

## Check the expiry date printed on the test wrapper

Check that you have everything:

1. test cassette.
2. lancet & spare lancet.
3. antiseptic wipe.
4. Buffer (check to ensure cap is on and buffer is in the bottle).
5. pipette.

**If anything is incorrect please contact us and we will resolve the issue.**

## When to do the test...

**For optimal performance, testing is recommended first thing in the morning. You should avoid strenuous exercise or sexual activity for 24 hours beforehand.**

We have designed the test to be easy to use, and easy to read the results. Please do read the instructions and if you can watch the video.

This test is intended for screening purposes only and should not be relied upon as a diagnostic tool. If you have symptoms or concerns, seek advice from a qualified healthcare professional regardless of the result.

## DON'T EAT, DRINK, SMOKE OR VAPE DURING THE TEST

The following items are useful: (not provided)

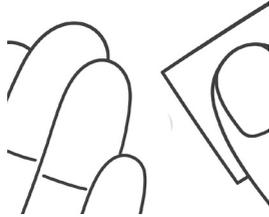
1. A mobile phone (as a timer).
2. Some cotton wool, tissue or a small plaster for after the test.

**Instruction for use must be read entirely before taking the test. Allow the test to equilibrate to room temperature for 30 minutes (10-30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity ≤ 60%, Temp: 10-30°C). Please use immediately if the humidity exceeds 60%**

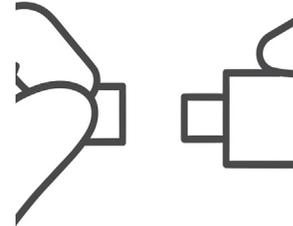
Colour images and a "how to use video" are available on the website: [Pluscheck.co.uk](http://Pluscheck.co.uk) or scan the QR code opposite.



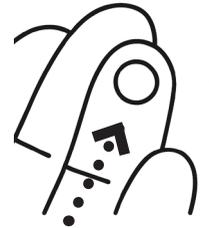
**1** Wash and dry your hands then use the antiseptic wipe on the spot where you will use the lancet. Typically we don't use the fingertip as the skin can be thicker. Half way down your small finger is a good place. But any spot can work.



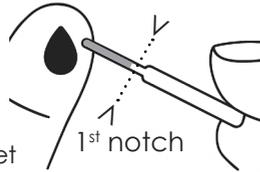
**2** Remove the clear cap from the purple lancet and press it firmly against your skin until it clicks. You may feel a brief sensation. Rest your finger on a work surface if you need to.



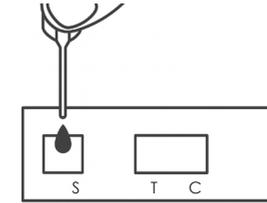
**3** Massage your finger upwards and also squeeze so a droplet of blood will form.



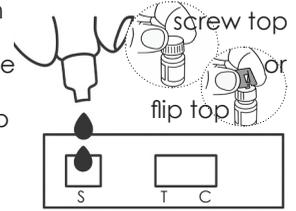
**4** Hold the pipette in the droplet of blood, **don't squeeze the bulb**, it will fill on its own. Fill more than half way, up to the first notch but not past it. Massage finger and repeat if necessary to get enough sample in the pipette.



**5** Squeeze the blood sample into the cassette well marked (S).

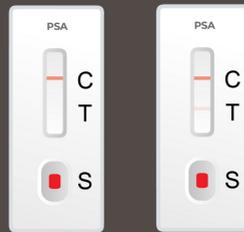


**6** Open the cap on the buffer then add 2 drops to the sample (S). Some kits have a flip top lid, if so squeeze the lid sides to open the bottle.



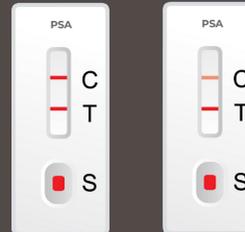
**START YOUR TIMER AND WAIT 10 MINUTES THEN READ THE RESULT. DON'T LEAVE IT LONGER AS RESULTS ARE INVALID AFTER 20 MINUTES.**

### NOT RAISED



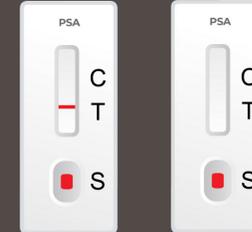
One coloured line appears in the control line region (C) also a faint line may appear in the test line (T) BUT is weaker than the control line. A NOT RAISED result does not rule out prostate disease or cancer, and PSA levels may change over time.

### RAISED



Two distinct coloured lines appear. The test line (T) will be equal to OR stronger / darker than the (C) line

### INVALID



The result is invalid if no coloured line appears in the control line region (C), even if a line appears in the test line region (T).

98/79/C, EN ISO 18113-1:2011  
EN ISO 18113-2:2011  
EN 13612:2002  
EN ISO 23640:2015  
EN 13641:2002  
EN ISO 15223-1:2021  
EN 13975:2003  
EN ISO 14971:2019  
EN ISO NOTIFIED BODY: 13485:2016  
EN ISO 17511:2021  
IEC 62366-1:2015

## (PSA) Prostate Specific Antigen Rapid Test



### INTENDED FOR HOME USE

This reagent is designed to detect prostate-specific antigen (PSA) in human whole blood using a colloidal gold immunochromatographic assay. The test is intended for qualitative screening purposes only to provide an indicative result.

This test is not intended for clinical diagnosis. A result indicating a raised PSA level does not confirm the presence of prostate cancer or any other medical condition. PSA levels may be influenced by a range of factors and conditions.

Whether the test indicates a raised PSA indicator or not, users are advised to seek further assessment and interpretation from a qualified healthcare professional.

### TEST PRINCIPLE

This test is based on the colloidal gold immunochromatographic assay principle. The nitrocellulose membrane is coated with anti-PSA antibody 1, while the conjugate pad is labelled with colloidal gold-conjugated anti-PSA antibody 2.

During testing, the blood sample reacts with the colloidal gold-labelled anti-PSA antibody 2. The resulting complex migrates along the membrane by capillary action and reacts with anti-PSA antibody 1, producing a visible coloured line.

If the PSA concentration in the sample is below the limit of detection, the test line will be weaker than the control line or absent, indicating no raised PSA indicator.

If the PSA concentration in the sample is at or above the limit of detection, the test line will appear equal to or stronger than the control line, indicating a raised PSA indicator.

Regardless of PSA presence, a coloured line will appear in the control (C) region when the test has been performed correctly, confirming test validity.

### MAIN COMPONENTS

Sample pad, colloidal gold conjugate pad, nitrocellulose membrane, absorbent paper, and PVC board. Colloidal gold conjugate pad labelled with anti-PSA monoclonal antibody 2, nitrocellulose membrane coated with anti-PSA monoclonal antibody 1, control line coated with goat anti-mouse IgG antibody. Sample diluent: Phosphate containing buffer. Disposable plastic pipette.

### MATERIALS NEEDED BUT NOT PROVIDED

1. Timer (use your phone, watch or smart device)
2. Appropriate biohazard waste container and disinfectants.

### STORAGE AND EXPIRY

Store in a dry environment at 4-30°C, avoid hot and sunshine, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. There is an expiry date printed on the test cassette seal.

### SAMPLE REQUIREMENTS

Whole blood samples must be collected in a clean environment.

### LIMITATIONS

1. The results of this test are for home reference only.
2. This reagent is used for qualitative screening purposes.
3. Concentration of PSA cannot be determined by the test.
4. This test is intended as a screening guide only and is not designed for clinical diagnosis.

### QUALITY CONTROL

There are the test line and the control line on the surface of the reagent. Neither the test line nor the control line is visible in the result window before applying a sample. The control line is used for procedural control and should always appear if the test procedure is performed properly, and the test reagents of the control line are working.

The appearance of control line (C) is confirmed sufficient sample volume, adequate membrane wicking and correct procedural technique.

### PERFORMANCE CHARACTERISTICS

The limit of detection of the test is 4ng/mL.

A clinical evaluation was conducted on 412 samples (including 134 positive samples and 278 negative samples) comparing the results obtained using (PSA) Prostate Specific Antigen Rapid Test and other commercially available PSA tests. The results are as follows:

PSA Test	Comparator Method		Total
	Positive	Negative	
Positive	131	2	133
Negative	3	276	279
Total	134	278	412

PPA: 97.76% (95%CI: 93.63%-99.24%)

NPA: 99.28% (95%CI: 97.42%-99.80%)

OPA: 98.79% (95%CI: 97.19%-99.48%)

### Explanation of Terms

PPA: Positive Percent Agreement = True Positives / (True Positives + False Negatives)

NPA: Negative Percent Agreement = True Negatives / (True Negatives + False Positives)

OPA: Overall Percent Agreement = (True Positives + True Negatives) / Total

CI: Confidence Interval

3. Analytical specificity

3.1 Interfering substances

Hyperlipidemia samples, hemolysis samples (Hb<10g/L), hyper bilirubin samples and HAMA were detected respectively, which should have no influence on the interpretation of the detection results.

3.2. Cross-reactivity

The concentrations of alpha-fetal protein (1000ng/mL), carcinoembryonic antigen (1000ng/mL), carbohydrate antigen CA-125(1000U/mL), CA-19-9 (1000U/mL), and rheumatoid factor positive samples were detected respectively, which should have no influence on the interpretation of the detection results.

### PRECAUTIONS

- 1.This test is intended for screening purposes only and is not designed for diagnostic use.
- 2.Do not use quality control samples or reagents other than those specified for use with this test.
- 3.Keep the test sealed and protected from moisture. Allow the test kit to reach room temperature before use.
- 4.Use the test kit as soon as possible after removal from the aluminium foil pouch. Prolonged exposure to air may affect test performance due to moisture.
- 5.Do not use blood samples that have been stored for extended periods or that may be contaminated. The blood sample should be used immediately after collection.
- 6.Dispose of all used materials in accordance with local regulations for potentially infectious substances.
- 7.Incorrect operation may affect test performance, including but not limited to insufficient or excessive sample volume, inadequate sample mixing, incorrect buffer application, or reading the result outside the specified time window.