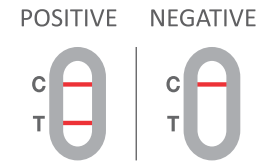


berkeleyhealth MENOPAUSE FSH

Self-Test for the determination of the Follicle Stimulating Hormone - FSH in urine



MENOPAUSE AND FSH

Menopause is defined as the time when there has been no menstrual periods for 12 consecutive months and no other biological or physiological cause can be identified.

The menopause is caused by a modification of the hormonal balance in woman's body. This change arises generally when close to 45 years old. But true signs are observed around 55 years old. An irregular duration of periods is an early indication of the menopause beginning (peri-menopause).

Menopause is the consequence of the end of ovary follicle life-cycle leading to increase of Follicle Stimulating Hormone (FSH) circulating level.

Concentration of FSH increases during menopause passing from values less than 20 mIU/mL up to approximately 80 mIU/mL.

WHO ARE THE INTENDED USERS

WOMEN > 45 years.

WHY - BENEFITS

Checking the presence of high levels of FSH is a useful tool for verifying a potential ongoing menopause status.

TEST PRINCIPLE

MENOPAUSE FSH TEST is an immunochromatographic test that detects FSH through special goldconjugated monoclonal antibodies included in the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
25 mIU/mL	100%	86.9%	94.0%

Performance data obtained by clinical study with 100 participants enrolled. Roche Cobas 8000 has been utilized as reference method.

CONTENT:

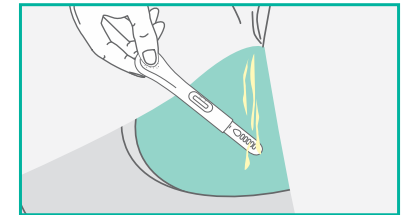
2 sealed aluminium pouches containing each: 1 spoon device and 1 desiccant bag; 1 instructions for use leaflet.

CLINICAL EVIDENCES

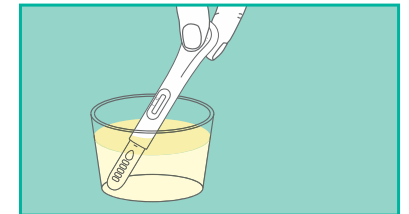
1. Robert J. Norman "Fertility testing" *Australian Prescriber*, 2002;25:38-401
2. Buckler H. "The menopause transition: endocrine changes and clinical symptoms." *J Br Menopause Soc.* 2005 Jun;11(2):61-5.
3. National Collaborating Centre for Women's and Children's Health (UK) "Menopause: Full Guideline". 2015 Nov. National Institute for Health and Care Excellence: Clinical Guidelines.

HOW TO USE IT

1) Remove the protective cap and place the absorbing tip right under the flow of urine for at least 10 seconds.



2) If easier, collect the urine in a clean, dry, residue-free container and dip the absorbing tip into the urine for 10 seconds.



3) Place the protective cap back onto the absorbing tip. Wait 5 minutes before reading the result.

