

**PSA Ultra Prostate Specific Antigen  
Semi-Quantitative Rapid Test Single Use Kit  
(Whole Blood/Serum/Plasma)**

A rapid test for the semi-quantitative detection of prostate specific antigen (PSA) in whole blood.  
It is for professional *in vitro* diagnostic use only

This is an extremely sensitive test  
The test is not concerned with volume  
The test is all about an ACCURATE RATIO between 'blood' and 'buffer'  
The test can only be accurate if the ratio between 'blood' and 'buffer' is EXACTLY 2:1  
The test, therefore, demands an exact dilution of  $\frac{2}{3}$  blood and  $\frac{1}{3}$  buffer

There are three (3) lines of the test device:

Line C                       Line R                       Line T 

Lines C & R must ALWAYS be present  
Lines C & R are 'control' lines  
Line T is the 'test line'  
Line T usually only appears after 5 minutes – NO reading should be taken after expiry of 10 minutes

**PROCEDURE FOR PSA TEST**

Provide pre-counselling in line with the CANSA Protocol  
Ask the candidate if he has ever had any treatment for prostate cancer  
If 'yes', the person does NOT qualify for a finger-prick PSA test  
Check the expiry date of the test kit – do not use if expired  
The test must remain in the sealed pouch until use  
Do not use the sterile lancet if its protective cap has been removed previously  
No eating, drinking or smoking in the area where the specimens or kits are handled  
Do not use the test if the pouch is damaged in any way  
Don a pair of disposable gloves  
Open the pouch  
Place the test device on a flat and level surface  
Clean the candidate's finger using the alcohol swab  
Allow the alcohol to dry – do not blow on the finger

Remove the protective cap of the lancet  
Push the lancet firmly into the chosen site  
Allow a large drop of free-flowing blood to collect at the puncture site  
Use the disposable dropper to collect blood  
There must be no air in the disposable dropper  
Hold the disposable dropper vertical  
Let **two (2) hanging drops of blood** drop into the specimen well (S)  
Hold the buffer container vertical and **drop one (1) hanging drop of buffer** into the specimen well (S)  
The drops of blood and buffer must be exactly the same size  
The test device MUST NOT be handled or moved at all  
Wait five (5) minutes and take the reading – timing is VERY important  
No reading should be taken after ten (10) minutes

Result:

Negative	No T line – both R & C lines are present
0 – 3 nanogram/mL	colour of line T is lighter than line R
3 – 10 nanogram/mL	colour of line T is the same as line R
10+ nanogram/mL	colour of line T is darker than line R

The test is **invalid** if Control line C and Reference Line R are not both visible

