

PROSTATE PSA TEST

Self-test for the determination of the Prostate-Specific Antigen (PSA) in whole blood samples



PROSTATE SPECIFIC ANTIGEN (PSA)

The Prostate Specific Antigen (PSA) is a protein produced by the epithelial cells of the prostate gland. Its function is to fluidify the ejaculate and to increase sperm mobility. PSA also plays a role in dissolving cervical mucus, allowing sperm to enter the uterus. Small quantities of PSA are normally found in the blood of men with a healthy prostate. PSA levels may increase with prostate pathologies (prostatitis, benign prostatic hyperplasia etc.), naturally with age or after prostate surgery or specific diagnosis tests (such as rectal examination, prostate biopsy etc.).

WHO ARE THE INTENDED USERS

PROSTATE PSA TEST is intended for:

- men who do not have symptoms, aged over 45, who wish to check their prostate;
- men with urinary tract symptoms (difficulty urinating, pain, increased frequency).

WHY - BENEFITS

Checking the level of the PSA is useful to verify prostate health status. In case of cancer, early detection and prevention can be life saving.

TEST PRINCIPLE

PROSTATE PSA TEST is an immunochromatographic assay which detects the PSA thanks to special monoclonal gold-conjugate antibodies embedded to test strip.

TECH SPECS

| CUT-OFF | SENSITIVITY | SPECIFICITY | OVERALL ACCURACY |
|---------|-------------|-------------|------------------|
| 4 ng/mL | 97,22% | 87,13% | 92,34% |

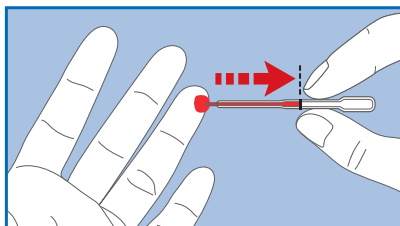
Performance data obtained by clinical study with 209 participants enrolled. Abbott Alinity has been utilized as reference method.

CLINICAL EVIDENCES

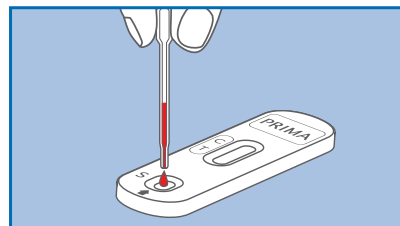
1. Catalona W.J., Southwick P.C., Slawin K.M., Partin A.W., Brawer M.K., Flanigan R.C., Patel A., Richie J.P., Walsh P.C., Scardino P.T., Lange P.H., Gasior G.H., Loveland K.G., Bray K.R.: Comparison of percent free PSA, PSA density, and age-specific PSA cutoffs for prostate cancer detection and staging. *Urology*. 2000 Aug 1;56(2):255-60.
2. Fritsche H.A., Babaian R.J.: Analytical performance goals for measuring prostate specific antigen. *Clin Chem*. 1993 Jul;39(7):1525-29.
3. Michael J. Barry, M.D.: Prostate-Specific-Antigen Testing for Early Diagnosis of Prostate Cancer. *The New England Journal of Medicine*, 2001; 344:1373-1377.

HOW TO USE IT

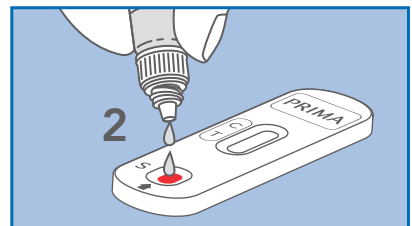
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.



VIDEO
TUTORIAL

| REF | DESCRIPTION | NUMBER OF TESTS | SHELF LIFE |
|----------|-------------------|-----------------|------------|
| 800080-1 | PROSTATE PSA TEST | 1 TEST | 30 MONTHS |