demonstrating antibody recognition, assuming that the procedure was done directly and that the reagents are chemically active.

**REAGENTS**
The MP Diagnostics (MPD) RST-hCG Urine Test Strip is coated with anti hCG antibody conjugated gold particles and anti hCG antibody. 50 test strips are supplied in a kit.

**PRECAUTIONS**
- For professional in vitro diagnostic use only. Do not use after the expiry date.
- The test strip must remain in the sealed pouch until use.
- Do NOT FREEZE.
- Do not use beyond expiry date.
- Dispose used strips in biohazard waste container.

**STORAGE INSTRUCTIONS**
Keep the kit at room temperature or refrigerated (2°C - 30°C) when not in use. The test strip is stable through the expiry date printed on the sealed pouch.

**SPECIMEN COLLECTION AND PREPARATION**

**Specimen Collection**
The urine specimen must be collected in a clean and dry plastic or glass container. Specimens collected at any time can be used; however the first morning urine generally contains the highest concentration of hCG. Urine specimens exhibiting visible precipitates should be filtered, centrifuged or allowed to settle and a clear specimen obtained for testing.

**Specimen Storage**
Specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage specimens may be frozen and stored below -20°C. Frozen specimens should be thawed, mixed and equilibrated to room temperature before testing.

**MATERIALS PROVIDED**
Test strips and Instruction manual.

**MATERIALS REQUIRED (NOT PROVIDED)**
Specimen collection container and a timer.

**ASSAY PROCEDURE**
MP Diagnostics (MPD) RST-hCG Urine Test Strip, specimens, controls and reference materials should be allowed to reach room temperature (15°C - 30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test strip and use it promptly.
2. Hold one end of the strip (the end with RST-hCG print) and dip the other end into specimen container for at least 10-15 seconds (avoid dipping over the MAX limit line).
3. Remove the test strip from urine specimen and lay the test strip side up on a non-absorbent, clean, and flat surface and start the timer for development.
4. Read the result after 3 minutes.

**INTERPRETATION OF RESULT**

(Please refer to the illustration above)
Positive: One red line is in the control region and the other in the test region. As titer of hCG present in the urine varies from specimen to specimen, any shade of red on the test line should be read as positive.

Negative: Only one red line in the control region appears. No red or pink line is seen in the test area.

Invalid: Control band fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most common reasons for invalid test. If this occurs, the assay should be repeated using a new strip. If the problem persists please contact your local distributor.

**QUALITY CONTROL**
The procedural control is included in the test. A colored band appearing in the control region of the result area on the membrane indicates proper performance and chemically active reagents. Good laboratory practices recommend the use of controls to ensure proper test performance.

**LIMITATIONS OF THE PROCEDURE**
1. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG. Therefore the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
2. If a urine specimen is too dilute (i.e. low specific gravity) it may not contain representative level of hCG. If pregnancy is still suspected, the first morning urine should be obtained 48 hours later and tested.
3. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain human anti mouse antibodies (HAMA) and such specimens may cause false positive or false negative results.
4. Because of the high degree of assay sensitivity, specimens tested as positive during the initial days after conception may later be negative due to natural termination of pregnancy. Natural termination occurs in 22% of clinically unrecognized
pregnancies and 31% of pregnancies overall. A test result that is weakly positive should be confirmed by testing again with a first morning urine sample collected 48 hours later.

5. A false negative result may occur when the levels of hCG are below the sensitivity level of the test. When the pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity
The MP Diagnostics (MPD) RST-hCG Urine Test Strip detects hCG at a concentration of 25 mIU/ml or greater and is capable of detecting pregnancy as early as 1 day after the first missed menstrual period.

Specificity
Specificity of MP Diagnostics (MPD) RST-hCG Urine Test Strip was determined from cross-reaction studies with known amounts of Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH) and Thyroid Stimulating Hormone (TSH). The addition of LH (300 mIU/ml), FSH (1,000 mIU/ml) and TSH (1,000 µIU/ml) to hCG negative and positive specimens showed no cross-reactivity.

Standardization
The test has been standardized to the World Health Organization Fourth International Standard.

Accuracy
A multi-center clinical evaluation was conducted comparing the results obtained using the MP Diagnostics (MPD) RST-hCG Urine Test Strip to another commercially available urine membrane hCG test. The urine study included 150 specimens and both assays identified 72 negative and 78 positive results. The results demonstrated a >99% overall accuracy of the MP Diagnostics (MPD) RST-hCG Urine Test Strip when compared to the other urine membrane hCG test.

<table>
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<th>hCG Reference Method (Urine)</th>
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</table>

Relative Sensitivity: 100.0% (95%-100%)*
Relative Specificity: 100.0% (95%-100%)*
Accuracy: 100.0% (98%-100%)* *95% Confidence Intervals

INTERFERENCE TESTING
The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen 20 mg/dl Caffeine 20 mg/dl
Acetylsalicylic Acid 20 mg/dl Genticis Acid 20 mg/dl
Ascorbic Acid 20 mg/dl Glucose 2 g/dl
Atropine 20 mg/dl Hemoglobin 1 mg/dl
Bilirubin (urine) 2 mg/dl
None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

LIMITED EXPRESSED WARRANTY DISCLAIMER
The manufacturer makes no express warranty other than that the test kit will function as an in vitro diagnostic assay within the specifications and limitations described in the product 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 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 damage, 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, please do the following:

1. Note the lot number and the expiry date.
2. Retain the kit and the results that were obtained.
3. Contact the nearest MP Biomedicals office or your local distributor.

INDEX OF SYMBOLS

Use by
Synonym for this:
Expiry Date
In vitro diagnostic medical device
Batch Code
Catalogue Number
Temperature Limitation
Manufacturer
Authorized Representative in the European Union
Do not reuse