Keul-o-test PSA K (test cassette)

PSA Test for serum, plasma or whole blood specimen

Single test cassette **Art. Nr. 602002**

CE

INTENDED USE

Keul-o-test PSA K is a one step in vitro diagnostic test based on immunochromatographic assay. It is designed for the detection of human PSA in serum, plasma or whole blood samples.

SUMMARY AND EXPLANATION

Prostate-specific antigen (PSA)is an intracellular glycoprotein (34KDa) synthesised only by the prostate gland. PSA, a normal constituent of prostate tissue, is also present in benign hyperplastic and malignant prostatic tissue, in metastatic prostatic carcinoma, in prostatic fluid and seminal plasma. However, it will not be detected in cancers of lung, colon, breast, rectum, pancreas, stomach or thyroid.
The amount of PSA in the blood normally increases through time as a man's prostate enlarges with age. However, the normal level of PSA concentration in men, aged 40 to 50, is less than 2.5 ng/ml. The concentration of PSA is increased in blood of prostate cancer patients. The predictive value of PSA test is superior to that of either rectal examination or ultrasound alone. Since elevated levels of PSA are also seen in BPH (Benign Prostatic Hyperplasia) and other inflammation of urogenital tissues, measurement of blood PSA concentration is not recommended as a sole test procedure for diagnosis of cancer. But the combination of PSA test with ultrasound provides a better method of detecting prostate cancer than a rectal examination or an ultrasound alone.
The PSA test is effective in screening men for prostate cancer or monitoring its development and monitoring the response to treatment.

PRINCIPLE OF THE TEST

Keul-o-test PSA K is an immunochromatographic assay. When the sample is added to the sample pad, it moves through the conjugate pad and mobilises gold anti-PSA conjugate that is coated on the conjugate pad. The sample then moves along to the membrane by capillary action and reacts with anti-PSA antibody that is coated on the test region. If PSA is present in the sample at concentrations of 4.0ng/mL or greater, a coloured line appears in the test region. If PSA is present at a lower level or not present at all, in the sample, the test region will remain white. The sample continues to move to the control region (regardless of the concentration levels) and forms a coloured line, indicating the test is working and its result is valid.

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COMPOSITION

Mouse anti-PSA monoclonal antibody 1----------0.134±0.05 µg
Mouse anti-PSA monoclonal antibody 2---------- 0.256±0.05 µg
Anti-mouse immunoglobulin G---------- --------- 0.256±0.05 µg

STORAGE AND SHELF-LIFE

1. Store the test device packaged in a sealed foil pouch at 1 to 30°C(34-86°F). Do not freeze.
2. Shelf-life: 18 months from manufacturing date.

PRECAUTIONS

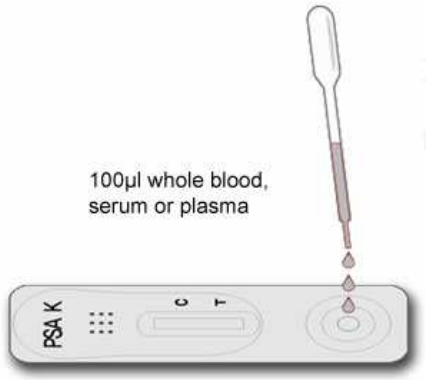
1. For *in vitro* diagnostic use only.
2. Do not use the test device after expiry date.
3. Handle all specimens as potentially infectious.

SPECIMEN COLLECTION AND PREPARATION

1. The serum, plasma or whole blood may be used as samples and should be collected under standard laboratory conditions.
2. Whole blood or plasma collection:
   Collect blood in a tube containing anticoagulant such as heparin or EDTA and centrifuge the blood to get plasma specimen.
3. Serum collection:
   Collect blood in a tube without anticoagulant and allow clotting.
4. It is recommended that fresh samples be used as soon as possible; whole blood sample should be tested within 3 hours of collection. If specimens must be stored, the red blood cells should be removed. Plasma or serum samples may be refrigerated for 24 hours at 2-8℃. If plasma or serum samples must be stored for more than 24 hours, they should be frozen at -20℃ or below.
5. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.

TEST PROCEDURE

1. Bring all materials and specimens to room temperature, and then open the foil pouch and place the device on a clean, dry and level surface.
   Note: Once the foil pouch is opened, the device should be used as soon as possible.
2. Write the specimen ID on the test device.
3. Use disposable pipette to transfer 100µl (about 3 hanging drops) of sample into the sample well.

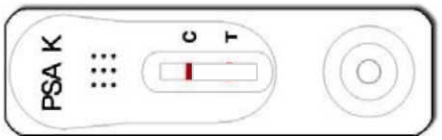


   Note: Use a fresh pipette or tip for each samples in order to prevent cross-contamination.
4. Wait for 10 minutes and then read the results. Do not interpret the test results after 15 minutes.

INTERPRETATION OF THE RESULTS

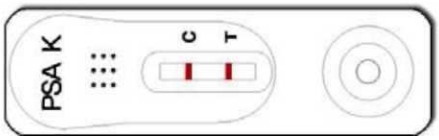
NEGATIVE:

If the test region(T) has no colour line and the control region(C) displays a coloured line, the result is negative.



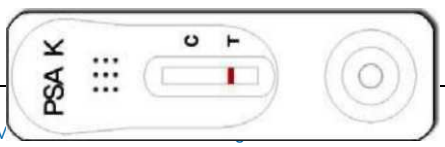
POSITIVE:

If the test region(T) has a coloured line and the control region(C) displays a coloured line, the test result is positive. The test result can be read as soon as a distinct coloured line appears in test region.



INVALID:

If there is no red line in control region (C), the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test device.



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QUALITY CONTROL

The control line is an internal control of the test reagents and procedure. It will appear if the test has been performed correctly and the reagents are reactive.
The First international standard (NIBSC code 96/670) may be used as a reference standard.

LIMITATIONS OF THE TEST

1. For samples that test result is positive by **Keul-o-test PSA K**, more specific confirmatory testing should be done.
2. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established.
3. The use of a rapid test alone is not sufficient to diagnosis prostate cancer even if antigen present. Also, a negative result at any time does not preclude the possibility of prostatic cancer.

EXPECTED VALUES

Keul-o-test PSA K is designed to yield a positive result for PSA concentrations at 4.0ng/mL or greater.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity
Keul-o-test PSA K can detect PSA with concentration of 4.0ng/mL or greater.

2. Clinical Accuracy
A clinical evaluation was conducted using a total 1.224 clinical specimens. The **Keul-o-test PSA K** was tested on whole blood, plasma and serum specimen matrices. No. discordant result was obtained from all specimen matrices. The serum / plasma specimens from study subjects were also tested using a licensed Enyme Immunoassay (CanAg EIA test and ADVIA Centaur CP).

1. Serum-Test

Keul-o-test PSA K	Quantitative Assey		
	Positiv (>4.0 ng/ml PSA)	Negativ (<4.0 ng/ml PSA)	Total
Positive	58	3	61
Negative	0	105	105
Total	58	108	166

Relative Sensitivity : > 99%(58/58)
Relative Specificity : 97.2%(105/108)
Overall Accuracy : 98.2%(163/166)

2. Plasma-Test

Keul-o-test PSA K	Quantitativer Assay		
	Positiv (>4.0 ng/ml PSA)	Negativ (<4.0 ng/ml PSA)	Total
Positive	23	25	48
Negative	0	481	481
Total	23	506	529

Relative Sensitivity : > 99%(23/23)
Relative Specificity : 95.1%(481/506)
Overall Accuracy : 95.3% (504/529)

3. Vollblut-Test

Keul-o-test PSA K	Quantitativer Assay		
	Positiv (>4.0 ng/ml PSA)	Negativ (<4.0 ng/ml PSA)	Total
Positive	23	21	44
Negative	0	485	485
Total	23	506	529

Relative Sensitivity : > 99%(23/23)
Relative Specificity : 95.8%(485/506)
Overall Accuracy : 96.0%(508/529)

INTERFERING SUBSTANCES

The following substances do not interfere with **Keul-o-test PSA-Test qualitative** test result.

- Bilirubin (20mg/dL)
- Heparin (6IU/dL)
- Human adbumin (20,000mg/dL)
- Triglycerides (1,250mg/dL)
- EDTA (800mg/dL)
- Hemoglobin (250mg/dL)
- Sodium citrate (500mg/dL)

REFERENCES

1. Reiter RE et al., Prostate stem cell antigen: A cell surface marker overexpressed in prostate cancer. Proc Natl Acad Sci U S A. 1998, 95(4):1735~1740.
2. Haut MJ et al., Progressing prostate carcinoma. The oncologist. 2001, 6(2):183~196.
3. Woolf SH et al., Screening for prostate cancer with prostate-specific antigen. An examination of the evidence. N Engl J Med. 1995, 333(21):1401~1405.

CE0123: This product fulfills the requirements for Directive 98/79/EC on in vitro diagnostic medical devices.

	Hersteller		Σ	Inhalt ausreichend für <n> Tests
IVD	Nur für in-Vitro-diagnostische Zwecke		LOT	Chargenbezeichnung
2	Nur einmal verwenden			Verwendbar bis
	Gebrauchsanweisung beachten			Lagertemperatur

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akt. 02.02.2010