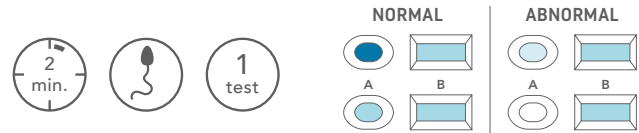




SPERM TEST

Rapid self-test for in-vitro qualitative estimation of sperm concentration in human semen



MALE INFERTILITY

Male infertility can be a health issue for men and is primarily responsible for inability to conceive after 1 year of regular, unprotected intercourse. Particularly, male factor infertility affects nearly 50% of infertile worldwide couples who want to conceive and to require empirical therapy. Sperm count is considered lower than normal if you have fewer than 15 million sperm per milliliter of semen.

WHAT IS SPERM TEST

SPERM TEST is designed to be used for in vitro qualitative estimation of the sperm concentration of human semen. The test will determine if the number of sperms is adequate for conception, subject to female partner's ovulation in time. A low sperm concentration would indicate less likelihood of conception.

WHO ARE THE INTENDED USERS

Men who want to check their sperm concentration.

WHY - BENEFITS

Checking the sperm concentration is a useful tool for verifying the male fertility status.

TEST PRINCIPLE

SPERM TEST is biochemical assay for in vitro qualitative estimation of sperm concentration in human semen. Sperm cells are trapped on the first surface layer of the membrane, while a staining solution is used to dye sperm cells. The darker is the colour of well A, the higher is the sperm concentration. If the colour of well A is lighter than the standard colour of reference well B, it means that the concentration of sperm is less than 15 million/mL. If the colour of well A test is darker than the standard colour of reference well B, it means that the sperm concentration is greater than 15 million/mL.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
15 million/mL	98,10%	99,50%	99,10%

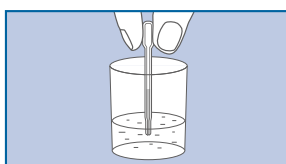
Performance data obtained by clinical study with 236 participants enrolled. Sperm Concentration Rapid Test (Colorimetric) has been utilized as reference method.

CLINICAL EVIDENCES

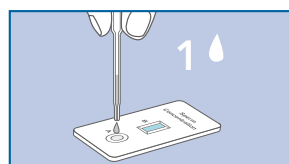
- Centola G.M.: Semen assessment. Urol Clin North Am. 2014 Feb;41(1):163-7. doi: 10.1016/j.ucl.2013.08.007. Epub 2013 Sep 13.
- Cooper T.G., Noonan E., von Eckardstein S., Auger J., Baker H.W., Behre H.M., Haugen T.B., Kruger T., Wang C., Mbizvo M.T., Vogelsong K.M. World Health Organization reference values for human semen characteristics. Hum Reprod Update. 2010 May-Jun;16(3):231-45.

HOW TO USE IT

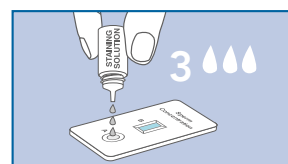
1) Collect the semen directly into the collection cup. Shake it evenly in the collection cup and leave it to stand for 15 minutes until the semen liquefies.



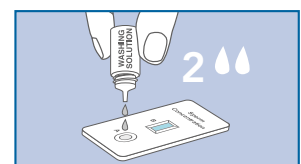
2) Using the provided pipette, dispense one drop of semen into test well A.



3) Add three drops of the blue staining solution to well A. Let it soak for 1-2 minutes.



4) Apply two drops of the transparent washing solution to well A, and let it soak for 1-2 minutes, then read the results immediately by comparing the colour of A to B.



CONTENT: 1 sealed aluminium pouch containing: 1 test device, 1 desiccant bag and 1 pipette; 1 vial with dropper tip containing the staining solution; 1 vial with dropper tip containing the washing solution; 1 collection cup and 1 instructions for use leaflet.



REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100082-1	SPERM TEST	1 TEST	24 MONTHS