

\*FDA 510(k) Cleared

### Urology

PSA Plus  
Testosterone

### Thyroid hormone

TSH  
Free T4  
Total T3  
Thyroid Duo

### Emergency

PCT  
BNP  
Troponin I  
Cardiac Triple  
D-Dimer

### Others

Vitamin D  
COVID-19



Why wait for the result?  
**Get FRENDO!**

#### Key feature 01

## Accelerating decision-making

The FREND™ System is a point-of-care testing (POCT) that uses microfluidic and Immunofluorescence technology. Accurate and fully automated FREND™ System offers fast results. With a simple 3 step operation and a wide range of disease markers, the system supports quick decision-making.

#### Key feature 02

## Easy & Fast Operation

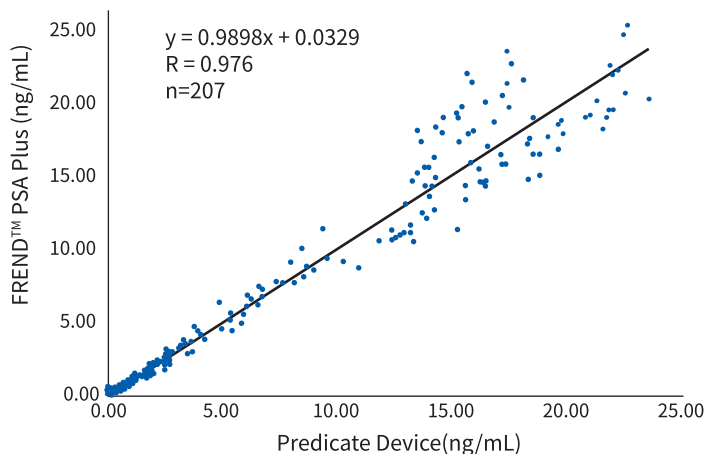
The quantitative results can be obtained in less than 3 minutes with only 35 µL of sample volume. The FREND™ System offers an intuitive and user-friendly interface. System QC and software updates are just a click away.

#### Key feature 03

## Superior Accuracy

The FREND™ System received FDA 510(k) clearance as the *in-vitro* diagnostics which provides a high correlation with large machinery and accurate results.

**Correlation value of FREND PSA Plus is more than 0.97 compared to predicate device**



Source: DOCRO Inc. (USA)



## User-friendly Interface

The FREND™ System offers intuitive and easily accessible GUI. It stores up to 1,000 test results. Users can transfer the data easily to PC through USB and print out the test result with a printer provided.

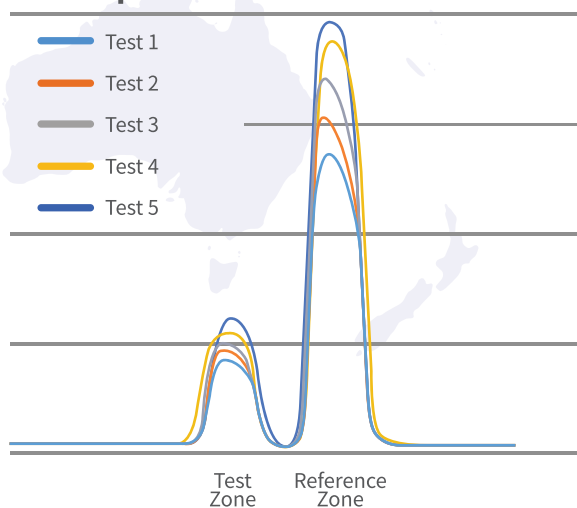
## Excellent Quality Control

The FREND™ System provides free QC cartridge to quickly check the integrity of the system. The code chip significantly reduces possible errors in between-test values and LOT variation, hence provides more accurate results.

<Correct Test-to-Test variations>

	Fluorescence Intensity		Ratio (Test/Reference)
	Test Zone	Reference Zone	
Test 1	32557	112542	0.289
Test 2	24603	84160	0.292
Test 3	26133	93322	0.280
Test 4	30427	104619	0.291
Test 5	21302	74288	0.287
AVERAGE	27004	93786	0.288
S.D.	4516	15348	0.005
CV%	16.7	16.4	1.7

### Example



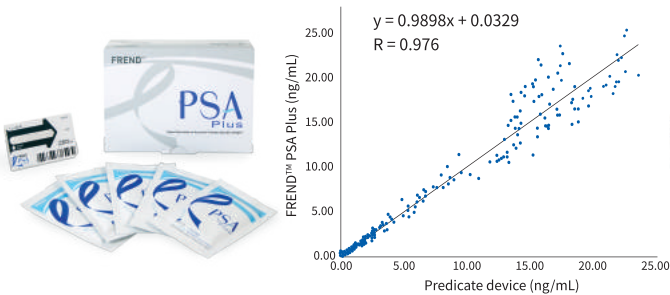
Source: NanoEntek R&D

# UROLOGY

## PSA Plus

MFDS  0123  FDA 510(k) cleared

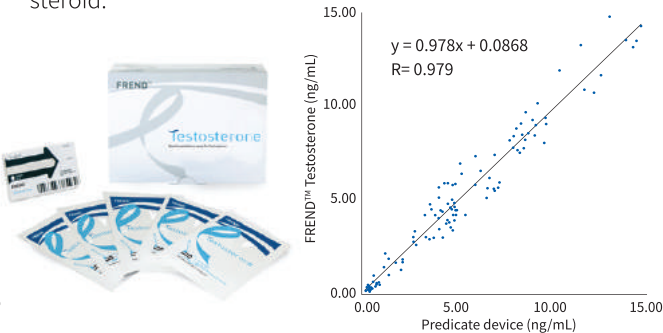
Prostate-specific antigen (PSA), also known as gamma-semi-protein or kallikrein-3 (KLK3), is a glycoprotein enzyme encoded in humans by the KLK3 gene. It is a member of the kallikrein-related peptidase family and is secreted by the epithelial cells of the prostate gland. PSA is produced for the ejaculate, where it liquefies semen in the seminal coagulum and allows sperm to swim freely.



## Testosterone

MFDS  FDA 510(k) cleared

Testosterone is a steroid hormone from the androgen group and is found in humans and other vertebrates. In humans and other mammals, testosterone is secreted primarily by the testicles of males and, to a lesser extent, the ovaries of females. Small amounts are also secreted by the adrenal glands. It is the principal male sex hormone and an anabolic steroid.



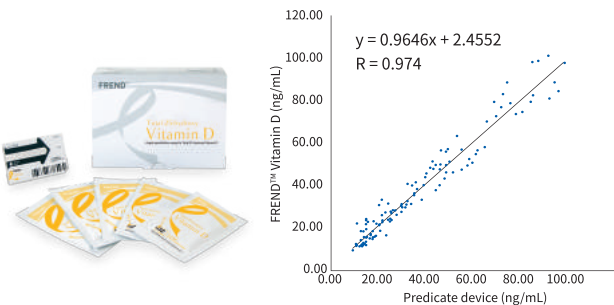
Test item	Principle	AMR	Sample type	Sample volume	Time	Pretreatment	Package	Storage	Expiration date
FREND PSA Plus	Immunofluorescence	0.05 ~ 25 ng/mL	Plasma or Serum	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	24 month
FREND Testosterone	Immunofluorescence	0.2 ~ 15 ng/mL	Plasma or Serum	70 µL	< 3 min	O	20 tests / Kit	2 ~ 8 °C	18 month

# VITAMIN

## Vitamin D

MFDS  FDA 510(k) cleared

Vitamin D is a steroid hormone involved in the activation of calcium, which is important in the formation and maintenance of bones. Lack of calcium and vitamin D for a long period of time can cause osteoporosis.



# RESPIRATORY

## COVID-19 IgG/IgM Duo

MFDS 

The FREND™ COVID-19 IgG/IgM Duo can be used to check whether patient has developed immune response to SARS-CoV-2 using human serum or plasma. It detects anti-SARS-CoV-2 IgG and IgM produced by viral infection, it helps identify coronavirus disease 2019 (COVID-19) infections.



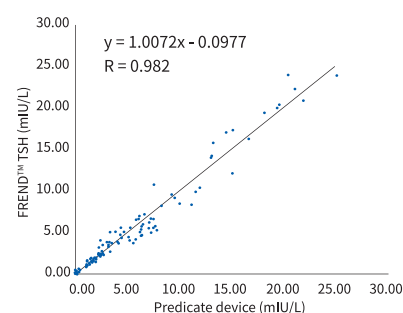
Test item	Principle	AMR	Sample type	Sample volume	Time	Pretreatment	Package	Storage	Expiration date
FREND Vitamin D	Immunofluorescence	10 ~ 110 ng/mL	Plasma or Serum	35 µL	< 3 min	O	20 tests / Kit	2 ~ 8 °C	12 month
FREND COVID-19 IgG/IgM Duo	Immunofluorescence	N/A	Plasma or Serum	35 µL	< 3 min	X	20 tests / Kit	2 ~ 8 °C	6 month



# THYROID

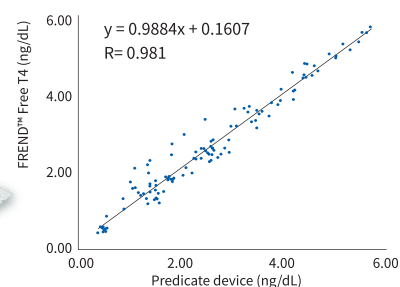
## TSH/Thyroid Duo MFDS CE FDA 510(k) cleared

Thyroid-stimulating hormone (also known as thyrotropin, thyrotropic hormone, TSH, or hTSH for human TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine (T4), and then triiodothyronine (T3) which stimulates the metabolism of almost every tissue in the body. It is a glycoprotein hormone synthesized and secreted by thyrotrope cells in the anterior pituitary gland, which regulates the endocrine function of the thyroid.



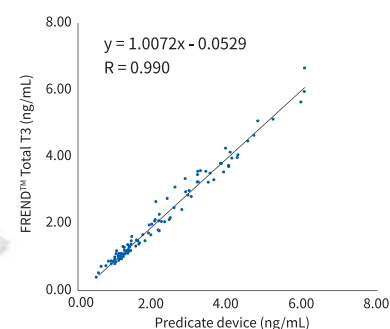
## Free T4 MFDS CE FDA 510(k) cleared

A hormone that is made by the thyroid gland and is one of the most important thyroid hormones. Four iodine molecules are attached to the molecular structure of thyroxine. Along with the more powerful thyroid hormone triiodothyronine (T3), thyroxine affects almost every process in the body, including body temperature, growth, and heart rate.



## Total T3 MFDS CE

Triiodothyronine, also known as T3, is a thyroid hormone. It affects almost every physiological process in the body, including growth and development, metabolism, body temperature, and heart rate.



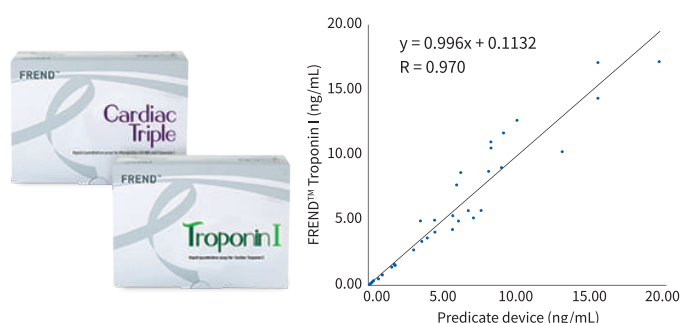
Test item	Principle	AMR	Sample type	Sample volume	Time	Pretreatment	Package	Storage	Expiration date
FREND TSH	Immunofluorescence	0.06 ~ 25 mIU/L	Plasma or Serum	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	24 month
FREND Thyroid Duo	Immunofluorescence	TSH: 0.06 ~ 25 mIU/L Free T4: 0.4 ~ 6 ng/dL	Plasma or Serum	70 µL	< 3 min	O	20 tests / Kit	2 ~ 8 °C	12 month
FREND Free T4	Immunofluorescence	0.4 ~ 6 ng/dL	Plasma or Serum	70 µL	< 3 min	O	20 tests / Kit	2 ~ 8 °C	18 month
FREND Total T3	Immunofluorescence	0.25 ~ 8 ng/mL	Plasma or Serum	70 µL	< 3 min	O	20 tests / Kit	2 ~ 8 °C	12 month

# EMERGENCY

## Cardiac Triple/Troponin I

MFDS 

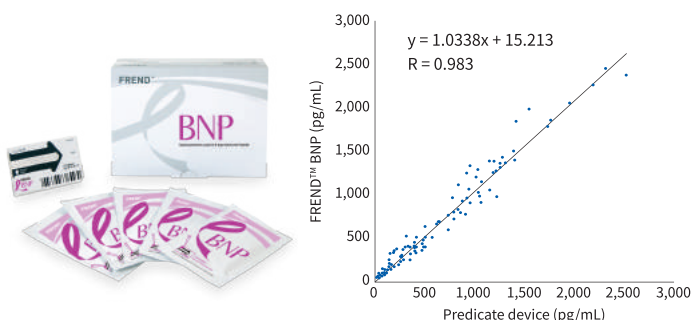
Cardiac Triple test measures the level of CK-MB, Troponin I and Myoglobin to detect and monitor heart attack or injury to heart muscle. It is fast and accurate quantitative *in vitro* diagnostic of the protein in human serum or plasma based on the lab-on-a-chip technology.



## BNP

MFDS  NMPA

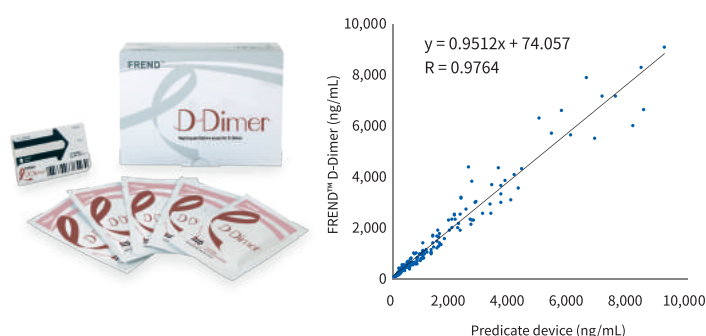
Brain natriuretic peptide (BNP) is a 32-amino acid polypeptide secreted by the ventricles of the heart in response to excessive stretching of heart muscle cells (cardiomyocytes). The release of BNP is modulated by calcium ions.



## D-Dimer

MFDS 

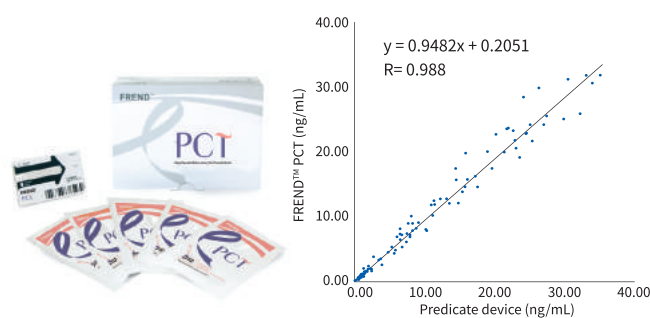
D-dimer is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. The concentration of D-dimer may be determined by a blood test to help diagnose thrombosis. It is used in the diagnosis of DVT (Deep Vein Thrombosis) or PE (Pulmonary Embolism).



## PCT

MFDS 

Procalcitonin (PCT) is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.



Test item	Principle	AMR	Sample type	Sample volume	Time	Pretreatment	Package	Storage	Expiration date
FREND Cardiac Triple	Immunofluorescence	Troponin I: 0.05 ~ 20 ng/mL CK - MB: 1 ~ 80 ng/mL Myoglobin: 5 ~ 500 ng/mL	EDTA - Plasma	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	12 month
FREND BNP	Immunofluorescence	30 ~ 2500 pg/mL	EDTA - Plasma	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	12 month
FREND Troponin I	Immunofluorescence	0.05 ~ 20 ng/mL	EDTA - Plasma	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	12 month
FREND D-Dimer	Immunofluorescence	50 ~ 10,000 ng/mL FEU	Citrate - Plasma	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	12 month
FREND PCT	Immunofluorescence	0.07 ~ 32 ng/mL	Serum	35 µL	< 3 min	X	25 tests / Kit	2 ~ 8 °C	18 month

With just simple 3 steps operation  
**FREND™ System provides accurate results easily and quickly**

## Test procedure



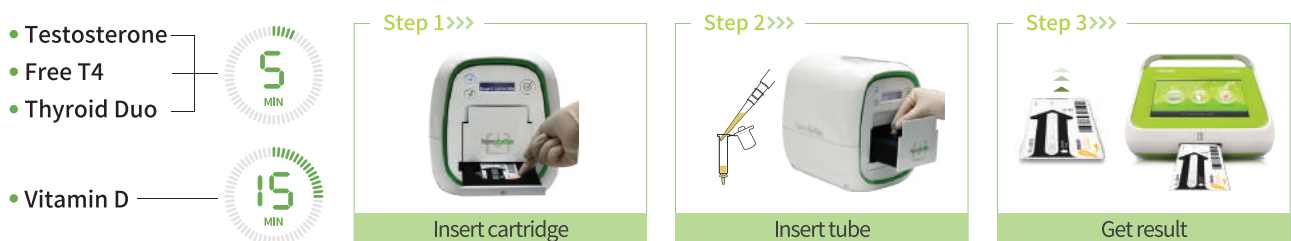
## Pretreatment procedure

The following 5 items require a pretreatment process.

**Heating Block** - Manual pretreatment device that can be used with all 5 test items.



**AP System** - Automated pretreatment device that automatically performs incubation to sample injection.



# FREND™ System

## provides a wide range of test items

## FREND™ System Application

Class	Test item	Cat. no	Sample type	Sample volume	AMR	Pretreatment	Certification
UROLOGY	PSA Plus	FRPS 025	Plasma or Serum	35 µL	0.05 ~ 25 ng/mL	-	CE, MFDS, FDA, NMPA
	Testosterone	FRTE 020 (HB) FRTEAP 020 (AP)		70 µL	0.2 ~ 15 ng/mL	O	CE, MFDS, FDA
VITAMIN	Vitamin D	FRVD 020 (HB) FRVDAP 020 (AP)		35 µL	10 ~ 110 ng/mL	O	CE, MFDS, FDA
RESPIRATORY	COVID-19 IgG/IgM Duo	FRCOD 020		35 µL	N/A	-	CE, MFDS
THYROID	Thyroid Duo (TSH/Free T4)	FRTD 020 (HB) FRTDAP 020 (AP)		70 µL	0.06 ~ 25 mIU/L (TSH) 0.4 ~ 6 ng/dL (Free T4)	O	CE, MFDS, PMDA
	TSH	FRTS 025		35 µL	0.06 ~ 25 mIU/L	-	CE, MFDS, FDA, PMDA
	Free T4	FRT4 020 (HB) FRT4AP 020 (AP)		70 µL	0.4 ~ 6 ng/dL	O	CE, MFDS, FDA
	Total T3	FRTT3 020		70 µL	0.25 ~ 8 ng/mL	O	CE, MFDS
EMERGENCY	Cardiac Triple (TnI, CK-MB, Myoglobin)	FRCT 025	EDTA - Plasma	35 µL	0.05 ~ 20 ng/mL (Troponin I) 1 ~ 80 ng/mL (CK-MB) 5 ~ 500 ng/mL (Myoglobin)	-	CE, MFDS
	Troponin I	FRTI 025		35 µL	0.05 ~ 20 ng/mL	-	CE, MFDS
	BNP	FRBN 025		35 µL	30 ~ 2500 pg/mL	-	CE, MFDS, NMPA
	D-Dimer	FRDD 025	Citrate - Plasma	35 µL	50 ~ 10,000 ng/mL FEU	-	CE, MFDS
	PCT	FRPC 025	Serum	35 µL	0.07 ~ 32 ng/mL	-	CE, MFDS

## FREND™ System Specification

Specification	FREND System		Heating Block	FREND AP
Electrical rating	Voltage	100 ~ 240 V~	100 ~ 240 V~	100 ~ 240 V~
	Current	1.7 A	1.5 A	1.7 A
	Frequency	50 / 60 Hz	50 / 60 Hz	50 / 60 Hz
Output	Voltage	DC 12 V	DC 12 V	DC 12 V
	Current	3.33 A	5.0 A	5.0 A
Dimensions		Width: 240 mm Length: 260 mm Height: 175 mm	Width: 190 mm Length: 200 mm Height: 50 mm	Width: 195 mm Length: 230 mm Height: 210 mm
Weight		3 Kg	1 Kg	4 Kg
Storage conditions		Temperature: 15 ~ 30 °C Humidity: 10 % ~ 80 %	Temperature: 5 ~ 30 °C Humidity: 20 % ~ 95 %	Temperature: 20 ~ 30 °C Humidity: 10 % ~ 80 %



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