Atlas Medical

DIRECT hCG LATEX PREGNANCY KIT

A latex agglutination test for the detection of human Chorionic Gonadotropin in urine

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C CE

INTENDED USE

ATLAS direct hCG kit is a rapid test for detection of human Chorionic Gonadotropin (hCG) in urine, predominantly indicating pregnancy. The test can be performed within week one of a missed menstruation.

INTRODUCTION

HCG (human chorionic gonadotropin) is a glycoprotein hormone produced almost exclusively during pregnancy. hCG is initially secreted by placental trophoblastic cells shortly after implantation of the fertilized ovum into the uterine wall. The rapid rise in serum levels of HCG after conception makes it an excellent marker for early confirmation and monitoring of pregnancy.

Detectable levels of Chorionic Gonadotropin (hCG) in urine start at 5 mIU/ml during the first week of gestation and rise to 100,000 mIU/ml at the second to third months. hCG level doubles approximately every 2 days during the first trimester. Values decline by 10% to 15% of peak concentrations during the second and third trimesters.

PRINCIPLE

If present in urine, the hCG hormone reacts with the test's anti-hCG monoclonal antibodies, pre-coated on latex microspheres, to give macroscopically visible agglutination.

MATERIALS

MATERIAL PRIVIDED

- **Latex reagent:** Milky latex particles coated with monoclonal antibodies to hCG. **Mix well before use.**
- **Positive control.** Stabilized human serum reactive with the test reagent. **Ready to use.**
- **Negative control.** Stabilized human serum non-reactive with the test reagent. **Ready to use**.
- **Glass slide.**
- **Stirring sticks.**
- **Package insert.**

NOTE: This package insert is also used for individually packed reagent.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Handle specimens as though they contain infectious agents.
- Do not use reagents from different lots interchangeably.
- Allow kit components and specimens to reach the room temperature before use, as cold reagents and/or specimens may decrease assay performances. Equilibration for 20-30 minutes at room temperature is recommended.
- Do not use kit components beyond the expiration date.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Use a clean pipette tip and stirring stick for each specimen. Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.

STORAGE AND STABILITY

- The reagent is stable for 24 months if kept refrigerated at 2-8°C.
- Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

- Generally, the first morning urine contains the highest concentration of hCG and is, therefore, more recommended for testing. However, urine collected at other times of the day can also be used.
- Urine should not be stored in the refrigerator for more than one to two days. For longer storage, the sample must be kept frozen at -20°C.
- Frozen samples should be totally thawed and equilibrated to the room temperature before testing.

PROCEDURE

1. Bring reagents to room temperature.
2. Place 100 µl of patient's urine, one drop positive and one drop negative controls each onto different circles of the slide.
3. Mix the latex reagent well then add one drop directly to each sample/control.
4. Mix using the supplied stick and spread the mixture over the entire circle.
5. Gently rock the slide for two minutes.
6. Agglutination may be observed at two minutes. Direct light source may help to observe the results.

INTERPRETATION OF THE RESULTS

Positive: Visible agglutination within 2 minutes.

Negative: No agglutination at the end of the 2 minutes.

For urine samples with high concentrations of hCG, agglutination will appear within 1 minute, therefore, it is not necessary to continue until the end of 2 minutes.

For negative urine samples or samples with low concentrations of hCG, the 2 full minutes must be fulfilled.

QUALITY CONTROL

- Positive and Negative Controls should be included in each test batch.
- Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the hCG Negative Control; and agglutination with large aggregates is observed with the hCG Positive Control.

PROCEDURE LIMITATIONS

- This test provides a presumptive s for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive judgement.
- Elevated levels of hCG may be found in trophoblastic disease, choriocarcinoma, and embryonal cell carcinoma. Islet cell tumors may also produce hCG, as well as other carcinomas.
- A false negative can be obtained if a high dose effect sample is tested.

- Ectopic pregnancies may produce lower-than-expected levels of hCG. If this condition is suspected, further testing using a quantitative assay may be necessary.
- Detectable levels of hCG may persist several weeks following normal or caesarean delivery, and spontaneous or therapeutic abortion.
- Approximately, one third of all conceptions end in natural termination. This may produce positive results when testing early in the pregnancy followed by negative results after the natural termination. Low positive results may be confirmed by retesting with first morning urine 48 hours later.
- Urine from very early stages of pregnancy may contain hCG at low levels. This may cause the reaction to occur more slowly and produce a degree of agglutination which may not be readily visible. Such reactions should be considered doubtful and the test should be repeated on a first morning urine collected 48 hours later.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity of ATLAS hCG kit is 0.2IU/ml (200mIU/mL), as verified against World Health Organization 3rd international reference standard 75/537. In normal pregnancies, a positive reaction is thus possible within 7 days after a missed period. Should the first test prove negative, repeat 1-2 weeks later, unless menstruation occurs.

Specificity

The use of monoclonal antibodies in the elaboration of ATLAS hCG kit assures a high degree of specificity for hCG. Cross-reactivity with LH (human Luteinizing Hormone) is so low that concentrations of 4.0 UI/ml or less do not produce agglutination (this is approximately 20-30 times higher than the maximum excretion rate of LH in urine from menopausal women). High levels of hCG may occur in urine from patients suffering chorionic epithelioma or hydatid mole.

A total of positive 314 urine samples, as confirmed by an ELISA of a detection limit of 25UI/L, were investigated with ATLAS hCG kit. Of the 314, 311 were consistent with ELISA, whereas 3 gave a negative result. These 3 negative urines were quantified using an in-house hCG standard and were found to be under the limit of detection of ATLAS hCG. Therefore, it can deduced that the specificity of a positive result with ATLAS hCG kit is 99%.

Urine Sample 1	80 IU/L
Urine Sample 2	64 IU/L
Urine Sample 3	125 IU/L

Detection Limits

ATLAS hCG kit detects up to 250,000 mIU/ml of hCG in Urine samples.

REFERENCES

- Robert O. Hussa: The Clinical Marker hCG. Praeger Publishers, New York 1987.
- Siegfried Schwartz, Peter Berger and Georg Wick: The Antigenic Surface of Human Chorionic Gonadotropin as Mapped by Murine Monoclonal Antibodies. Endocrinology 118(1),(1986)189-197

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control