



MIDSTREAM PREGNANCY TESTS

INTENDED USE

Thyme Home Pregnancy Midstream test is a rapid immunoassay for the qualitative detection of Human Chorionic Gonadotropin (hCG) in urine as an aid in the early detection of pregnancy.

For self-testing at home.

For *in-vitro* diagnostic use only, not for internal use.

Do not reuse.

INTRODUCTION

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. From the onset of pregnancy, the hCG concentration in a woman's serum and urine increases rapidly, making the hormone a good marker for pregnancy testing.

PRINCIPLE

The test device detects Human Chorionic Gonadotropin (hCG) through visual interpretation of colour development in the internal strip. Urine is added to the test by holding the absorbent tip downward and directly into your urine stream. The sample migrates through the reaction pads where the hCG, if present, interacts with reagents on the membrane. If there is sufficient hCG in the urine specimen, a coloured band will form in the test (T) region of the membrane.

The presence of a coloured band in the test (T) region of the device indicates a positive result, whilst the absence of any colour in the test (T) region indicates a negative result.

The coloured band that appears in the control (C) region of the device serves only as an indication that sufficient volume of the urine sample has been added.

REAGENTS

The test contains anti-hCG particles and anti-hCG antibodies coated on the membrane.

MATERIALS

Materials provided:

Midstream test device and a desiccant packed in a foil pouch. The desiccant is for storage purposes only and is not used in the test procedure.

Instructions for use.

Materials required but not provided:

Timer

WARNINGS / PRECAUTIONS

Do not open the foil pouch until you are ready to do the test.

Do not use after the expiry date as printed on the carton.

Do not use the test device if the foil pouch has been damaged or opened.

For single use only – do not reuse.

Discard the test device after use.

CONDITIONS FOR COLLECTION OF SPECIMEN

For detection of an early pregnancy, it is recommended that the first morning urine specimen is used.

PERFORMANCE AND ACCURACY

Depending on the hCG concentration in the specimen, a positive result may be observed within 30 seconds.

However, to confirm a negative result, the complete reaction time of 3 minutes must be observed.

For the detection of an early pregnancy, it is recommended that the first morning urine is used.

The sensitivity of this test is 25mIU/ml.

100% correlation with commercially available pregnancy tests.

