Sbio Preg Test (Urine/ Serum) DIPSTICK

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

REF	91412025
Σ	25 T

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	Use by (Last day of stated month)		Consult Instructions for use	IVD	*In vitro* Diagnostic Medical dipstick	DIPSTICK	Dipstick
	Date of Manufacture	REF	Catalogue Number	Σ	Contains sufficient for <n> tests	EC REP	Authorised Representative in the European Community
LOT	Batch Number/ Lot Number		Do not reuse	Preg Test	One step test for detecting human gonadotropin hormone		This side up

Xn	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
NaN_3 R22 S23-46-61	
	Temperature Limitation
	Manufacturer

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 is 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 dipstick, 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. DIPSTICK: 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. 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. Collect urine/serum specimen in a clean test tube. Ensure that only sufficient quantity of the specimen is collected to allow submerging the orange area of the dipstick (About 1 cm high).
2. Bring the sealed pouch to room temperature. Open the pouch and remove the dipstick and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless or pink discard the dipstick and use another dipstick. **Once opened, the dipstick must be used immediately.**
3. Dip the orange area of the dipstick in the urine/serum specimen **submerging only the orange area.**
4. For urine samples: Dip the dipstick in the urine sample for 10-15 seconds and place horizontally on a flat surface.
   Alternatively the dipstick may be left to stand in the specimen submerging for the entire duration of the test ensuring only the orange area is left submerged in the specimen.
   For serum samples: Leave the dipstick in the specimen for entire duration of the test ensuring only the orange area is submerged in the specimen.
5. Read the results **at the end of fifteen minutes** as follows:

NEGATIVE : Only one colored band appears on the dipstick.

POSITIVE : Two distinct colored bands appear on the dipstick.

INVALID: The test should be considered invalid if neither the test band nor the control band appears. The test should also be considered invalid if the band appears only at the test region and not at the control region. In such cases repeat the test with a new dipstick ensuring sufficient dip time.

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), 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

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