



clearblue

DIGITAL PREGNANCY TEST

UNIPATH



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Technical Information



An unmistakable result for greater certainty

Fertilisation and Early Pregnancy

Fertilisation occurs when the female egg and male sperm fuse together, usually in one of the woman's Fallopian tubes. It is possible for an egg to be fertilised up to 24 hours after ovulation.

After the first sperm has penetrated the egg, the membrane around the egg becomes impermeable to other sperm cells. The fertilised egg continues down through the Fallopian tube into the uterus, where it implants in the uterus lining. This generally occurs during the week after ovulation.

When the fertilised egg implants in the uterus lining the hormone human Chorionic Gonadotrophin (hCG) is produced and enters the maternal circulation. This hormone stimulates production of the hormones progesterone and estrogen, which maintain the uterus lining, prevent menstruation and so maintain the pregnancy.

For the majority of women, detecting pregnancy as early as possible is clearly an advantage as it enables them to plan appropriately. The **clearblue** Digital Pregnancy Test makes this possible. It does this by testing for the presence of the hormone hCG in urine. The level of hCG rapidly increases during early pregnancy, and is expected to be at a detectable level by the day a woman's period is due.

Published literature has shown that the level of the hormone hCG is expected to reach at least 50mIU/ml on the day of the missed period^{1,2}. The sensitivity of the **clearblue** Digital Pregnancy Test is 50mIU/ml hCG in urine.

How does the clearblue Digital Pregnancy Test work?

The **clearblue** Digital Pregnancy Test consists of a Cartridge, contained in a foil wrapper, and an electronic Holder.



The Holder can only be used with the Cartridges included in the **clearblue** Digital Pregnancy Test pack. The Holder incorporates a liquid crystal display that indicates to the user whether their result is pregnant or not pregnant using words. In addition the Display can show test progress and error messages.

The **clearblue** Digital Pregnancy Test is available in a pack containing three Cartridges and one Holder. Cartridges are not available separately and once all the Cartridges in the pack have been used, the Holder should be disposed of.

To use the **clearblue** Digital Pregnancy Test, the user must first remove the Cartridge from its foil wrapper, and remove the cap. The Cartridge must then be inserted into the Holder by aligning the blue arrow on the Cartridge with

the blue arrow on the Holder. When inserted correctly, the Cartridge will "click" into place, the Holder will automatically switch on, and the "Test Ready" symbol will appear on the Display.

The user is then required to hold the Absorbent Sampler in her urine stream for 5-7 seconds. Alternatively she can collect a sample of urine in a container, and immerse just the Absorbent Sampler in the collected sample for 15 seconds.

The technology used in the Cartridge is similar to that used in the traditional **clearblue** Pregnancy Test. However, the lines cannot be read by eye. Instead the Holder uses an optical system to measure the density of the lines in the control and result zones on the Cartridge. A red light shines onto these specific areas, and the light reflected is converted into an electrical signal.

Once the Cartridge is inserted into the Holder, the Test is calibrated automatically. The measurement system will then monitor the Cartridge to determine when a sample has been applied. When the system detects that the sample has been applied, the "Test Ready" symbol on the display begins to flash to show that the Test is working.

The Holder measures the flow of urine along the Cartridge. If

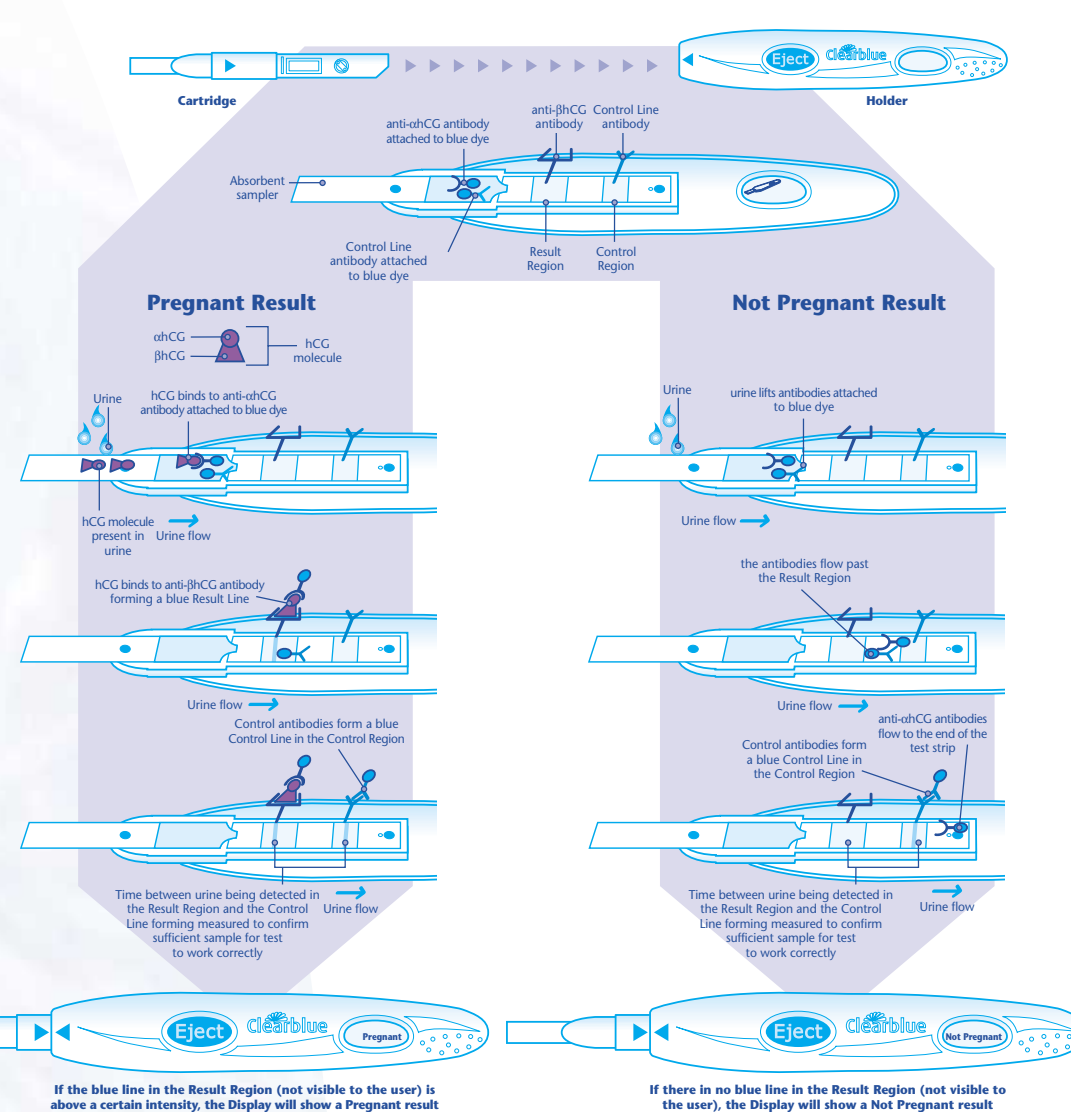
insufficient urine has been applied an error symbol will appear on the Display – a static Test and "see leaflet". If the fluid moves through the Test too fast then this indicates over sampling and the same error symbol will be displayed.

The Holder monitors the control line zone, and once a valid control line has been detected the test line is monitored. Within 3 minutes the Display will show a "Pregnant" or "Not Pregnant" result in words.

Once the Display shows either a "Pregnant" or "Not Pregnant" result or an error symbol then the user may eject the Cartridge by pressing the Eject Button on the Holder. A result will continue to be shown on the Display for a period of approximately one hour. Any error symbol will be shown for approximately 30 minutes. A further test is possible when the Display has returned to a blank screen.

If the Cartridge is removed from the Holder at any time before the result appears, the Display will show a flashing Test and "see leaflet" symbol. The user should re-insert the Cartridge immediately. The Test may continue to work, and show a result within 3 minutes. If the Cartridge is not re-inserted quickly enough the error symbol will change to a static Test and "see leaflet".

How the clearblue Digital Pregnancy Test Works



The scientific principle of how the **clearblue** Digital Pregnancy Test works is shown in the figure above.

References:

- 1 Lenton EA, Neal LM, Sulaiman R. Plasma concentrations of human chorionic gonadotrophin from the time of implantation until the second week of pregnancy. *Fertil. Steril.* 1982;37 (6) :773-8
- 2 Chard T. Pregnancy tests – a review. *Hum.Reprod.* 1992;7 (5): 701-10