

QR CODE
Use this QR code for rapid access to our video

Other necessary materials not provided with the kit:

- Watch or Timer

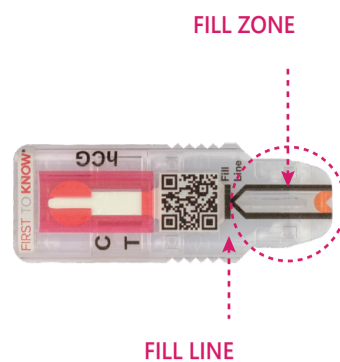
NOTE:

Carefully read these instructions before performing the test.

This test is easy to do, however, it will be even easier if sample loading is performed correctly. Special attention should be paid to ensure that:

Special attention should be paid to ensure that:

- The sample reaches the **FILL LINE**.
- The **FILL ZONE** is completely filled by the sample.



NOTE:

To ensure adequate blood flow it is important to:

- Have warm hands;
- Keep a standing position;
- Keep hands lower than the chest.



CONTENTS OF THE BOX

Each box contains all the necessary material to perform two tests:

- Two (2) sealed aluminum pouches each containing one (1) First To Know® device and desiccant (In-vitro Diagnostic Medical Device regulated by Directive 98/79/CE) **CE 0373**
- Three (3) disposable sterile lancets manufactured by Owen Mumford Ltd. (Medical Device regulated by directive 93/42/CEE) **CE 0120**
- Two (2) alcohol swabs manufactured by Germo Spa Italia (PMC Reg. Min. Sal. n 12671)
- Two (2) bandages manufactured by Eurofarm Spa Italia (Medical Device regulated by directive 93/42/CEE) **CE**
- Instruction for use

PREPARATION

1 WASH YOUR HANDS

Wash your hands thoroughly with warm water and soap for about one minute and dry them.



2 TAKE THE DEVICE OUT OF THE POUCH

Open the sealed pouch, take out the device, and place it on the table. Leave the desiccant in the pouch.



NOTE:

After opening the pouch, use the device promptly.

3 LANCET PREPARATION

Hold the lancet by the side, twist the grey cap 5-6 times, then gently pull it outward to remove it. **DO NOT PUSH THE RELEASE TAB YET.**

NOTE:

A frequent mistake is to push the release tab at this point of the procedure.

At this point you only need to remove the cap.

The release tab must be pushed when specified by the procedure.

If the release tab is pushed prematurely, the lancet becomes unsuitable for use as it is spring loaded to retract immediately after activation (as a safety measure).

4 DISINFECTION OF THE FINGER TIP

Select the finger to puncture. Middle finger is suggested. Disinfect the tip of the selected finger using the swab provided.



NOTE:

For proper use of the swab, read the instructions on the back side of its package.

5 MASSAGE PALM AND FINGER

Gently massage the finger and palm of the hand. Direct the blood toward the base of the selected finger and continue from the base of the finger toward the tip.



RUN THE TEST

To run the test you need:

- One (1) First to Know® device contained in a sealed pouch
- One (1) sterile lancet
- One (1) alcohol swab
- One (1) Bandage

NOTE:

The test can be executed anywhere, however it is important to have a flat horizontal surface to place all materials needed for the test. It is also important to choose a place free of distractions.

6 PALM UPWARD

While standing up, place your hand on a flat surface with the palm facing up. This will help to keep your hand steady.



7 WHERE TO PRICK

Place the lancet against the tip of the chosen finger in an off-center position toward the pinky as shown in the image.



8 PRICK THE FINGER TIP

Firmly press the lancet to the finger. The harder you press, the less discomfort you will feel. Press the release tab. The tip of the lancet will retract automatically.



9 GETTING THE DROP OF BLOOD

Massage the finger at the base toward the tip until a drop of blood appears. Press under the finger tip until an abundant drop of blood appears. Do not press directly on the punctured site.



10 APPLYING THE DROP TO THE DEVICE

Gently touch the drop of blood to the tip of the device so that the blood can enter and fill the FILL ZONE.



NOTE:

It is possible that steps 9 and 10 may need to be repeated more than once in order to get enough blood to fill the FILL ZONE.

If this is the case, gently touch the drop of blood with the tip of the device.



Get another drop of blood.



REPEAT until the blood fills the FILL ZONE.

FILL LINE

11 TAP THE DEVICE TWICE

After filling the FILL ZONE, hold the device with the tip facing up and tap the device twice on a table or hard surface; then place it in a horizontal position on a flat surface. If necessary, apply the bandage on the pricked finger.

TAP THE DEVICE TWICE



READING THE RESULTS



After setting the device on a flat surface, wait 10 minutes before reading the results. Results must be read after 10 minutes but before 30 minutes. Results read before 10 minutes and after 30 minutes are not valid.

LINES "C" AND "T"

Two lines may form at the areas marked "C" and "T" in the reading window of the device.

"C" Control line: indicates if the test performed correctly.

"T" Test line: indicates whether or not the test is Positive or Negative.



POSITIVE RESULT "PREGNANT"

The formation of colored lines at **BOTH the "C" and "T" areas** indicate a **positive result** regardless of the intensity of the lines.



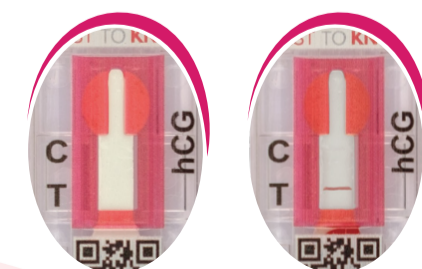
NEGATIVE RESULT "NOT PREGNANT"

The formation of a colored line in the "C" area and **no line in the "T" area** indicates a **negative result**.



INVALID RESULT

If within 10 minutes **no line appears** in the "C" area or a line appears only in the "T" area, the **test is not valid** and it must be repeated using another device.



NOTE:

No clinically relevant decision should be made based solely on the results of this test. Please, consult your physician if you need to make clinically relevant decisions.