

BioCheck™

Female Fertility Test Package Insert

REF: BSFT - English - For Self Testing

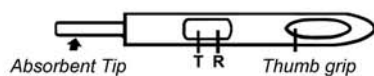
PRINCIPLE

Babystart BioCheck™ is a rapid, one-step lateral flow immunoassay for the qualitative detection of FSH in urine to aid in the assessment of a woman's fertility. The test utilizes a combination of antibodies including a monoclonal FSH antibody to selectively detect elevated levels of FSH. The assay is conducted by urinating on the Absorbent Tip or immersing the Absorbent Tip in urine, and obtaining the result from the coloured lines. Follicle Stimulating Hormone (FSH) maintains the regular function of a woman's ovaries and sex hormones and thus is intimately involved with a woman's fertility. Rising levels of FSH tend to be associated with reduced fertility. They can be raised in women with irregular periods and will steadily rise as a woman gets older. As menopause approaches the levels get particularly high and act as an early warning system. Babystart BioCheck™ is thus especially useful for those women with irregular cycles or aged 30 or more. With this test a positive test result suggests reduced fertility and/or peri-menopause and a doctor should be consulted. In any case the user should not take any decision of medical relevance without first consulting a medical practitioner.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

Diagram for illustration only



- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 2-30°C or 36-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- Do not open the test foil pouch until you are ready to start the test

KIT CONTENTS

· Test midstream · Package insert

WHEN TO TEST

Take the test at any time during the month and repeat with the second test 1 week later.

INSTRUCTIONS

- Remove the midstream test from the foil pouch and familiarize yourself with the product.
- Remove the Cap.
- Hold the midstream test by the Thumb Grip with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet. See illustration at right. NOTE: Do not urinate on the Test and Reference windows. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream test into the urine for at least 10 seconds.
- After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the Test and Reference windows facing upwards, and then begin timing.
- As the test begins to work, you may notice a light coloured flow moving across the Test and Reference windows. Read the result at 3 minutes. If no coloured line appears, wait one minute longer. Do not read the result after 10 minutes.



READING THE RESULTS

POSITIVE: Two distinct coloured lines are visible, and the line in the Test Window (T) is the same as or darker than the line in the Reference Window (R).



NEGATIVE: Two coloured lines are visible, but the line in the Test Window (T) is lighter than the line in the Reference Window (R), OR there is no line in the Test Window (T).



INVALID: Reference line fails to appear. The result is invalid if no coloured line appears in the Reference Window (R), even if a line appears in the Test Window (T). You should repeat with a new test.



INTERPRETATION OF RESULTS

A Negative Test result indicates that your FSH levels are not raised. This is good indication although not proof of fertility. However, if you do have irregular periods or any menopause-like symptoms we still recommend you see your doctor. If you see a Positive test result you should repeat the test again in 5-7 days. If both tests are positive then this indicates that you have high FSH levels. If this is so you should see your doctor if trying for a baby. High FSH levels can also be an indicator of the peri-menopausal state and if symptoms such as irregular periods, hot flashes, mood swings, insomnia and fatigue exist, you should discuss your results and symptoms with your doctor. If the second test is negative this indicates that your FSH levels are not raised and again is a good indication although not proof of fertility.

LIMITATIONS

There is the possibility that this test may produce false results. Consult your doctor before making any medical decisions. Invalid results are most likely caused by not following the instructions properly. Review the instructions and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUESTIONS & ANSWERS

- Q: How does the test work?
A: The Babystart BioCheck™ measures FSH and can tell you whether your body is producing excess FSH, signaling that your fertility is decreased or that your body is in the peri-menopause stage.
- Q: When can I use the test?
A: We recommend performing the test using first morning urine as it contains the most hormone and will give the most accurate result. It can be performed at any time during the month and repeated with the second test 1 week later.
- Q: How will I know the test worked?
A: The appearance of a coloured line in the Reference Window (R) tells you that you followed the test procedure properly and the proper amount of urine was absorbed. If you do not see a line in the Reference Window (R) you should review the procedure and repeat with a new midstream test. The test is not reusable. If you still experience problems, contact your distributor.

- Q: I received a positive result. Can I stop using contraception?
A: No, this is a screening test for raised FSH levels, which is just one aspect of fertility. It is not intended to determine whether you should use contraception or not.
- Q: I am not sure that I held the test in my urine stream long enough. Will I still get an accurate result?
A: In order to receive an accurate result, you should hold the Absorbent Tip of the test in your urine stream for at least 10 seconds and wait 3 minutes to read the result. If the line in the Reference Window (R) fails to develop, you should repeat with a new midstream test.
- Q: How accurate is the test?
A: A clinical evaluation was conducted comparing the results obtained using the Babystart BioCheck™ to another commercially available urine membrane FSH test. The clinical trial included 200 urine specimens: both assays identified 92 positive and 108 negative results. The results demonstrated >99.0% overall accuracy of the Babystart BioCheck™ when compared to the other urine membrane FSH test.
- Q: How sensitive is Babystart BioCheck™?
A: The Babystart BioCheck™ detects follicle-stimulating hormone (FSH) in urine at concentrations of 25 mIU/mL or higher.

babystart™ products are manufactured by;
 Med-Direct International Ltd,
 Summit Point, Summit Crescent,
 Smethwick, B66 1BT,
 United Kingdom

CE 0088

Index of Symbols

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

Version bsft02 Effective Date: