VITASSAY

hCG s&u

Rapid test for the qualitative detection of Human Chrionic Gonadotropin (hCG) in human serum and/or urine samples to aid in the early detection of pregnancy.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay hCG s&u is a rapid one step immunochromatographic assay for the qualitative detection of human Chrionic Gonadotropin (hCG) in human urine and/or serum specimens to aid in the early detection of pregnancy.

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnostic of a possible human Chorionic Gonadotropin.

INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone also known as ¨the hormone of pregnancy¨ has an important role in human reproduction because its crucial part in establishing and maintaining pregnancy, through placentation and early embryo development. hCG can be detected in urine and/or serum as early as 6 days after conception and peaked between 56 and 68 days.

PRINCIPLE

Vitassay hCG s&u is a qualitative immunochromatographic assay for the detection of Human Chrionic Gonadotropin (hCG) in human serum and/or urine samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Human Chrionic Gonadotropin.

During the process, the sample reacts with the antibodies against hCG, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the red control line always appears.

The presence of this red line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if the pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay hCG s&u**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.
- The presence of yellow lines in the result window (control line zone and test line zone), before using the test, is completely normal and does not imply failure of the test functionality.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF) on the sealed pouch.

The test is stable until the expiration date printed.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **25** tests/kit **Vitassay hCG s&u.** ▪ Instructions for use. ▪ **25** Disposable pipettes	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer.

SPECIMEN COLLECTION

The samples must be recognized in a clean and dry container.

Samples can be stored in the refrigerator (2-8ºC/35.6-46.4ºF) for 1-2 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20ºC (-4ºF). Samples must be brought to room temperature before testing.

SPECIMEN PREPARATION

Urine Assay:

The urine specimen may be clear, clean and without turbidimetry. It should be collected, preferably at the beginning of the day, in a plastic or dry glass container.

Urine specimens exhibiting visible precipitates should be centrifugated, filtered, or allowed to settle to obtain a clear specimen for testing.

Serum Assay:

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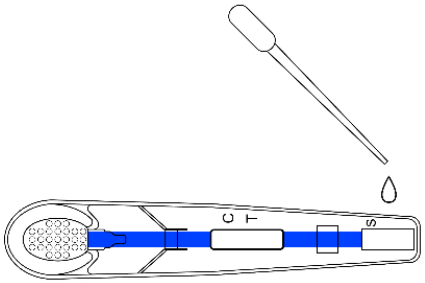
Blood should be collected aseptically into a clean tube without anticoagulants.

To avoid problems of hemolysis it is necessary to separate the serum from blood as soon as possible. To perform the test the sample must be clear and without hemolysis.

PROCEDURE

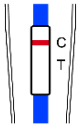
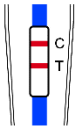
Allow the test, urine and/or serum samples and controls to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Remove the **Vitassay hCG s&u** from its sealed bag just before using it.
2. Dispense 5 drops of urine/serum specimen in the sample window marked with the letter S (figure 1).
3. Wait for coloured bands to appear. Depending of the concentration of hCG hormone, positive result may be observed as soon as 1 minute. Read the result at **5-10 minutes** after dispensing the sample. Do not read the results later than 10 minutes.



Dispense 5 drops of clear specimen in the sample window marked with the letter S.

INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one red line in the control zone **(C)**.	There is no Human Chrionic Gonadotropin presence. No infection caused by Human Chrionic Gonadotropin.
	**POSITIVE** In addition to the red line (**control line** C), a red line appears (**test line T**).	There is presence of Human Chrionic Gonadotropin. Infection caused by Human Chrionic Gonadotropin.
ANY OTHER RESULTS	Invalid result, we recommend repeating the assay using the sample with another test. **Note:** Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.	

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of hormone in the specimen.

QUALITY CONTROL

Internal procedural control is included in **Vitassay hCG s&u**. Red line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay Vitassay hCG s&u** must be carried out within 2 hours of opening the sealed bag.
- Very dilute urine and/or serum specimens may not contain representative levels of hCG.
- Very low levels of hCG (less than 50 mIU/mL) can occur in urine and/or serum specimen collected shortly after ovum implantation. However, because during the first trimester of pregnancy many pregnancies are eliminated naturally, if a positive result is weak or doubtful, it should be confirmed using the first urine in the morning after 48 hours.
- The intensity of test line may vary depending on the concentration of hormone.
- There are trophoblastic diseases and certain non-trophoblastic neoplasms (testicular tumors, prostate, breast and lung cancers) in which high concentrations of hCG are produced.
- The use of other samples different from urine and/or serum human samples has not been established.
- Can be appear human anti-mouse antibodies (HAMA) because of a patient´s treatment with monoclonal antibodies for diagnosis or therapy, causing false positives or false negatives in the results.
- Positive results determine the presence of hCG in urine and/or serum samples; nevertheless, a positive result should be followed up with additional laboratory techniques to confirm the results. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigens is lower than the detection limit. If pregnancy is still suspected, a first morning urine/serum specimens should be collected 48 hours later and tested.
- Positive results may be obtained in samples containing less than 25 mIU/mL of hCG hormone. These results should be interpreted together with the available clinical evidence.

EXPECTED VALUES

hCG levels vary enormoulsy between pregnancies. The amount of hCG will vary greatly with gestational age and between individuals. Negative results are expected in healthy non-pregnant women and healthy men.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (detection limit)

Detection limit value of **Vitassay hCG s&u** is: 25 mIU/mL in urine and/or serum samples (based in WHO 3rd IRP 75/537).

Clinical sensitivity and specificity

An evaluation, with samples of urine and/or serum from women suspected of being pregnant, was performed using **Vitassay hCG s&u** and these results were compared to the clinical results.

Results were as follows:

		Clinical results		
		Positive	**Negative**	**Total**
Vitassay hCG s&u	**Positive**	351	0	351
	Negative	0	74	74
	Total	351	74	425

Vitassay hCG s&u vs Clinical results			
Sensitivity	**Specificity**	**PPV**	**NPV**
>99%	>99%	>99%	>99%

The results showed that **Vitassay hCG s&u** has a high sensitivity and specificity to detect Human chorionic gonadotropin.

Cross reactivity

The following homologous hormones were tested for cross reactivity: LH, FSH and TSH. The hormones were added to serum and/or urine samples containing hCG at concentration of 0, 20, 100 mIU/mL. No cross reactivity was found up to the following levels: LH→1,000 mIU/mL, FSH→1,000 mIU/mL and TSH→1,000 mIU/mL.

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SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
REF	Catalogue number		

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