

# HCG Pregnancy Rapid Test Strip

## HCG Pregnancy Rapid Test Strip developed by Clongene

The CLUNGENE<sup>®</sup> HCG Pregnancy Rapid Test Strip is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (HCG) in urine for early detection of pregnancy.



## Product Features

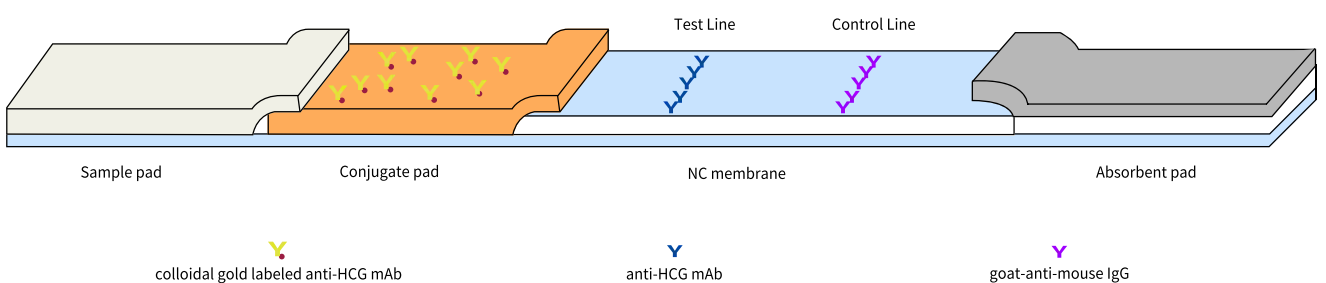
CE certification

Results available at 3-5 minutes

No equipment required

Results are clearly visible

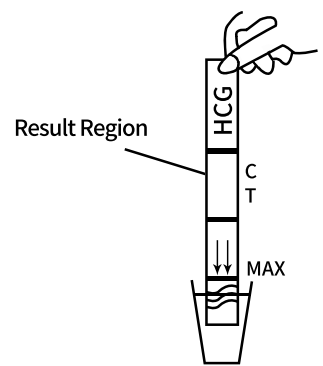
## Principle



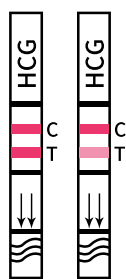
The HCG pregnancy rapid test is used to detect HCG in urine. A red line would be visible in the test region (T), if HCG concentration is equal to or greater than 25mIU/ml. In the absence of HCG, there is no line in the test region (T).

## Test Procedure

1. Remove the test strip from the sealed pouch.
2. Holding the strip vertically, carefully dip it into the specimen with the arrow end pointing towards the urine.
3. Remove the strip after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface.
4. Interpret the test results at 3-5 minutes.



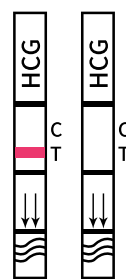
## Interpretation of Results



Positive



Negative



Invalid

## Performance Characteristics

### Sensitivity

The CLUNGENE<sup>®</sup> HCG Pregnancy Rapid Test Strip will detect HCG concentrations between 25mIU/ml to 500,000mIU/ml.

### Specificity

Add LH (500mIU/ml), FSH (1000mIU/ml) and TSH (1000 $\mu$ IU/ml) to negative specimens, the pregnancy test result showed that there is not impact.

### Cross-Reactivity

11 potentially interfering substances were added to either HCG negative urine specimens or HCG positive urine specimens, no cross-reactivity was observed.