

babystart[®] FOCUS

babystart FOCUS package insert

BSFOCUS English

For self Testing

The babystart FOCUS is a personal ovulation microscope that allows you to predict ovulation – the most fertile time of your menstrual cycle - and therefore indicates the best time to have intercourse when planning a pregnancy. When a woman is about to ovulate, her saliva begins to form a distinct fern-like pattern due to an increase in hormone levels – as seen through the babystart FOCUS. This “ferning” pattern is best seen around 2 days before and 2 days after ovulation allowing you to predict ovulation and peak fertility. With babystart FOCUS just add a drop of saliva to the lens and let the sample dry. After around five minutes, view the sample through the microscope lens. Press the LED light button and focus by turning the eyepiece of the microscope. If you are ovulating or about to ovulate, a ferning, crystal-like pattern can be seen.

Instructions – How to Use

Step 1: Carefully remove the lens by pulling it out of the casing

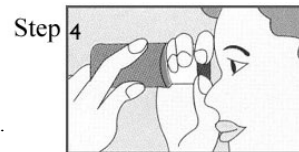
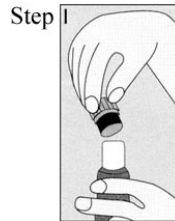
Step 2: Place a drop of saliva onto the surface of the lens.
Try to avoid creating any air bubbles

Step 3: Allow the saliva sample to dry for at least 5 minutes and then replace the lens into the body of the FOCUS.

Step 4: Look into the lens and rotate the lens while bringing it close to the eye (remember to remove eyeglasses). Adjust the eyepiece to focus and push the light button to observe test results.

Step 5: Clean the lens after every use with a clean paper towel or lens cleaner.

TIP: Try to test first thing in the morning. Wait at least 2 hours after eating, drinking, smoking or brushing teeth, before testing.



Reading the Results:

Not fertile:

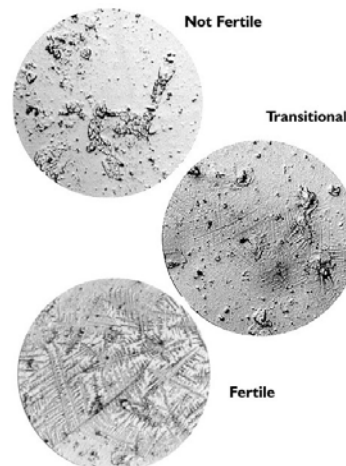
Simple dot patterns and lines indicate no ovulation.
You are not fertile at this time.

Transitional:

Small ferning patterns – or crystal forms – appear among the spots and lines. Ovulation may occur in 3 to 4 days.
At this time, conception is possible, though not yet likely.

Fertile:

Strong ferning - or crystal - patterns dominate the sample.
Ovulation is about to occur or already occurring.
This is the most fertile time of your cycle.



Limitations:

There is the possibility that this test may produce false positives or false negative results. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test. Some other reasons are: not all women fern; you may not be able to see the fern due to poor eyesight; women who fern on some days of their fertile period don't necessarily fern on all of their fertile days; ferning may be disrupted by smoking, eating, drinking, brushing your teeth.

Questions and Answers:

1. Q: Can I use the babystart FOCUS to avoid pregnancy?

A: No, the test should not be used as a form of contraception. The babystart FOCUS indicates the *peak* fertile time of your cycle and therefore the best time of your cycle to try and conceive. However, sperm can survive for 72 hours or more, and so conception is possible before or after the ferning appears and thus the babystart FOCUS should not be used as a method to avoid pregnancy.

2. Q: How accurate is the babystart FOCUS?

A: A clinical evaluation was conducted comparing the results obtained using the babystart FOCUS with an established reference indicator of subject ovulation, namely urine-based testing of the LH surge. The clinical evaluation consisted of 42 female subject volunteers of childbearing age (ages 20 to 35). The total duration of the study was 58 calendar days. The results demonstrated an 89.2% agreement between LH surge and positive ferning results and also that the end user and professional interpretation of babystart FOCUS images were in 100% agreement.

Q: How sensitive is the babystart FOCUS test?

A: In the clinical evaluation above a positive FOCUS result (ferning) was cross-referenced with a urine based LH test threshold of 30mIU/ml/LH, indicating "LH surge" and imminent ovulation.

Q: Do alcohol or common medications affect the results?

A: No, but you should consult your doctor if you are taking any hormonal medication. Also, recent oral contraceptive use, breastfeeding, or pregnancy could affect the test results.

3. Q: What time of the day should I perform the test?

A: Testing first thing in the morning is recommended, however, the test can be performed at any time of day providing you try and test at the same time each day. Wait at least 2 hours after eating, drinking, smoking or brushing teeth, before testing.

4. Q: Will what I eat or drink affect the test result?

A: No – but you should wait at least 2 hours after eating, drinking, smoking or brushing teeth, before testing.

5. Q: How long will the results remain visible?

A: The test should be read as soon as the sample has dried, (approximately five minutes) for best results. However, the pattern produced by the saliva can remain for several days if not disturbed and can as such be used to show results to your doctor. This means that it is very important to clean the lens thoroughly between testing.

Q: Once I see a strong ferning pattern, when is the best time to have intercourse to try and conceive?

A: It is likely that ovulation is about to occur. This is your most fertile time. Sexual intercourse within the next 24 to 48 hours is advised.

6. Q: I am now using the basal body temperature method (BBT). Does this test replace the BBT?

A: The babystart FOCUS does not replace the BBT method. The shift in basal body temperature primarily indicates that ovulation has *already* occurred. The babystart FOCUS indicates that ovulation is *about* to occur.










7. Q: I saw the ferning pattern and had intercourse during these fertile days but have not become pregnant. What shall I do?

A: There are many factors that can affect your ability to become pregnant. It can take normal, healthy couples many months to achieve a pregnancy and often you may need to use the FOCUS for some months before achieving pregnancy. If pregnancy is not achieved after 12-18 months, you and your partner should consult a doctor.

8. Q: I saw the ferning pattern and had intercourse during these fertile days. I think I may be pregnant. How soon can I find out?

A: babystart pregnancy tests can provide you with results as early as 7-10 days after conception.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #



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