

# Clearblue™ DIGITAL

with + or - RESULT

- Clearblue™ Digital is over 99% accurate from the day your period is due.
  - Clearblue™ Digital can be used up to 4 days before your period is due.
- Please read this leaflet carefully before doing a test.**

## Pregnancy Test

### 1 Do the test

If testing from the day your period is due, you can test at any time of the day.  
If testing before your period is due, use the first urine of the day.

- When you are ready to test, remove the test stick from the foil wrapper and take off the blue cap. Use the test stick straight away.
- Throughout testing **never** hold the test stick with the absorbent sampler pointing upwards.



#### EITHER TEST IN YOUR URINE STREAM

- Place just the absorbent sampler pointing downwards in your urine stream for **5 seconds only**.
- Take care not to get the rest of the test stick wet.
- Keep the absorbent sampler pointing downwards or lay the test stick flat until your result appears.
- You may wish to replace the cap.



OR

#### COLLECT A SAMPLE OF YOUR URINE IN A CLEAN, DRY CONTAINER

- Place just the absorbent sampler pointing downwards in the urine, as shown, for **20 seconds only**.
- Keep the absorbent sampler pointing downwards or lay the test stick flat until your result appears.
- You may wish to replace the cap.



### 2 WAIT...

- The wait symbol will flash to show the test is working.
- When the wait symbol stops flashing your result will appear. If the wait symbol does not appear after you have used the test, refer to question 5 in the Questions and Answers overleaf.



### 3 SEE YOUR RESULT

- Within **3 minutes**, the display will show your result.
- Some results may be shown in as little as 1 minute.
- Your result will remain on the display for approximately 24 hours.



If your result is 'Pregnant' '+', refer to question 7 in the Questions and Answers.



If your result is 'Not Pregnant' '-', refer to question 8 in the Questions and Answers.



Book Error



Blank Error

#### TEST ERRORS

Please read the section 'Test errors' overleaf if you have used the test stick and the display shows the following:

#### DISPOSING OF YOUR CLEARBLUE™ DIGITAL PREGNANCY TEST

- Before disposing of your test, remove the battery from the test stick. Insert a coin into the slot on the back of the test stick. Break open the plastic circle.
- Remove the battery and dispose of it according to the appropriate recycling scheme.  
**Caution:** Do not disassemble, recharge, or dispose of the battery in fire. Do not swallow. Keep away from children.
- Dispose of the rest of the test stick according to the appropriate recycling scheme for electrical equipment.
- Do not dispose of electrical equipment in fire.



### QUESTIONS & ANSWERS

- How accurate is Clearblue™ Digital pregnancy test?**  
Clearblue™ Digital pregnancy test is over 99% accurate in laboratory tests, when used from the day your period is due.
- How does Clearblue™ Digital pregnancy test work?**  
When you are pregnant your body produces the pregnancy hormone hCG (human Chorionic Gonadotrophin). The amount of hCG in your body increases in the early stages of pregnancy. Clearblue™ can detect tiny amounts of this hormone in your urine (the sensitivity of this test is 25mIU/ml).
- When can I test with Clearblue™ Digital pregnancy test?**  
Clearblue™ Digital pregnancy test can be used up to 4 days before your period is due. If you test before your period is due and get a 'Not Pregnant' '-' result, there is still a chance that you may be pregnant.  
See the chart below for results from clinical testing of Clearblue™ Digital pregnancy test with early pregnancy samples.

Testing Early	
Number of days before the period is due	% of samples from pregnant women giving a 'Pregnant' '+' result
-1	95%
-2	90%
-3	82%
-4	51%

To work out when your period is due, calculate your usual cycle length by counting the number of days from the first day of your period until the day before your next period starts.

- If you have irregular cycles, you should allow for your longest cycle in recent months before testing.

- If you have no idea when your period is due we recommend testing not less than 19 days after the last time you had unprotected sex.
- If testing from the day your period is due, you can test any time of the day. If testing early, use the first urine of the day. Avoid excessive fluid intake before testing.
- If the result is 'Not Pregnant' '-' and pregnancy is still suspected refer to question 8.
- Can any medication or medical conditions affect the result?**
  - Always read manufacturers' instructions for any medication you are taking before conducting a test.
  - Fertility drugs containing hCG can give misleading results (these fertility drugs are usually given by injection, and testing too soon after administration may give a false 'Pregnant' '+' result).
  - Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the result.
  - If you have recently stopped using hormonal contraception or are using fertility therapies like clomiphene citrate, your periods may be irregular, leading you to test too soon.
  - If you have recently been pregnant (even if not carried to full term) you may get a false 'Pregnant' '+' result.
  - Ectopic pregnancy, ovarian cysts, menopause and some very rare medical conditions can give misleading results.
  - If you have a 'Pregnant' '+' result it is possible that you later find that you are not pregnant due to natural loss of the pregnancy which can occur in the early stages.

If you do get unexpected results you should discuss them with your doctor.

- I have used the test, but the wait symbol has not appeared. What does this mean?**  
The test has not been performed correctly. Please refer to 'Test errors' below.

- I have used the test but no result has appeared on the display. What does this mean?**  
Your result should appear on the display within 3 minutes. If no result appears please refer to 'Test errors' below.
- My test says I'm pregnant. '+' What should I do?**  
If your result is 'Pregnant' '+' you should see your doctor who can advise you on what steps you should take next.
- My test says I'm not pregnant. '-' What should I do?**  
You may not be pregnant, or the level of pregnancy hormone may not yet be high enough to be detected, or you may have miscalculated the day your period was due.
  - If you tested early, test again when your period is due.
  - If your period is overdue, test again in 3 days time. If this test gives you a 'Not Pregnant' '-' result and you still have not had your period, see your doctor.

### TEST ERRORS

**Book Error** – an error has occurred during testing. It may be that:

- The absorbent sampler was not kept pointing downwards or the test was not laid flat after urine was applied.
- Too much or too little urine was applied. You should test again using a new test taking care to follow the instructions.

**Blank Error** – the test has not performed as expected. This may be because the instructions for use were not followed. You will need to perform another test. Please follow the instructions for use carefully.

## www.clearblue.com

For product enquiries, please contact Customer Support at the address below:-

This device is for home use. For *in vitro* diagnostic use only. Store at room temperature. Keep out of the reach of children. Use test stick once. Do not use if the foil wrapper is damaged. Do not use a test stick that has passed its expiry date. These instructions are for model number CB8004.

### EMC - Guidance and Manufacturer's Declaration

The Clearblue Digital Pregnancy Test is intended for use in the electromagnetic environment specified below.

The customer or the user of the Clearblue Digital Pregnancy Test should assure that it is used in such an environment. This product is tested to EN60601-1-2:2002.

Electromagnetic Emissions			Electromagnetic Immunity		
Test	Compliance	Electromagnetic Environment – Guidance	Test	Compliance Level	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Clearblue Digital Pregnancy Test uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	Electrostatic discharge IEC61000-4-2	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
RF emissions CISPR 11	Class B	The Clearblue Digital Pregnancy Test is suitable for use in all establishments, including domestic establishments.	Radiated RF IEC61000-4-3 *)	3V/m (from 80MHz to 2.5 GHz)	d = 1.2√P from 80 MHz to 800 MHz d = 2.3√P from 800 MHz to 2.5 GHz where P is the maximum power rating of the transmitter in watts and d is the recommended separation distance from the transmitter in metres.
NOTE a). These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					



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Marketing Authorization Holder: SPD Swiss Precision Diagnostics GmbH (SPD),  
Route de St Georges 47, 1213 Petit-Lancy, Geneva, Switzerland.  
Manufacturing Site: Alere (Shanghai) Diagnostics Co. Ltd. Shanghai, China  
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IVD	In Vitro diagnostic medical device	LOT	Batch code	Do not re-use
Temperature Limit 2°C - 30°C	Use-by date	Manufacturer		