

# CLEAR CHOICE

GB

## INSTRUCTION

HCG URINE PREGNANCY TEST (midstream) For Self-Testing

### INTENDED USE:

HCG Urine Pregnancy Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the early detection of pregnancy.

### SUMMARY AND PRINCIPLE OF THE ASSAY:

HCG is produced by the placenta during pregnancy, shortly after the embryo attaches to the uterine lining. Usually HCG can be detected by a home pregnancy test within 3-4 days after implantation.

So sensitive it may be used as early as 6 days before the day of your missed fixed period (5 days before day of expected fixed period), any time of day.

The further into the pregnancy you are, the higher the levels of HCG in your urine. This pregnancy Midstream detects HCG in urine at a concentration of 10mIU/ml (Milli-International Units) or greater. The concentration of HCG in non-pregnant women is normally 5.0mIU/ml. At the time of the last missed menstrual period, urine HCG levels are about 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml seen at the end of the first trimester.

### CONTENTS:

Each pouch contains:

1. HCG Urine Pregnancy Midstream Test
2. Desiccant (Discard - Do not eat)

Each box contains:

1. One foil pouch
2. Instruction for use

### STORAGE AND STABILITY:

The test kit can be stored at room temperature (2 °C to 30 °C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

### PRECAUTIONS:

**1. FOR IN -VITRO DIAGNOSTIC USE ONLY (IVD), NOT for internal use.**

2. Read directions for use carefully before performing this test.

3. Do not use beyond the expiration date.

4. Do not re-use the test Midstream. Discard it in the dustbin after single use.

5. Do not use the midstream if the foil pouch is damaged.

6. Once the foil pouch has been opened, the midstream should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.

7. Treat urine samples and used test devices as if they are potentially infectious. Avoid contact with skin.

8. Keep out of reach of children.

### TEST PROCEDURE:

**1. WHEN CAN I CARRY OUT THE TEST?**

You can take this pregnancy test from the 6 days before the day of your missed period (5 days before day of expected period), any time of day.

**2. SPECIMEN COLLECTION AND HANDLING**

A urine specimen must be collected in a clean and dry container. The first urine specimen in the morning is preferred since it generally contains the highest concentration of HCG; however, urine specimens collected at any time of the day may be used.

**3. TO CARRY OUT TEST**

1. Bring the sealed pouch and urine to room temperature. To begin testing, open the sealed pouch and remove the Midstream.

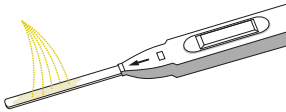
2. Hold the round end of cover with one hand. Use the other hand to pull out the test device and expose the absorbent.

3. Point the absorbent tip downward; place the absorbent tip in urine stream for at least 10 seconds to be thoroughly wet. Otherwise, you can collect your urine into a clean cup and dip half of the absorbent pad into the urine for at least 10 seconds.

4. Re-cap the device and wait for color bands to appear. Depending on the concentration of HCG in the urine specimen, positive results may be observed in as short as 40 seconds. However, to confirm a negative result, the complete reaction time (5 minutes) is required. Do not read results after 10 minutes.

5. Discard the test after use. Put the used midstream into special container if possible and regard it as if it is infectious. Don't litter.

### 4. INTERPRETATION OF RESULTS



**NEGATIVE:** Only one visible colored band in control region, no colored band in test region, which indicate the result of the test is negative., no HCG has been detected in the urine. This means you are either not pregnant or you have tested too early. If you are not sure repeat the test in 48 hours.

**POSITIVE:** Two visible colored bands in both test region and control region, which indicate the result of the test is positive, then this means there is a strong possibility that you are pregnant — HCG has been detected in your urine. One line may be lighter than the other, they do not have to match and this is still a positive result

**INVALID:** No visible colored band(s) at all, or only one colored band in test region, which indicate the kit is invalid. Repeat the test with a new test kit!

### REAGENTS:

HCG Urine Pregnancy Test Midstream per foil pouch.

Ingredients: Test device comprised colloidal gold coated with anti  $\beta$ -HCG antibody ; NC membrane coated with mouse anti  $\alpha$ -HCG antibody and rabbit anti mouse IgG.

### LIMITATION OF THE PRODUCT:

1. Alcohol may interfere with the test result. It is not recommended to use the test after drinking alcohol.

2. Occasionally urine specimens containing less than 10mIU/ml also yield positive results.

3. If you test too early, HCG level may still be low and so can give a negative result. In this case, another urine specimen should be obtained at least 48 hours later and tested.

4. HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.

5. In cases where very high levels of HCG are present (>500,000mIU/ml) a false negative result can occur due to a "Prozone" effect. If pregnancy is still suspected, simply dilute specimen 1:1 with deionized water and retest.

6. If a urine sample is too dilute (ie: low specific gravity) it may not contain a representative level of HCG. If pregnancy is still suspected, a first morning urine sample should be obtained and retested 48 hours later.

7. As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult their doctor for the final diagnosis of pregnancy before making any decision of medical relevance.

**Manufacturer: FORANS Medical GmbH, Martener Straße 275, 44379 Dortmund, Germany**

**Distributor: SIA FORANS Piepilsetas, Krustkalni novads, Kekavas pagasts, LV-2111, Latvia, info@forans.lv**

IVD

In vitro Diagnostic Use



Keep away from sunlight



tests per package



Can not be reused



Disposal of all waste material should be in accordance with local guidelines.



Use before



Consult instructions for use



Store at between 2-30°C



Manufacturer



Keep dry



Batch number



Batch number

REV-0/2019.03

