Sbio Preg Test (Urine/ Serum) DEVICE

Rapid one step test for the detection of hCG in Urine/Serum during Pregnancy

REF	91402025
Σ	25 T

CE

Temperature Limitation	Manufacturer	PIPETTE — Disposable Plastic Sample Applicator	EC REP — Authorised Representative in the European Community	Xn NaN$_3$ R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
Use by (Last day of stated month)	Consult Instructions for use	DEVICE — Device		
Date of Manufacture	REF — Catalogue Number	Σ — Contains sufficient for <n> tests	Do not reuse	
LOT — Batch Number/ Lot Number	IVD — *In vitro* Diagnostic Medical Device	This side up	Preg Test (Urine/Serum) — One step test for detecting human gonadotropin hormone in Urine/ Serum	

INTENDED USE

SBio (Urine/ Serum), one step pregnancy test is a rapid, self performing, qualitative, two site sandwich immunoassay for the determination of Human Chorionic Gonadotropin (hCG), a marker for pregnancy, in urine/serum specimens.

SUMMARY

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy. The appearance of hCG in urine/ serum soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made. SBio Preg Test (Urine/Serum), one step pregnancy test detects the presence of hCG in urine/ serum specimens, qualitatively, at concentrations as low as 10 mIU/ml in less than five minutes.

PRINCIPLE

SBio Preg Test (Urine/Serum), one step pregnancy test utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly within the test device, the colored Agglutinating sera for hCG-colloidal gold conjugate complexes with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating sera for hCG coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

A. Each individual pouch contains :

1. DEVICE :Contains membrane assembly predispensed with Agglutinating sera for hCG-colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for hCG and Agglutinating sera for rabbit globulin at the respective regions.
2. PIPETTE : Disposable plastic sample applicator.
3. Desiccant pouch.

B. Package Insert

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4°C To 30°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE.

NOTES

(1). For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use. (2). Do not use beyond expiry date. (3). Read the instructions carefully before performing the test. (4). Handle all specimens as potentially infectious. (5). Follow standard biosafety guidelines for handling and disposal of potentially infective material. (6). Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

Urine as sample: Though random urine specimens can be used, first morning urine specimen is preferable as it contains highest concentration of hCG. Specimens should be collected in clean glass or plastic containers. If testing is not immediate, the urine specimens may be stored at 2°CTo 8°C for upto 72 hours. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.
Serum as sample: No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum is preferable, serum specimens may be stored at 2°C To 8°C for upto 24 hours, in case of delay in testing. Do not use hemolysed or contaminated

specimens. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

1.Bring the sealed pouches to room temperature. Open the pouch and remove the device, applicator and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless or pink discard the device and use another device. Once opened, the device must be used immediately.

2. Dispense two drops of urine/serum specimen into the sample well 'S' using the applicator provided. Refrigerated specimens must be brought to room temperature prior to testing.

3. Read the results at the end of five minutes, for urine samples and at the end of fifteen minutes for serum samples as follows:

NEGATIVE : A colored band appears on the control region 'C'.

POSITIVE : In addition to the control band, a colored band also appears on the test region 'T'.

INVALID : The test should be considered invalid if no colored band appears on the device. The test should also be considered invalid if a colored band appears only at the test region 'T' and not at the control region 'C'. In such cases, repeat the test with a new device ensuring that the test procedure has been followed accurately .

4.Although, depending on the concentration of hCG in the specimen, positive results may start appearing as early as 30 to 60 seconds, negative results must be confirmed only at the end of five minutes.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: SBio Preg Test (Urine/Serum), one step pregnancy test detects the presence of hCG in urine/serum specimens, qualitatively, at concentrations as low as 10 mIU/ml. Concentrations of about 100 mIU/ml of hCG are reached by the first day of the missed menstrual period in normal pregnancy. Thus SBio Preg Test (Urine/Serum) (Urine/Serum), one step pregnancy test is able to detect pregnancy at very early stages.

2. Specificity: Healthy men and healthy non-pregnant women do not have detectable levels of hCG by SBio Preg Test (Urine/Serum), one step pregnancy test. Homologous hormones and other potentially interfering substances spiked beyond peak physiological concentrations did not cross react with SBio Preg Test (Urine/Serum), one step pregnancy test.

3. Accuracy: The results obtained by SBio Preg Test (Urine/Serum), one step pregnancy test correlated very well when run in parallel with other commercially available tests for pregnancy, using known positive and negative specimens.

LIMITATIONS OF THE TEST

(1). A number of conditions other than pregnancy including trophoblastic and non-trophoblastic neoplasms such as hydatidiform mole, choriocarcinoma etc. cause elevated levels of hCG. Such clinical conditions must be ruled out before a diagnosis of pregnancy can be made. (2).Highly dilute urine specimens and specimens from very early pregnancy may not contain representative levels of hCG. If pregnancy is still suspected, repeat the test with first morning urine after 48-72 hours after the initial test. (3). As with any assay employing animal antibodies, presence of cross-reacting heterophilic antibodies may yield discrepant results. (4). As with all diagnostic tests, the results must be correlated with clinical findings.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1).Batzer. F. R., Hormonal evaluation of early pregnancy, Fertility and Sterility, (July 1980),34. 1. (2).Thompson, R. J., Jackson, A. P., Langlois, N. 1986, Circulating antibodies to mouse monoclonal immunoglobulins in Normal subjects-incidence, species, specificity and effects on a two-site assay for creatinekinase-MB isoenzyme, Clin. Chem. 32, 476-481.

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