INTENDED USE
The MCG Rapid Test Device (Urine) is a rapid visual immunassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine specimen. This kit is intended for use as an aid in the early detection of pregnancy.

INTRODUCTION
Human chorionic gonadotropin (HCG), a glycoprotein hormone secreted by viable placentual tissue during pregnancy, is excrated in urine approximately 20 days after the last menstrual period. HCG levels rise rapidly, peaking after 60-80 days. The appearance of HCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection of pregnancy.

The MCG Rapid Test Device (Urine) detects human chorionic gonadotropin through visual interpretation of color development in the internal strip. Anti-HCG antibodies are immobilized on the test region of the membrane, and anti-HCG antibodies immobilized on the control region. During testing, the HCG antigen reacts with anti-HCG antibodies conjugated to colored particles and precipitated onto the sample pad of the strip. The reaction forms a colored band on the membrane. Color development is observed using the naked eye.

PRINCIPLE
The MCG Rapid Test Device (Urine) detects human chorionic gonadotropin through visual interpretation of color development in the internal strip. Anti-HCG antibodies are immobilized on the test region of the membrane, and anti-HCG antibodies immobilized on the control region. During testing, the HCG antigen reacts with anti-HCG antibodies conjugated to colored particles and precipitated onto the sample pad of the strip. The reaction forms a colored band on the membrane. Color development is observed using the naked eye.

MATERIALS
- Individually packed test devices
- Disposable pipettes
- Specimen collection container
- Centrifuge

For professional in vitro diagnostic use only.
Do not use after the expiration date indicated on the package. Do not use if the test foil is damaged. Do not re-use.
This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled according to usual safety precautions (e.g., do not ingest or inhale).
Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
Read the entire procedure carefully prior to testing.
Do not eat, drink or smoke in the area where the specimens and kits are handled.
Do not freeze.
Specimens should be centrifuged, filtered, or allowed to settle completely before testing. Avoid repeated freezing and thawing of specimens.
Specimens must be completely thawed and mixed prior to testing. Avoid repeated freezing and thawing of specimens.
If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of biological materials.

PROCEDURE
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification before use.
2. Add 3 drops of specimen (approximately 120 µL) directly onto the specimen well (S) and start the timer.
3. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
4. As the test begins to work, color will migrate across the result area in the center of the device.
5. Wait for the colored band(s) to appear. The result should be read at 3 minutes. Do not interpret the result after 48 hours.

NOTE: Low HCG concentrations may produce very weak T lines after a prolonged period of time. Therefore, do not interpret the result after 48 hours.

INTERPRETATION OF RESULTS

POSITIVE:
One or more colored bands appear in the control region (C). A faint band may also be visible in the test region (T). The test result is considered positive.

NEGATIVE:
No color band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID:
Control band fails to appear. Results from any test which has not followed the test procedure correctly should only be considered invalid. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

QUALITY CONTROL
Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique. Precautionary controls are not provided with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST
1. The MCG Rapid Test Device (Urine) is for professional in vitro diagnostic use, and should be used only for the qualitative detection of human chorionic gonadotropin.
2. Younger or older urine specimens, exhibiting lower or higher specific gravity, may not contain representative levels of HCG.
3. The test is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
4. HCG levels may be below the lowest detectable level of the test, thus, a negative result does not necessarily mean that pregnancy has not occurred.
5. Although pregnancy testing is generally performed in the first trimester of pregnancy, the test can be validly used for test results during any period of pregnancy.
6. The test is intended as a qualitative test only, and cannot determine the concentration of analytes in the specimen.

SPECIMEN COLLECTION AND STORAGE
- The MCG Rapid Test Device (Urine) is intended for use with human urine specimens only.
- Although urinary pH levels may vary from one day to the next, first morning urine specimens are preferable as they contain the highest concentration of HCG.
- Urine specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Collected urine specimens must be put in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of biological materials.

SPECIMEN CHARACTERISTICS
- The MCG Rapid Test Device (Urine) is designed for use with human urine specimen only. Although urinary pH levels may vary from one day to the next, first morning urine specimens are preferable as they contain the highest concentration of HCG.
- Urine specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Collected urine specimens must be put in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of biological materials.

SPECIFICITY
The MCG Rapid Test Device (Urine) was determined in cross-reactivity studies with known amounts of urinary Hormone (AU), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 mIU/mL hTSH all gave negative results.

INTERFERENCE TESTING
The following substances were added to hCG free and urine samples spiked with 25 mIU/mL hCG:
- None of the substances interfered with the assay at the listed concentrations.
- Serum human chorionic gonadotropin concentrations

LITERATURE REFERENCES

GLOSSARY OF SYMBOLS
- EIA: Enzyme Immunosorbent Assay
- hCG: Human Chorionic Gonadotropin
- hTSH: Human Thyroid Stimulating Hormone
- hFSH: Human Follicle Stimulating Hormone
- hLH: Human Luteinizing Hormone
- AU: Antibodies to Uterine Tissue
- Foil pouch: Package insert
- Overall Agreement: Overall Agreement: 99.9% (%99.9)*
- 95% Confidence Interval: 95% Confidence Interval: 2.9% (2.9)*
- EIA: Enzyme Immunoassay
- Total: Total
- MCG Rapid Test: MCG Rapid Test

IMPORTER:
Mert Laboratuar ve Mıkalımän Tic. Ltd. Şti.
Ağva, İskilip Sarı. 1357 Sok. No:13
İzmir Yeşilçay’a Ankara TURKEY
Tel: +90 312 4578781
Fax: +90 312 4578738

Medpoint®
Assure Tech (Hanzhong) Co., Ltd.
27th, Floor, Building 1, No.10, Xianyang RD., West 2-2nd Zone, Hanzhong, China 320030
Weikang Ltd.
Shanghai B 29 Harley Street
LONDON. W1G 9QX, U.K.
GEBELİK TESTİ (IDRarda)

Test kartı, örnek ve kontrolleri oda ısısına getiriniz (15-30 C)


2. iki damla örnek (yaklaşık 120 mikrolitre) direkt olarak örnek çukuruna (S) damlatınız ve kronometreye basınız.

Pipette oluşacak hava kabarçıklarını deney çukuruna pipete etmeyiniz. Netice penceresine herhangi bir soluyon dökülmeyiniz.

Deneyin rengin membranda yürümesiyle başlamış demektir.

DENEYİN DEĞERLENDİRİLMESİ:

• POSİTİV: İki band membran üzerinde görülür. Bir band Kontrol bölgesini (C) diğer band Test (T) bölgesini gösterir.

• NEGATİF: Sadece kontrol (C) bölgesinde renkli band görülür. Test (T) bölgesinde renkli band görülmez.

• GECERSİZ: Kontrol bandı görülmez. Bu durumda testi tekrar yapınız.