EXPIRY DATE

IN VITRO DIAGNOSTIC MEDICAL DEVICE

LOT CODE

SYNONYM for this lot:

CATALOGUE NUMBER

ATTENTION

INSTRUCTION FOR USE

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

CONTAINS SUFFICIENT FOR <n> TESTS

CONSULT INSTRUCTIONS FOR USE

DO NOT REUSE

DESCRIPTION OF KIT COMPONENTS

MPD ASSURE® H. pylori Rapid Test devices in individually sealed pouches with desiccant. Store at 2°C to 28°C.

CHARGE BUFFER: 0.1% Sodium azide solution. Store at 2°C to 28°C.

PLASTIC SAMPLE APPLICATORS: 20 pieces

INSTRUCTION MANUAL: 1 copy

INTRODUCTION

H. pylori, a spiral urease-producing bacteria was first isolated and characterized by Warren and Marshall in 1983. A high correlation has been found between the presence of this organism and gastritis, gastric ulcers and duodenal ulcers and a correlation between long term infection with H. pylori and gastric cancer has been implicated. The success in treatment of ulcers due to H. pylori and the risk of developing gastric cancer if chronic infection is left untreated points towards the need for reliable early diagnosis.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The MPD ASSURE® H. pylori Rapid Test is an indirect solid-phase immunochromatographic assay where antibodies to the test sample (serum, plasma or whole blood) form antibody-antigen complexes with immobilized H. pylori antigens on the membrane as the test sample migrates upwards from the sample well. The bound antibody-antigen complexes are detected by the test sample (serum, plasma or whole blood). It is intended as a clinical diagnostic test for diagnosing infection with H. pylori in patients with gastric disorders. In addition, the presence of antibodies to a recombinant current infection marker (CIM) is indicative of current infection.

HEALTH AND SAFETY INFORMATION

1. In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.
3. Wipe any spills of sera, plasma or blood promptly with 1% alcohol swabs.
4. Gloves must be worn.
5. Optimal assay performance requires STRICT ADHERENCE to the assay procedure described in this Instruction Manual. Deviations from the procedure may lead to aberrant results.
6. Do not interchange reagents between kit lots.
7. Do not use kit components beyond the expiry date printed on the kit box.
8. The chase buffer reagent contains sodium azide as a preservative. Handle reagent carefully to avoid spills on work surface. Clean up spills with absorbent paper and water.
9. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
10. For best results allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.

STORAGE INSTRUCTIONS

1. Store entire kit at 2°C to 28°C. Test devices should be kept sealed until required for use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Lancets
2. Alcohol swabs

SPECIMEN COLLECTION

Whole blood can be collected in anti-coagulant containing tubes and used as outlined in the assay procedure immediately or stored at 2°C to 8°C for not more than 48 hours before use.

Serum / plasma samples should be stored at 2°C to 8°C if the test is to be run within 7 days of collection or frozen at -20°C or colder if the test is to be delayed for more than 7 days. Clear, non-hemolyzed samples are preferred. Lipemic, icteric or contaminated (particulate or bacterial) samples should be filtered (0.45μm) or centrifuged before testing.

ASSAY PROCEDURE

IMPORTANT: Strict adherence to the assay procedure will ensure optimal assay performance. Deviations from the procedure may lead to aberrant results.

Note: Allow device, sample applicator, chase buffer and patient’s test sample to warm to room temperature before running assay. If precipitates are noted in the chase buffer reagent, shake the bottle vigorously and allow to warm up further if necessary. Omit this step if the kit is stored at 18°C to 28°C.

1. Label the test device with the sample name.
2. Proceed with the appropriate assay procedure as indicated in Figure 1 or Figure 2.
3. When drawing whole blood, wipe finger tip with alcohol swab, let dry, and prick with lancet. Face the pricked finger tip upwards. Draw the blood with the provided sample applicator to the 25 μl mark (apply slight pressure to the bulb section before drawing blood). Dispense the sample completely into the square well.

ANALYTICAL PRECAUTIONS:

1. For in vitro diagnostic use only.
2. For Professional use only.
3. Please refer to the product labelling for information on potentially hazardous components.

QUALITY CONTROL

1. Running of the positive and negative controls (not included) is optional.
2. Control line contains a pink dye which is the only line visible before running the assay. During the assay, the pink line will turn a darker color indicating the test was correctly run. If the pink line remains unchanged in color, the test is invalid.

Figure 1: Assay Procedure for Whole Blood Samples

Figure 2: Assay Procedure for Serum/ Plasma Samples
**BIBLIOGRAPHY**


**LIMITED EXPRESSED WARRANTY DISCLAIMER**

The manufacturer makes no expressed warranty other than that the test kit will function as an in vitro diagnostic assay within the specifications and limitations described in the Instruction Manual when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer’s liability is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damages, injury or economic loss however caused by the product in the use or in the application thereof.

**TECHNICAL PROBLEMS / COMPLAINTS**

Should there be a technical problem / complaint:
1. Note the kit(s) lot number(s) and the expiry date.
2. Retain the kit(s) and the test device(s).
3. Contact the nearest MP Biomedicals office or your local distributor.

**PERFORMANCE**

Patients from different geographical regions were tested using the MPD ASSURE® H. pylori Rapid Test. Results were compared against gold standard tests for active infection (histology, culture, rapid urease test and urea breath test) - refer table below.

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* paediatric population