SILEX®

CE IVD

Semi-quantitative HCG Pregnancy Rapid Test

SI-HCGW2

INTENDED USE

Semi-quantitative HCG Pregnancy Rapid Test is a rapid chromatographic immunoassay for the detection of HCG hormone in urine to help in early diagnosis of pregnancy. The test provides a visual, Semi-quantitative result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY HCG is a hormone produced by trophoblastic tissue and it appears around the 8-9th day after ovulation, or around the 4th day after conception. In a 28-day cycle with ovulation occurring at day 14, HCG can be detected in urine or serum in minute quantities around day 23, or 5 days before the expected menstruation. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period. In normal females, HCG in urine provides an early indication of pregnancy. The elevated HCG levels are also associated with trophoblastic diseases and certain nontrophoblastic neoplasms. Thus, the possibility of other diseases must be eliminated before the diagnosis of pregnancy can be made. HCG consists of two subunits, alpha and beta. Alpha subunits of these various glycoprotein hormones are structurally very similar, but beta subunits differ in amino acid sequences. These differences are responsible for their biological and immunological specificity. Semi-quanti tative HCG Pregnancy Rapid Test is an antigen-capture immunochromatographic assay, which detects the presence of HCG in human serum or urine samples. Monoclonal antibodies specifically againstHCG (beta or alpha unit) are 1) conjugated with colloidal gold a nd deposited on the conjugate pad, and 2) immobilized on the test line of the nitrocellulose mem brane. When the urine sample is added the gold-antibody conjugate is rehydrated and the HC G, if any in samples,interacts with the gold conjugated antibodies. The antigen- antibody-gol d complex will migrate toward the test window until the Test Zone (T1/T2/T/T4) w h ere it will be captured by immobilized antibodies,forming a visible pink line (Test band), indicating a positive res ult. If HC G is absent in the sample,no pink line will appear in the Test Zone (T1/T2/T/T4), indicati ng a negative result.To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is a n indication of an invalid result. Urine samples containing HCG levels equal to or greater than the detection limit will test positive. Samples containing HCG at levels less than the detection limit may also produce a very faint positive line.

PACKAGE CONTENTS

- Postinstucinan: midstream cassete, desiccane
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clean or timine specimen collection container (plastic or glass).
- Clock or timer.

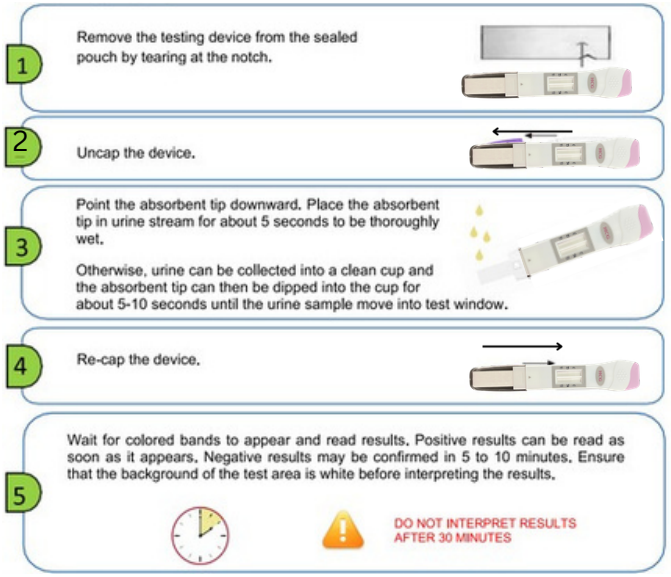
WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date shown on the pouch. Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not mix and interchange differentspecimens.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used kits in a proper biohazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

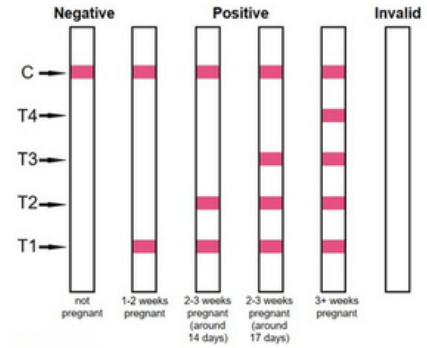
SPECIMEN PREPARATION

- Urine specimen may be collected at any time of day. However, urine specimens collected in early morning are most desirable as the HCG concentration is the highest at that time.
- Urine specimens may be collected in any clean and dry plastic or glass container (not provided). If specimens cannot be assayed immediately, it may be stored at 2-8°C for up to 48 hours prior to testing. Specimens should be equilibrated to room temperature before testing if they were refrigerated or frozen.

TEST PROCEDURES



RESULT INTERPRETATIONS



Invalid

No visible band inthe control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot numbe.

Positive

1. A clear pink control band (C) and a detectable test band (T1) appears, indicating HCG concentration range from 10-100 mIU/mL.
2. A clear pink control band (C) and detectable test bands (T1) and (T2) appears, indicating HCG concentration range from 100-500 mIU/mL.
3. A clear pink control band (C) and detectable test bands (T1), (T2) and (T3) appears, indicating HCG concentration range from 500-2000 mIU/mL.
4. A clear pink control band (C) and detectable test bands (T1), (T2), (T3)and (T4) appears, indicating HCG concentration is over 2000 mIU/mL.

Negative

A pink colored band appears only at the control region(C), indicating HCG concentration is less 10 mIU/mL.

QUALITY CONTROL HCG Test Kit has included an internal control in the test. If a test device is valid and the assay was performed properly, a pink colored band will always appear in the control region (C) regardless of positive or negative results. It is recommended that control specimens of both HCG negative and HCG positive be used with each new kit. Users, however, should follow their state and local regulations and guidelines regarding GLP requirements.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device. Shelf life: 36 months.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an in vitro diagnostic test designed for professional use only. 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. Asides from pregnancy, a number of conditions such as trophoblastic diseases, proteinuria, hematuria, choriocarcinoma, ovarian and testicular teratomas can cause elevated levels of HCG. These diagnoses should be considered if appropriate to the clinical evidence. Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay. Ectopic pregnancy cannot be distinguished from normal pregnancy using HCG measurements alone. Samples from patients on chemotherapy for cancer should be ruled out before running the assay. Positive HCG levels may be detectable for several weeks following delivery orabortion. Specimens which tested positive during the initial days after conception may be negative later due to natural termination of the pregnancy. This test can NOT be used to guide the diagnosis of pair trisomy 21.

INDEX OF SYMBOLS

	Do not reuse	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Temperature limitation		Contains sufficient for < n > tests
	Caution	REF	Catalog number
	Manufacturer		Consult instructions for use
EC REP	Authorized representative in the European community	CE	CE Mark

DTS TRADING INC.LTD
Floor 3, 43-45 St. John Street, London, EC1M 4AN
www.dtstrading.com
www.silextest.com
Blue Cross Bio-Medical(Beijing) Co., Ltd
Beiqijia Industry Zone, Changping District, Beijing, P.R. China 102209

EC REP **Shanghai International Holding Corp. GmbH(Europe) Address: Eiffestrasse 80, 20537 Hamburg Germany Tel:0049-40-2513175 Fax:0049-40-255726 E-mail:shholding@hotmail.com**

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