Hipro Biotechnology Co.,Ltd

EN
ENGLISH

tPSA

Total Prostate Specific Antigen Test Kit
(Nephelometry Immunoassay Method)

Instructions for Use

Version: A/2

REF HP-tPSA-25

Manufacturer

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Product Name

General Name: Total Prostate Specific Antigen Test Kit (Nephelometry Immunoassay Method)

Specification

Package Specification
25 Tests/ Kit.

Intended Use

The total Prostate Specific Antigen (tPSA) Test Kit is designed for in vitro diagnostic use only for quantitative measurement of total Prostate Specific Antigen(tPSA) in human serum. This test kit is indicated for the measurement of total PSA to be used as an aid in management of patients with prostate cancer. It can not be used as the basis for early diagnosis or diagnosis of malignant tumor, and is not used for tumor screening in the general population.

Test Principle

Use the antibody-antigen reaction to directly determine the percentage of total PSA in human serum. The mouse-anti-human PSA antibody was coated on the latex particles. The PSA in the sample reacts with the antibody to form the antigen-antibody complex. The complex causes the scattering intensity change under incident light. The scattering light change rate is in positive correlation with PSA concentration in the sample. By measuring the rate of change of the scattered light intensity at specific wavelength and comparing it with the standard curve of the percentage concentration of PSA, the percentage of PSA in the sample can be calculated.

Component

The total PSA test kit consists of two reagents R1 and R2, as shown on Figure 1.

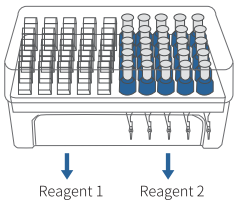


Figure 1

Name	Content	Quantity
Reagent 1 (R1)	Goo d's diluent	0.1mmol/L
	PEG	Proper amount
	NaN_3	1%
	Surface active agent	Proper amount
Reagent 2 (R2)	Latex particles coated with mouse-anti-human PSA antibody	2.0mg/mL
	NaN_3	0.1mol/L
IC card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened. Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

The specimen type of total PSA is human serum, avoiding hemolysis.

There is a quantitative capillary on R2 for required sample volume. The capillary should be fully collected.

If the sample can not be tested within 8 hours, it can be stored at 2°C~8°C for 24 hours, while stored up to 14days at -20°C.

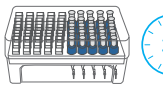
Procedures

HP-083/4-II POCT Immunoassay System

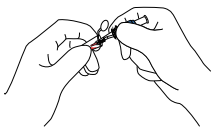
Note:

- Please read user manual of HP-083/4-II before use.
- The analyzer will finish self check after start-up.
- Insert the IC card of total PSA test kit to let analyzer read the parameter.
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

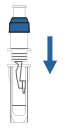
Step 1 Sample Preparation



1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

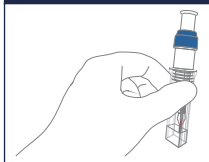


1c Insert the R2 into R1.

Note:

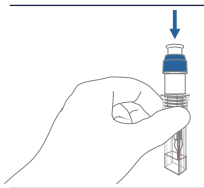
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing



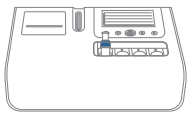
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note: Do not hold the wide sides of R1.



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.



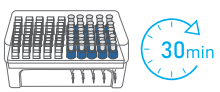
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

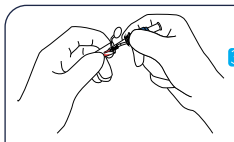
Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use.
- The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

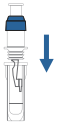
Step 1 Sample Preparation



3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.

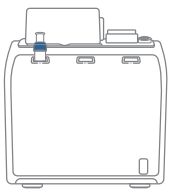


3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Quality control

It is recommended that each laboratory routinely uses quality control materials and establish its own control ranges. The control intervals and limits should be adapted to each laboratory' s individual requirements.

Reference Value

＜4.00ng/mL.

If the test result is ⩾ 4.00ng/mL, it may indicate prostate cancer and it is recommend for medical advice. The results should be in conjunction with other medical history.

The value is indicative only and may differ from other published values as a result of differences in methods and in the population being studied. It is recommended that each laboratory establish its own reference range.

Limitations

There is no effect to test result if hemoglobin⩽5g/L, bilirubin ⩽300μmol/L and triglycerides⩽10mmol/L.

Performance Characteristics

1 Linearity: within range 1.00ng/mL ～ 100ng/mL, r⩾0.990

2 Limit of Blank :⩽0.8ng/mL

3 Within-lot precision: CV⩽10%

4 Between-lot precision: R⩽10%

5 Accuracy: B ⩽ ±15%

Precautions

1. For in vitro diagnostic use only.
2. For prescription use only.
3. The test kit and disposal should be disposed as infectious.
4. It is not recommended to reuse the reagents.
5. It is not recommended to use the test kit beyond the expiration date.
6. Do not freeze the test kit.
7. Do not mix different lots of the test kit.
8. Wash with water if the reagents splash on your skin or in your eyes.
9. Follow the laboratory rules while handling with sample.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
	Temperature Limit		
	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

Shang Hong, Wang Yusan, Shen Ziyu et al. National Clinical Laboratory Operating Procedures (4th edition) [M]. Beijing: People's Medical Publishing House, 2015:549-550.

Approval Date&Revision Date

Approval Date: Apr 26, 2022

Revision date：Jan 1, 2023

Revision Date：Dec 22,2023

CE IVD

尺寸：24*25cm展开尺寸，横向三折页再垂直方向两次对折