hCG
Rapid Test (Urine)
Package Insert

【For the qualitative detection of Human chorionic gonadotropin (HCG) in urine】

INTENDED USE

HCG Rapid Test is an in vitro diagnostic (IVD) qualitative test for rapid detection of HCG in urine. This product can be used for professional testing and self-testing.

PRINCIPLE

HCG Rapid Test is two-side sandwich immunoassay for the qualitative determination of human chorionic gonadotropin (HCG) in urine. The membrane was precoated with anti-alpha HCG capture antibodies on the test band region and goat anti mouse on the control band region. During the test, the urine specimen is allowed to react with anti beta HCG monoclonal antibody-colloid gold conjugate, which was predried on the test strip. The mixture then moves forward on the membrane by the capillary action. For a positive specimen, the conjugate binds to the HCG forming an antibody-antigen complex. This complex is captured by anti alpha HCG antibody on the test region to produces a visual pink color band when HCG concentration in specimen is equal to or greater than 25mIU/ml. Regardless of the presence of HCG, as the mixture continues to move across the membrane to the control band region, the complex is captured by immobilized goat anti mouse antibodies to form a distinct pink colored control band. The presence of the control band indicated: 1) a normal flow is obtained, 2) antibody precoated on control line and colloidal gold conjugate are functional.

COMPONENTS

MATERIALS PROVIDED

Product type	Professional testing	Self-testing
Strip	Test Device Package Insert	Test Device Urine specimen collection container Package Insert
Cassette	Test Device Package Insert	Test Device Urine specimen collection container Dropper Package Insert
Midstream	Test Device Package Insert	Test Device Package Insert

MATERIALS NOT PROVIDED BUT REQUIRED

Timer

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use after expiration date.
3. Test strip/Cassette/Midstream should remain sealed until ready for use. Do not use if pouch is damaged or opened.
4. Read this package insert carefully before performing the test.
5. Do not re-use the test strip/Cassette/Midstream
6. Do not touch the membrane.
7. Do not eat the desiccant in the pouch.

STORAGE AND STABILTY

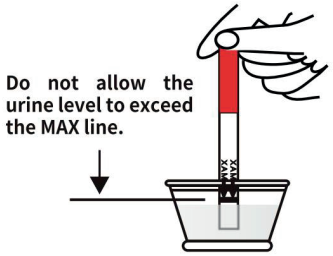
*The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch. Expiration date of this kit is 24 months after its manufacture date.
*The test must remain in the sealed pouch until use.
*Do not freeze.
*Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMENS COLLECTION

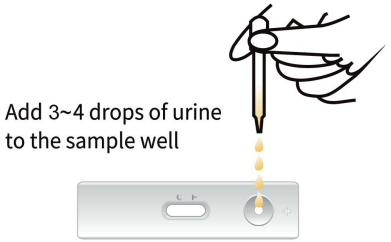
1. The urine specimens must be collected in a clean dry container either plastic or glass without preservatives. No centrifugation or filtration of urine is required. Specimens collected at any time may be used.
2. The urine specimens can be stored at, if not tested immediately, 2-8 °C for up to 3 days after collection.

PROCEDURE

1. Collect urine specimen with a clean dry container either plastic or class.Remove the strip/cassette/midstream from pouch.
2. **Strip:** Dip the strip in the urine sample for a few seconds. Make sure that the urine level is below "Max" line. As soon as solvent front reached the membrane area place the strip on a clean surface.



Cassette: Draw urine with dropper and hold the dropper vertically then transfer 3-4 drops of urine to the specimen well S of the test cassette.



Midstream: Remove the Cap and hold the mid-stream with the exposed absorbent tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.

3. Wait for 5 minutes to read result, even though some positive results may be observed within a minute. Do not try to interpret results after 10 minutes.

INTERPRETATION OF RESULTS

An internal procedural control is included in the test. A red-purple line will appear in the control region (C), which confirms sufficient specimen volume and correct operation for the test.

POSITIVE RESULT:

Positive: Two pink colored bands appear in the membrane area.

NEGATIVE RESULT:

Negative: Only one pink colored band appears in the membrane area.

INVALID RESULT:

Invalid: If no bands appear, the test should be repeated using a new strip/Cassette/Midstream.

LIMITATIONS

1. If a urine specimen is too diluted, it may not contain representative levels of HCG. If pregnancy is still suspected, first morning urine should be obtained from the person and repeated the test. The HCG concentration less than 25mIU/ml will be detected as negative.
2. A number of conditions other than pregnancy such as trophoblastic disease, proteinuria, hematuria, choriocarcinoma, ovarian and testicular teratomas can cause elevated levels of HCG. These diagnoses should be considered if appropriate to the clinical evidence.
3. Fertility drugs containing HCG may give false "pregnant" results. Other fertility therapies such as clomiphene citrate, pain killers and hormonal contraceptives (e.g. contraceptive pill) should not affect the results.
4. Immunological interfering substances such as those used in antibody therapy treatments may invalidate the assay.
5. Samples containing very high levels of HCG 600,000mIU/ml may yield a test band with color intensity lighter than that which is expected. When high dose "hook effect" is suspected it is recommended the test be repeated with a 1:10 dilution of the specimen with DI H2O.
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.
7. The manufacture, the Distributor or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between		Batch number
	For single use		European representative
	Manufacturer		Date of manufacture
	Expire date		Contains sufficient for <n> tests