DIRECT MONOCLONAL 
LATEX 
PREGNANCY TEST KIT

Catalogue Number  Kit Size
DPT/010  50 test
DPT/012  100 test

INTRODUCTION
The Plasmatec Direct Monoclonal Latex Pregnancy Test Kit is designed for the qualitative detection of human chorionic gonadotrophin in urine. Human chorionic gonadotrophin (HCG) is a glycoprotein hormone secreted by the developing placenta beginning shortly after fertilisation. At the time of the first missed menstrual period, HCG concentrations in serum and urine are about 100mIU/ml and double in concentration every 1.2 to 2 days. Peak levels of over 100,000 mIU/ml HCG are seen late in the first trimester of pregnancy (1-4). The early appearance of HCG in urine following conception have been made in the marker of choice in the early detection of pregnancy. The Plasmatec Direct Pregnancy assay is based upon the latex agglutination reaction between latex particles coated with anti-HCG antibodies and HCG present in the test specimen. The presence of HCG in the urine specimen results in the formation of an agglutination matrix which is visually differentiated from the non-agglutinating negative control.

KIT PRESENTATION
1. Pregnancy latex reagent (yellow label): a suspension of antibody coated latex particles in a buffer containing 0.1% sodium azide.
2. Positive pregnancy control (red label) with preservative.
3. Negative Pregnancy control (blue label) with preservative.
4. Pipette-stirrers, single use specimen dropper/stirrers.
5. Agglutination slide.

ADDITIONAL REQUIREMENTS
1. Specimen collection containers for urine.
2. Two minute timer.

STORAGE AND STABILITY:
The components of this kit are stable until the expiration date of the kit when stored at 2-8°C.

SAFETY PRECAUTIONS:
This test is for in vitro diagnostic use only. The reagents must be stored at 2-8°C when not in use.

SPECIMEN COLLECTION:
Urine specimens must be collected without preservatives in a clean dry container. First morning urine usually contains the highest concentration of HCG, however urine collected at any time during the day may be used.

ASSAY PROCEDURE:
1. Bring the reagents and specimen to room temperature before use.
2. Place one drop of the Negative Pregnancy Control onto a circle of the agglutination slide.
3. Place one drop of the Positive Pregnancy Control onto an adjacent circle of the agglutination slide.
4. Using the pipette-stirrers provided, place one drop of the urine specimen(s) onto the remaining circle(s) of the agglutination slide.
5. Shake and re-suspend the Pregnancy latex reagent. Add one drop to each of the test circles of the agglutination slide.
6. Stir with individual pipette-stirrers and spread mixture over entire area of the test circle.
7. Gently rock the agglutination test slide for two minutes and observe the test circles for agglutination. Interpret results at two minutes. Extended incubation may result in evaporation and erroneous results.

INTERPRETATION OF RESULTS:
1. Positive result: agglutination occurs within two minutes.
2. Negative result: agglutination does not occur within two minutes.

LIMITATIONS OF PROCEDURE:
1. This test is for use with urine only. Serum should not be used.
2. Urine HCG levels of greater than 200 mIU/ml are required for positive results.
3. A number of conditions other than pregnancy, including trophoblastic diseases and certain non-trophoblastic neoplasms, can result in elevated urine HCG levels(5,6). These diagnoses should be considered if consistent with the clinical evidence.

EXPECTED VALUES:
Healthy men and healthy non-pregnant females do not have HCG levels detected by this method. Urine HCG levels of 200 mIU/ML can be reached a few days after missed menstruation(1).

PERFORMANCE CHARACTERISTICS:
1. The sensitivity of the Plasmatec Direct Monoclonal Pregnancy Latex Test Kit has been set to 200mIU/ML when calculated against the WHO Second International Standard.
2. Accuracy of at least 99% is obtained under actual clinical conditions when compared against standard quantitative HCG methods.

References: