

BioMed-Pregnancy Test

A rapid latex slide test of urine for detection of pregnancy (direct method).



REF: (40 testl)
(50 test)
(100 test)

INTENDED FOR USE:

Rapid direct latex agglutination test for determining the presence of HCG in urine for detection of pregnancy.

PRINCIPLE:

The placental hormone HCG is excreted in the urine during pregnancy; its detection in urine is generally a positive test for pregnancy. Direct PREG slide test is designed for use on female urine specimens, after a missed menstrual period, to detect normal pregnancies.

As a latex agglutination test, PREG slide will detect HCG at levels of 0.2 IU/ml. Since levels as low as 0.2 IU/ml in urine have been reported as early as the time of the first missed period, in many cases, PREG detect positive pregnancies period to or at the time of expected but missed menstrual period. However, negative result may be obtained in many early pregnancies due to unusually low level of HCG. In these cases, the tests should be repeated about one week later.

Test components consist of a latex reagent in the form of a suspension of anti-HCG β and anti-HCG α antibodies bound to latex particles and positive control. The test specifically detects the complete HCG molecule by utilizing two different monoclonal antibodies. One raised against HCG- α subunit and the other against HCG- β subunit. Anti-HCG- β and anti-HCG- α antibodies bound to latex particles will react with HCG in the urine specimen and cause agglutination of the latex.

When the antibodies-bound latex is mixed with HCG in urine from pregnant woman, latex particles will agglutinate with HCG. This is a positive test for pregnancy. Since there is no HCG in the urine of non-pregnant women, the latex will not agglutinate. Thus, agglutination of the latex indicates a positive test for pregnancy.

SPECIMEN COLLECTION:

★ Urine collected into any suitable clean container may be used. Urine voided at any time may be employed in the test. However, the first morning specimen is preferable as it generally contains the highest concentration of HCG and thus provides the maximum test sensitivity.

★ It is not necessary to centrifuge or filter urine specimens unless they are unusually cloudy. Urine specimens may be stored at 2-8°C for periods up to 24 hours before testing. If specimens are to be retained for longer periods they should be frozen. Repeated freezing and thawing is to be avoided. Specimens stored at freezer temperatures may show a considerable amount of precipitate upon thawing which can be removed by centrifugation without affecting the test results.

★ If urine specimens are to be shipped they should be frozen and packed with sufficient amounts of dry ice to ensure their arrival in the frozen state

REAGENT COMPOSITIONS :

★ Latex Reagent: a suspension of polystyrene latex particles in buffer, coated with anti-HCG β and anti-HCG α antibodies.

- ★ Positive Urine Control: Urine control containing HCG (more than 2.0 IU/ml).
 - ★ Negative Urine Control
- All components contain 0.1% sodium azide as preservative.

PACKAGE: Collection and storage.

All reagents are stable up to the expiration date specified when stored at 2 - 8°C. Do Not Freeze. Avoid extended exposure of reagents to elevated temperatures.

Expiration date is specified on the kit label. Biological indication of product instability is evidence by inappropriate reaction of the latex reagent with the corresponding positive urine control.

PRECAUTIONS & WARNING :

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

REAGENT PREPARATION & STABILITY :

The reagents supplied in the kit are matched to provide optimal reactivity and must not be interchanged with reagents from another kit.

★ The control number appearing on the kit and on each reagent vial is identical and should be checked to assure that the reagents are designed to be used together.

REQUIRED MATERIALS NOT PROVIDED:

- ★ Materials supplied with PREG kit,
 - Antibody-bound latex reagent.
 - Positive urine control.
 - 3-cell glass slide.
 - Dispensing pipettes.
- ★ Material required, but not provided,
 - Lab rotator.
 - Laboratory timer.

PROCEDURE:

1. Bring all reagents and specimens to room temperature.
2. Shake the antibody-bound latex reagent gently, expel contents of dropper and refill, and then place one drop (50 μ l) onto glass slide. Using dispensing pipette, add one drop of the urine specimen (50 μ l) onto the glass slide, and mix both together with the flat end of the dispensing pipettes.
3. Continue to mix for about 2 minutes with rotator or by hand and observe for macroscopic clumping using the indirect oblique light source.
4. Positive control and negative control should be run with each series to urine specimens. The positive control supplied is to be used exactly as outlined in steps 1 through 3 above.
5. The reaction of the urine specimen is compared to the positive urine control.

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

A positive control will produce, usually within 2 minutes, coarse agglutinated flocs against a clear background, as demonstrated by the positive control.

If the indicated results, using the positive control and negative control are not obtained, the PREG kit should not be used.

Result

★ Negative result: No agglutination occurring within two minutes signifies the absence or low level of HCG in urine specimen and therefore a negative test for pregnancy.

★ Positive result: Agglutination occurring within two minutes signifies the presence of HCG in urine specimen, which is indication of pregnancy

REFERENCES:

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PERFORMANCE:

★ PREG is a rapid, specific test and based on its sensitivity (0.2 IU/ml) most specimens contain enough HCG to be detected prior to or at the time of the first missed period. A negative test obtained at this early period should be repeated after about one week.






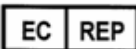



★ PREG test shows 99.4% agreement with result obtained by the use of other qualified immunological pregnancy test under actual clinical conditions.

LIMITATIONS :

★ Negative results may be obtained in very early pregnancy due to a low level of HCG. The test should be repeated about one week later.

★ Urine from patients with trophoblastic diseases such as choriocarcinoma or hydatidiform mole, which secrete HCG, could cause positive results in the absence of pregnancy.

★The pituitary gonadotropins such as FSH and LH will cross react with HCG immunologically, when present in urine. Normally, the levels become abnormally high, false positive result could be obtained. Test result from patients in menopause or post-menopause should be interpreted very carefully.

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

 Egy-Chem for lab technology Head Office: 83 Abdel-Hamid Badawy St.Heliopolise, Cairo, Egypt Tel :202- 26236727 / 202- 26236598 Fax :202- 26240986 Website: www.egy-chem.com E-mail: sales@egy-chem.com or sales@egy-chem.net	  MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
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