(Continued from Page 3)

Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Phenothiazine	20 mg/mL
Phenylpropanolamine	20 mg/mL
Salicylic Acid	20 mg/mL
Tetracycline	20 mg/mL

Urinary Analytes:

Bilirubin	2 mg/dL
Glucose	2000 mg/dL
Hemoglobin	25 mg/dL
Ketones	100 mg/dL
Protein	2000 mg/dL

Homologous Hormones:

hFSH	1000 mIU/mL
hLH	500 mIU/mL
hTSH	1000 µIU/mL

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Symbols Key

	Manufactured by
CE	CE Mark
EC REP	Authorized Representative
IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number
	Consult Instructions for Use
LOT	Batch Code
EXP YYYY-MM-DD	"Use By" date in year-month-day format
2°C (35°F) Min / 30°C (86°F) Max	Temperature Limitation
Σ n	Contains sufficient for <n> tests
	Do not reuse
CONT	Contents
STRIP	Test Strip
IFU	Instructions for Use
TEST PREG	Pregnancy Test

EC REP
MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany
+49-68 94-58 10 20

Manufactured by
PBM
Princeton BioMeditech Corporation
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P-5103-H

BioStrip® P

One-Step Pregnancy Test Strip

For *In Vitro* Diagnostic Use

Rapid Immunoassay for the Qualitative Detection of Human Chorionic Gonadotropin in Urine

For the Early Detection of Pregnancy

PBM

Catalog No.	BXI-113-25	25 Test Kit
	BXI-113-50	50 Test Kit
	BXI-113-100	100 Test Kit

Intended Use

BioStrip® P — One Step Pregnancy Test Strip is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

Summary and Principle of Procedure

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the placental trophoblastic cells shortly after the fertilized ovum is implanted in the uterine wall.[1-4] The primary function of hCG is to maintain the corpus luteum during early pregnancy. The appearance of hCG in both the urine and serum soon after conception and its rapid rise in concentration make it an excellent marker for confirmation of pregnancy. The hormone may become detectable in both urine and serum as early as 7 to 10 days after conception.[1-4] The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menses and peaking in the range of 30,000-100,000 mIU/mL by 10 to 12 weeks into pregnancy. The hormone is comprised of two non-covalently bound dissimilar subunits containing approximately 30% carbohydrate by weight.[5] The alpha (α) subunit is structurally similar to other human pituitary glycoprotein hormones, whereas the beta (ß) subunit confers unique biological and immunological specificity to the molecule[6,7].

The **BioStrip® P — One Step Pregnancy Test Strip** is a rapid urine test for detecting hCG. The test is a solid phase, immunochromatographic assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect elevated levels of hCG in urine with a high degree of sensitivity. In the test procedure, urine is added to the tube with an aid of a transfer pipette and a **BioStrip® P** is inserted into the test tube.

If hCG is present in the specimen, it will react with the conjugated dye, which binds to the antibody on the membrane and generate a colored line. Presence of two colored lines indicates a positive result, while one line at Control position indicates a negative result.

Reagents

The **BioStrip® P** kit contains enough reagents to perform all the tests.

- **BioStrip® P** with a polyclonal anti-hCG antibody coated membrane and a pad containing mouse monoclonal anti-hCG antibody–dye conjugate in a protein matrix containing 0.1% sodium azide.

Precautions

- For *in vitro* diagnostic use only.
- Do not use beyond the expiration date which appears on the package.
- The **BioStrip® P** should remain in the original sealed pouch until ready for use.

Storage and Stability

The **BioStrip® P — One Step Pregnancy Test Strip** should be stored at 2–30°C (35–86°F) in its sealed pouch.

Specimen Collection and Preparation

- Approximately 1 mL of urine is required for each test.
- For optimal detection of early pregnancy, a first-morning specimen is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time in a day may be used.
- Collect the urine specimen in a clean glass, plastic, or wax-coated container without preservatives.
- Urine containing excessive bacterial contamination should not be used since spurious results may occur with such specimens.

Specimen Storage

- If testing will not be performed immediately, the specimens should be refrigerated (2–8°C) or kept reasonably cool (below 25°C) for up to 24 hours.
- Specimens may be frozen (–20°C or below) for longer periods of storage. The frozen specimen must be completely thawed and thoroughly mixed prior to testing. Avoid repeated freezing and thawing.
- If specimens are to be shipped, add sodium azide to a concentration of 0.1% as a preservative and ship by the quickest means possible. Pack the samples in compliance with Federal regulations covering the transportation of etiologic agents.

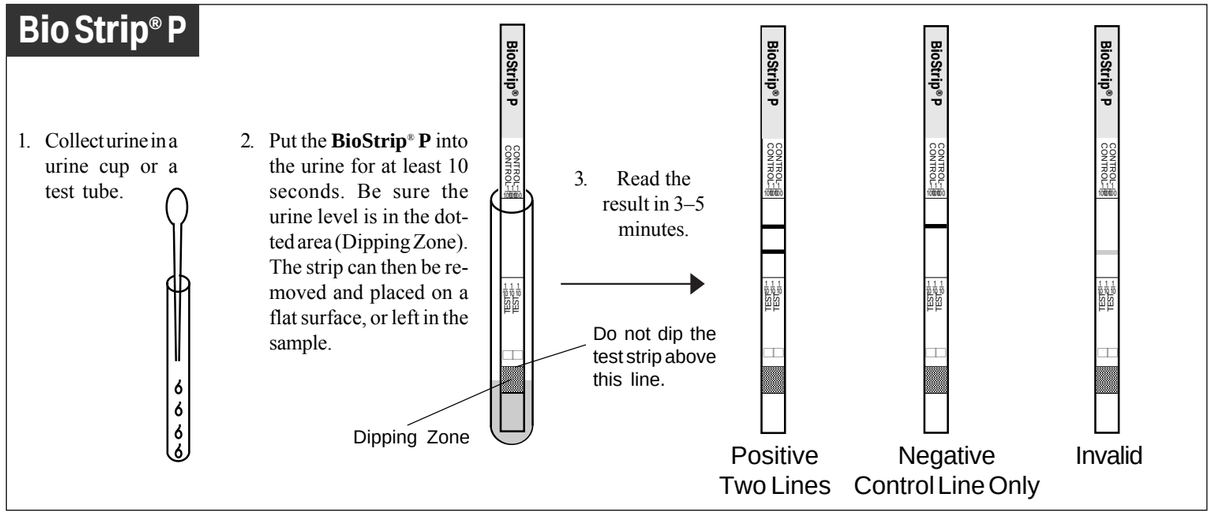
Procedure

Test Procedure Summary

The procedure consists of adding the specimen to the tube, inserting the test strip, and watching for the appearance of a colored line(s) on the membrane.

Procedural Notes

The instructions below must be followed in order to achieve optimal test reactivity with urine specimens. Follow the assay procedure and always perform the test under carefully standardized conditions.



- A test tube or any other sample container can be used for testing as long as the container will hold the required amount of urine sample and is free of contaminating substances.
- To avoid cross-contamination, use a new dropper or pipette tip and a test tube for each specimen.
- Use a test tube rack to hold the test tubes.
- Several tests may be run at one time.
- Keep the **BioStrip® P** in the sealed pouch until the test is ready to be performed.
- Handle all specimens as if capable of transmitting disease.
- After testing, dispose of the test tubes, the **BioStrip® P**, and the specimen dispenser following good laboratory practices. Consider each material that comes in contact with specimen to be potentially infectious.

Materials Provided

- **BioStrip® P**

Materials Required But Not Provided (Protocol 1)

- Disposable specimen dispensers
- Test tubes
- Test tube rack

Test Protocol 1

1. For each test, set up one test tube in a test tube rack.
2. Dispense 1 mL of the urine into the test tube, label the tube and insert a new **BioStrip® P**. Make sure the urine reaches the dotted area on the strip (Dipping Zone).
3. Read the result after 3 minutes, but within 5 minutes.

Test Protocol 2

1. Collect the urine in a urine cup.
2. Dip the **BioStrip® P** in the urine up to the dotted area (Dipping Zone), and keep it there for at least 10 seconds. The strip can then be removed and placed on a flat surface, or left in the sample.
3. Read the result after 3 minutes, but within 5 minutes.

Results

How to Read the Test

1. If there is one pinkish-purple line each in the Test line area and in the Control line area, the test result is **positive** (pregnancy hormone has been detected).
2. If there is no distinct pinkish-purple line in the Test line area other than the normal faint background color, and there is a pinkish-purple line in the Control line area, the test result is **negative**.

Positive

A specimen containing a detectable level of hCG will generate two pinkish-purple lines within 3 minutes. The time required to generate the line is dependent on the hCG concentration in the sample. Some positive results can be read as early as one minute. To be interpreted as positive, the pinkish-purple lines should be clearly distinguishable from the background color of the membrane.

Negative

In the absence of hCG, or in the case that the hCG concentration is below the detection limit of the test, there will be the Control line only with no apparent pinkish-purple line in the Test line area of the membrane.

Inconclusive or Invalid Results

A control line should always appear; the absence of a pinkish-purple control line indicates the test is invalid and should be repeated. If there is a suspected color band visible, but it is not distinct, the test is inconclusive. If there is a suspected procedural error made by the user, the result should be considered inconclusive.

Limitations

- Elevated hCG levels have been reported in patients with both gestational and nongestational trophoblastic diseases.[8, 9, 10] The hCG of trophoblastic neoplasms is similar to that found in pregnancy, so these conditions, including choriocarcinoma and hydatidiform mole, should be ruled out before pregnancy is diagnosed.
- An extremely low concentration of hCG during the early stage of pregnancy can give a negative result. In this case, testing of another specimen obtained at least 48 hours later is recommended.
- The hCG level may remain detectable for several weeks after normal delivery, delivery by cesarean section, spontaneous abortion, or therapeutic abortion.[11]
- The hCG level in the case of spontaneous abortion may be very low and eventually decrease. The test is highly sensitive, and specimens which test positive during the initial days after conception may later be negative due to natural termination of the pregnancy. Natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall.[12] Subsequent testing of a new urine or serum sample after an additional 48 hours is recommended in order to confirm that the hCG level is rising as indicated in a normal pregnancy.
- The concentration of hCG may be very low in the case of ectopic pregnancy.[13] A suspected ectopic pregnancy may be further evaluated using a quantitative hCG assay.
- Very high levels of hCG may exist in certain pregnancies and pathological conditions (e.g., choriocarcinoma and hydatidiform mole). This may weaken the intensity of the Test line.
- The physician should evaluate data obtained with this kit in light of other clinical information.
- Samples which contain excessive bacterial contamination or have been subjected to repeated freezing and thawing should not be used because such specimens can give spurious results.
- Urine samples with low specific gravity may not contain representative levels of hCG. If such a sample is negative or weakly positive, a first morning specimen should be tested.

Quality Control

Control standards are not provided with this kit; however, it is recommended that controls be tested as good testing practice. For information on how to obtain controls, contact PBM's Technical Services.

The control line in the Control area can be considered an internal procedural control. A distinct pinkish-purple line will always appear if the test has been performed correctly. If the control line does not appear, the test is invalid and a new test should be performed. If the problem persists, contact PBM for technical assistance. The internal procedural control may satisfy the requirements of testing a control on a daily basis. However, it is recommended to follow federal, state, and local guidelines.

Expected Values

BioStrip® P — One Step Pregnancy Test Strip is capable of detecting hCG levels of 25 mIU/mL (WHO 3rd International Standard). HCG levels in normal early pregnant women are varied. Average hCG levels are around 25 mIU/mL by the first day of the missed menstrual period.[13] The test is usually capable of confirming pregnancy by the first day of the missed menstrual period.

Performance Characteristics

Clinical Evaluation

A total of 245 blind clinical samples from women were tested, and the results are shown in Table 1. These specimens were assayed with **BioStrip® P — One Step Pregnancy Test Strip** and Tandem® Icon™ II according to the package inserts. Thirty-five samples from menopausal women were included.

Table 1. BioStrip® P — One Step Pregnancy Test Strip vs. Tandem® Icon™ II

Test Result	Tandem® Icon™ II	BioStrip® P
Positive (+)	76	76
Negative (–)	134	134
Menopausal	Not Determined	35 (Negative)

The data demonstrate the excellent correlation between **BioStrip® P — One Step Pregnancy Test Strip** and Tandem® Icon™ II. The clinical accuracy and sensitivity of the two tests are found comparable.

Specificity

Thirty-five urine specimens collected from menopausal women were tested. Specimens from menopausal women are known to interfere frequently with pregnancy tests due to cross-reactivity with other gonadotropin hormones. These specimens were assayed with **BioStrip® P — One Step Pregnancy Test Strip**. All 35 specimens were found negative.

Other Interfering Substances

At the level of claimed sensitivity, **BioStrip® P — One Step Pregnancy Test Strip** showed no interference when potentially interfering substances were added to urine samples which had hCG levels of 0 and 25 mIU/mL (Table 2).

Table 2. Concentrations of Potentially Interfering Substances Tested with the **BioStrip® P — One Step Pregnancy Test Strip**

Substance Added	Concentration Added
Drugs:	
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ampicillin	20 mg/dL

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