

Please use the reagent after reading this package insert

# PSA

## Quantitative turbidimetric latex assay for the measurement of PSA

### 【General attention】

1. This reagent is for in vitro diagnostic use, and do not use for other purpose.
2. The doctor in charge along with clinical conditions and other laboratory results, etc. must judge the clinical diagnosis based on the result of a measurement overall.
3. Please use it according to use and the dosage regimen described in the package insert. The reliability of the result of a measurement cannot be guaranteed when use excluding described use and dosage regimen.

### 【Reagent Composition】

1. Buffer (R1) ..... Liquid
2. Latex reagent (R2) ..... Liquid  
(Anti-human PSA (mouse) monoclonal antibody sensitized latex)

### 【Intended use】

Measurement of prostate specific antigen (PSA) in serum.

### 【Principle】

1. Principle of measurement  
Antibody adsorbed latex particles and PSA in the sample react immunologically, and causing the latex particles to agglutinate. This agglutination results in a change of turbidity, and the change in absorbance is a measure of the amount of PSA in the sample.
2. Feature
  1. Measurement principle is latex immuno turbidimetric assay.
  2. It is possible to adjust to various general-purpose automatic analyzers.
  3. unnecessary for preparation of reagent
  4. The preprocessing of the sample (dilution of the sample) is unnecessary.

### 【Handling Precautions】

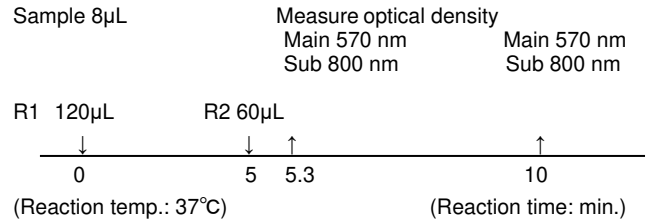
1. Measurement sample
  - A. Please use the fresh serum as a specimen for measurement. Please measure promptly after collecting serum, and if it is not possible to measure, preserve freezing. However, please do not repeat the freezing and thawing.
  - B. Please be careful, it is said PSA concentration will rise by physical stimulus such as palpation and biopsy.
2. Interfering substance etc.  
The following components hardly interfered with the test result: chyle (up to formazin turbidity 1930), bilirubin F  $\leq 18.3$ mg/dL, bilirubin C  $\leq 19.0$ mg/dL, Hemoglobin 490mg/dL and RF  $\leq 500$ IU/mL.
3. Others
  - a. Storage reagents at (2-10°C), and the freezing preservation must be avoid
  - b. Please request material separately about the adaptation example to various automated analyzers.

### 【Procedure】

1. Preparation of the reagents  
Buffer solution (R1) and Latex reagent (R2) are used as it is.
2. Stability  
The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-10°C and contaminations are prevented during their use.

### 3. Procedure

[Standard procedure]



### 4. Calibration

Using optional PSA calibrator and measure them as sample based on the above-mentioned procedure, and made the calibration line.

### 【Judgment method of result】

- (1) Normal reference values  
<4.0ng/mL  
Average value of serum PSA with this kit was 0.91ng/mL by measuring 74 serum samples which showed normal values with already approved kit, and the average value + 3SD was 3.93 ng / mL. From the above results, we set the normal reference value to be equal to or less than 4.0ng / mL.
- (2) The nonspecific reaction can happen in various infectious diseases and autoimmune disease patients' serums. Please judge the diagnosis based on the result of a measurement overall in consideration of other inspections and clinical conditions.

### 【CLINICAL SIGNIFICANCE】

Prostate specific antigen (PSA) is glycoprotein of molecular weight 34,000 which there is in prostatic organization and seminal plasma. The PSA out of the blood increases by prostate cancer, prostatomegaly, prostatitis, other prostatic diseases. Particularly, PSA out of the blood increases in prostate cancer patients remarkably. The PSA is used for a diagnosis of the prostate cancer and a judgment of the curative effect as tumor marker.

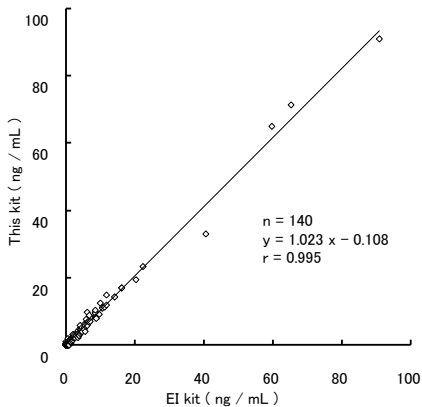
### 【PERFORMANCE】

#### 1. ANALYTICAL PERFORMANCE

1. Sensitivity
  - (a) When measured saline liquid as the sample, absorbance change ( $\Delta$ OD) is below 0.003/min.
  - (b) When measure known concentration sample, absorbance change of PSA concentration 30ng / mL is between 0.008 to 0.071/min.
2. Accuracy  
When measured the control serum of known concentration is measured, measurement value is within  $\pm 15\%$  of the known value.
3. Reproducibility  
When measure the same sample five times at the same time, the C.V of the absorbance value is 10% or less.
4. Measurement range  
Measurement range of the PSA in the sample is 1.0-95ng/mL.
5. Standard material for calibration  
WHO1st International Standard 96/670

## 2. Correlation

Correlation performance study were conducted with commercially available EIA kit (x), resulted in a good correlation:  $n=140$ ,  $y=1.023x - 0.108$ , and  $r=0.995$ .



### 〔Attention in handling for use〕

#### 1. Attention in handling (dangerous prevention)

- (1) An infectious microorganism such as hepatitis B viruses might exist in the sample, please handle it assuming that there is a risk for infection.
- (2) Sodium azide of 0.09w/v% is contained in the reagents as preservative. When entering eyes and mouths or adhering to the skin by mistake, flushing enough them with water as a stop-gap measure. If there is a necessity receive the doctor's treatment.

#### 2. Directions

- (1) Do not use the reagents after the expiration date.
- (2) After open the reagents, use them as early as possible. When preserve them, please close the lid and preserve on a specified condition.
- (3) Please do not use the bottle and the accessory in this kit for other purposes.
- (4) Please set the buffer and the latex reagent at the position correctly after gently mixing by invert the bottle before measure. Please remove the bubble when bubbling.
- (5) When the measurement value exceeds the measure range, please dilute with saline liquid, and measure the specimen material. Those obtained by multiplying the dilution factor in value is the measured value.
- (6) Please do not use the reagent with different lot.
- (7) Please make the working curve at each measurement. Moreover, please measure the calibration sample for two times or more respectively.
- (8) Please use the calibrator sold separately, and refers to the manual of the goods before use.
- (9) Preserve the reagent at refrigerated condition (2-10°C) and avoid the freezing.

#### 3. Attention for Disposal

- (1) Sodium azide of 0.09w/v% is contained in the reagents as preservative. The sodium azide might generate the metallic azide that it reacts with the lead pipe and the copper pipe and explosiveness is strong, and flush it in volumes of water, please when you abandon it.
- (2) An infectious microorganism such as hepatitis B viruses might exist in the sample, and process a used sample, the reagent container, and apparatus, etc. by sterilization, disinfection (0.5% solution of sodium hypochlorite), and incineration, etc.
- (3) Please process it according to regulations of Wastes Disposal and Public Cleaning Law and Water Pollution Control Law, etc. when you abandon and apparatus, etc.

### 〔Storage and validity period〕

1. Storage : 2~10°C
2. Validity period : 1 year after production  
Expiration date is displayed on the outer box and bottle labels.

### 〔Package〕

Product Name	Contents
PSA reagent	
Buffer (R1)	40mL ×1
Latex reagent (R2)	20mL ×1

### 〔Optional goods〕

(Product Name) (Contents)

PSA Calibrator 6 conc. × 1mL each

PSA Control 2 concentrations × 2mL each

The indicated value is displayed on the label

### 〔References〕

- 1) M.C.Wang, T.M.Chu, et al., Invest.Urol., 17,159,1979.

### 〔Inquiries〕

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### 〔Manufacturing and distribution〕

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