



## DIRECT hCG LATEX PREGNANCY KIT

A latex agglutination test for the detection of  $\beta$ -hCG in urine

For *In-Vitro* Professional Use  
Store at 2-8°C

### INTENDED USE

ATLAS Direct hCG kit is a rapid test for detection of beta human Chorionic Gonadotropin (hCG) in urine which has been widely used in the diagnosis of pregnancy.

### INTRODUCTION & PRINCIPLES

Detectable levels of Chorionic Gonadotropin (hCG) in urine start at 5 mIU/ml during the first week of gestation and rises to 100,000 mIU/ml at 2 to 3 months. The hCG level doubles approximately every 2.2 days during the first trimester<sup>1</sup>. Values decline from 10% to 15% of peak concentrations during 2nd and 3rd trimesters<sup>2</sup>.

ATLAS Direct hCG Latex kit contains one reagent of latex particles coated with monoclonal antibodies to hCG. The reagent is mixed with the urine samples.

### MATERIALS

#### MATERIAL PROVIDED

- Latex reagent.
- Positive and negative controls.
- Reaction slide and stirring sticks.

### PRECAUTIONS

- The Latex reagent should be mixed well prior to use to obtain a uniform suspension.
- This kit should be stored in an upright position and refrigerated between 2-8°C . Never Freeze.

### SPECIMEN COLLECTION AND PREPARATION

Generally, the first morning urine contains the highest concentration of the hCG hormone and therefore, it is more recommended for testing. However, urine collected at other periods can also be used. The urine in this case should have been kept in 2-8°C and used within 72 hours from collection time.

### PROCEDURES

1. Bring reagents to room temperature.
2. Place 50 $\mu$ l of patient urine, one drop positive and one drop negative controls into different circles of the slide.
3. Add one drop of latex reagent directly to each sample.
4. Mix using the supplied sticks and spread the mixture over the entire circle.
5. Gently rock the slide. Agglutination may be observed after two minutes. Direct light source may help to observe the results.

### READING THE RESULT

Presence of agglutination within two minutes indicates positive reaction.

Lack of agglutination within two minutes indicates negative reaction.

### PROCEDURE LIMITATION

1. This test provides a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
2. 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.<sup>3</sup>
3. Ectopic pregnancies may produce very low levels of hCG.<sup>4</sup> If this condition is suspected, further testing using a quantitative assay may be desirable.
4. Detectable levels of hCG may remain several weeks following normal pregnancy, delivery by cesarian section, spontaneous or therapeutic abortion<sup>5</sup>.
5. Approximately one third of all conceptions end in natural termination.<sup>6</sup> 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 a first morning urine 48 hours later.
6. 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 is less than that produced by the negative control. Such reactions should be considered doubtful and the test should be repeated on a first morning urine collected 48 hours later.

### SENSITIVITY AND SPECIFICITY

ATLAS Direct hCG Latex is capable of detecting down to 100mIU of hCG/ml. False results were not observed from structurally related hormones such as LH, FSH, and TSH.

### REFERENCES

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3. Steier JA, Bergso p, Myking OL: Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion, and removed ectopic pregnancy. Obstet Gynecol 64: 391-394,1984.
4. Jacobs DS, et al: Laboratory Test Handbook, 2nd Edition, Ohio, 1990, Lexi-Comp Inc., pp. 224, 305-307Wilcox EG, Weinberg CR, O'Connor JF, et al: Incidence of early loss of pregnancy. N Eng J Med 319: 189-194, 1988.

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