GUIDE BOOK

FREND™ System

Rapid Quantitative Immunoassay Analyzer

Digitally signed by Olaru Victoria
Date: 2022.07.15 13:00:33 EEST
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Location: Moldova

REV. No. 11

Contents

FREND™
FDA 510(k) Letter of Clearance

510(k) Cleared Letter

Indications for Use

510(k) Number (if known): k124056

Device Name: FREND™ PSA Plus on the FREND™ system

Indications For Use:

The FREND™ PSA Plus as performed on the FREND™ system, is a quantitative in vitro diagnostic test which measures total Prostate Specific Antigen (PSA) in human serum and plasma. The NanoEnTek FREND™ PSA Plus is designed for *in vitro* DIAGNOSTIC USE ONLY for the quantitative measurement of total Prostate Specific Antigen (PSA) in human serum, heparinized plasma, and EDTA plasma using the FREND™ System. This device is indicated for the serial measurement of total PSA in serum, heparinized plasma and EDTA plasma to be used as an aid in the management of patients with prostate cancer.

The FREND™ PSA Plus is indicated for use in clinical laboratories upon prescription by the attending physician as an aid to clinicians in managing patients with prostate cancer.

The information provided from this test may supplement decision-making and should only be used in conjunction with routine monitoring by a physician and the use of other diagnostic procedures. Because of the variability in the effects of various medications used in the treatment of prostate cancer, clinicians should use professional judgment in the interpretation of PSA results as an indicator of disease status.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): k124056

510(k) Cleared Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2014

NANOEN TEK USA, INC.
C/O JUDITH LOEBEL
DOCRO
I JACKS HILL ROAD, SUITES A & B
OXFORD CT 06478

Re: K131928
Trade/Device Name: FREND™ TSH
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: II
Product Code: JLW
Dated: February 4, 2014
Received: February 7, 2014

Dear Ms. Loebel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

510(k) Cleared Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NANOENTEK USA INC
MAUREEN GARNER
PRESIDENT
1983 HAZELWOOD ROAD
TOMS RIVER NJ 08753

February 17, 2016

Re: K152422
Trade/Device Name: FREND™ Free T4 Test System
Regulation Number: 21 CFR 862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: II
Product Code: CEC
Dated: December 31, 2015
Received: January 04, 2016

Dear Maureen Garner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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FREND™ Introduction

I. What is FREND™ System?

II. Advantages of FREND™ System

III. FREND™ System Tests

IV. FREND™ Measurement Principle

V. FREND™ Quality Control

What is FREND™ System?

Rapid Quantitative Immunoassay Analyzer

The FREND™ System is a small, fast and near-patient in vitro diagnostic for a quantitative measurement of biomarkers in patient samples.

Feature

- ✓ **Fast**
- ✓ **Easy to use**
- ✓ **Accurate**
- ✓ **Compact**

→

- ✓ **Treatment improvement**
- ✓ **Patients' satisfaction increase**
- ✓ **Test effectiveness increase**
- ✓ **Lab/Hospital's profit increase**

*** FREND: Fluorescence Response Enhanced Novel Diagnostic**

Advantages of FREND™ System

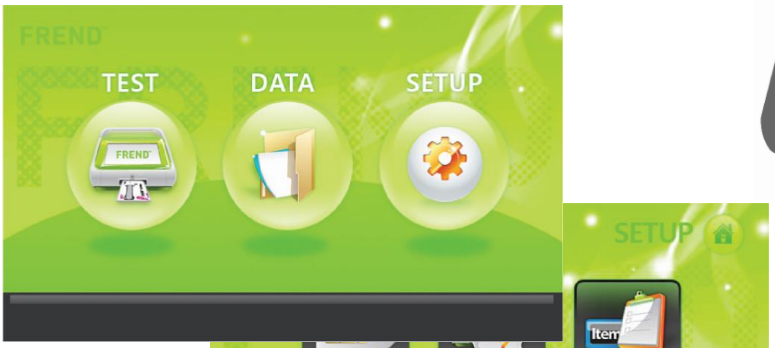
FAST

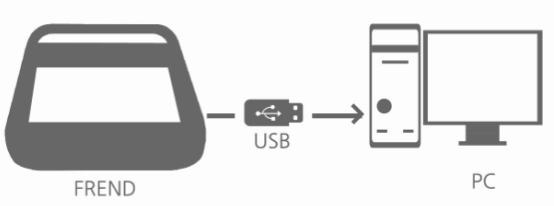
With the fast and easy procedure of testing, it is expected **to increase patients' satisfaction and a hospital's profitability** by improving effectiveness of testing.

- **3~10 min. Check Test Results**
  - **Available to get a test result while a patient stays in labs or hospital**
  - **Available for a patient to consult a doctor in same day a test is performed**
- **Simple 3 steps Test Procedure**
  - **Add sample -> Insert cartridge -> Get results**

Easy to use

Intuitive GUI of touch screen provides users with convenience of using the device, saved data is able to be transmitted to PC by using USB driver.

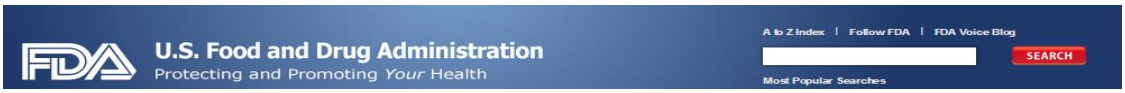




Advantages of FREND™ System

Accurate

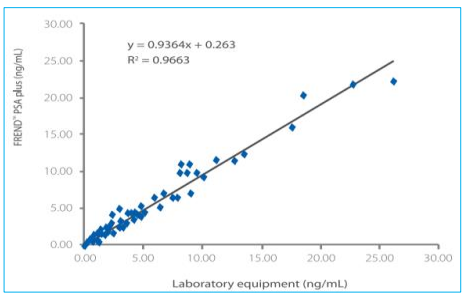
FDA 510(k) Clearance (PSA Plus, TSH, Free T4, Testosterone, Vitamin D)



New Search | Export to Excel | Download Files | More About 510(k)

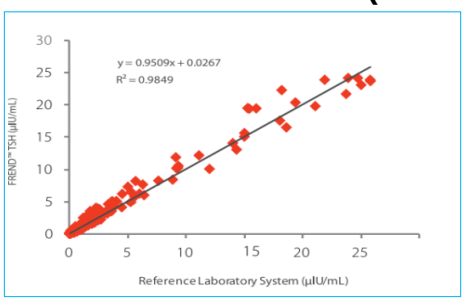
Device Name	Applicant	510(K) Number	Decision Date
Frend Tsh (Reagent Cartridge)	Nanoen Tek Usa, Inc.	K131928	03/14/2014
Frend Psa Plus (Reagent Cartridge)	Nanoen Tek, Inc.	K124056	05/29/2013

High and Remarkable Correlation with Central Lab Machine (PSA Plus, TSH)



[FREND PSA Plus]

• Correlation value of FREND PSA is more than **0.96** compared to TOSOH ST AIA-PACK PSA assay.



[FREND TSH]

• Correlation value of FREND TSH is more than **0.98** compared to TOSOH ST AIA-PACK TSH assay.

External controller

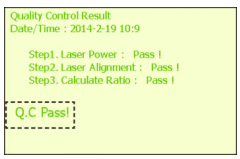
FREND™ provides not only for device quality control but also assay quality control. Check value assigned **external control** at Bio-Rad and CLINICA.

For System

Quality check by using QC code chip & QC cartridge

Check three(3) performances of FREND system for reliable operation

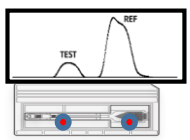
√ Step 1. Laser Power
√ Step 2. Laser Alignment
√ Step 3. Calculate Ratio



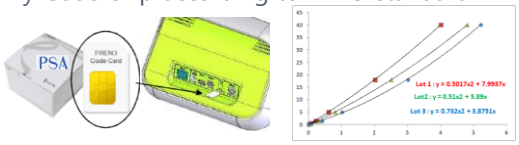
Daily Quality Check for FREND System takes just 1.5min!

For Assay(Cartridge)

1. Correct Test-to-Test Variation
- By test & reference ratio



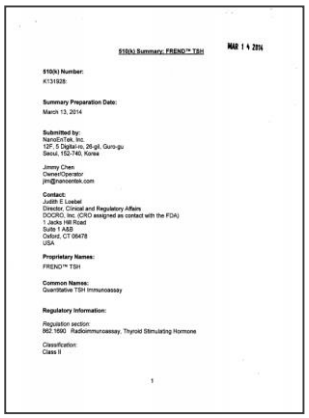
2. Correct Lot-to-Lot Variation
- By Code chip according to WHO standard



3. External Control
- FREND test assays are value assigned by **Bio-Rad**(www.qcnet.com) and **CLINICA**(www.cliniqa.com/Support/Documents.aspx)

Advantages of FREND™ System

Accurate



510(k) Summary: FREND™ TSH

510(k) Number: K131928

Summary Preparation Date: March 13, 2014

Submitted by: NanoEnTek, Inc. 12F, 5 Digital-ro, 26-gil, Guro-gu Seoul, 152-740, Korea

Jimmy Chen Owner/Operator jim@nanoentek.com

Contact: Judith E Loebel Director, Clinical and Regulatory Affairs DOCRO, Inc. (CRO assigned as contact with the FDA) 1 Jacks Hill Road Suite 1 ASB Oxford, CT 06478 USA

Proprietary Names: FREND™ TSH

Common Names: Quantitative TSH Immunoassay

Regulatory Information: Regulation section: 862.1690 Radioimmunoassay, Thyroid Stimulating Hormone

Classification: Class II

FDA 510(k) Clearance: FREND & Reagents

EC Certificate

Full Quality Assurance System

Manufacturer: NanoEnTek Inc.

EC-Representative: MT Promedit Consulting GmbH

Product Category(ies): Products for determination of tumor markers (PSA)

CE : FREND & Reagents

의료기기 제조 및 품질관리기준 적합인정서

(Certificate of GMP)

NanoEnTek, Inc

Certificate Of GMP

CERTIFICATE

No. Q1N 10 09 64394 029

Holder of Certificate: NanoEnTek Inc.

Facility(ies):

Certification Mark:

Scope of Certificate:

Applied Standard(s):

ISO13485 Certificate

Compact

Light (3kg) and compact size (240mm X 260mm X 175mm) make the device free from moving it and installing sites.

FREND™ System Tests

	Urology	Thyroid	Cardiac	Nutrient	Infection
Sandwich Assay	PSA	TSH	Cardiac Triple (Myoglobin / Troponin I / CKMB)		PCT
			BNP		
			Troponin I		
Competition Assay with Heating Block	Testosterone	Free T4		Vitamin D	
		Thyroid Duo (TSH/FT4)			
		Total T3			

FREND™ System Tests

Emergency	Cardiac Triple	BNP	Troponin I	PCT
AMR	Myoglobin : 5.00 ~ 500.00 ng/mL Troponin I : 0.05 ~ 20.00 ng/mL CK-MB : 1.00 ~ 80.00 ng/mL	30.0 ~ 2500.0 pg/mL	0.05 ~ 20 ng/ml	0.07 ~ 32 ng/mL
Sample Type	Plasma (EDTA)	Plasma (EDTA)	Plasma (EDTA)	Serum/Plasma (Citrate/Lithium heparin/EDTA)
Sample volume	35 µL	35 µL	35 µL	35 µL
Reaction Time	< 3 min.	< 3 min.	< 3 min.	< 3 min.
1 Box	25	25	25	25
Storage	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)

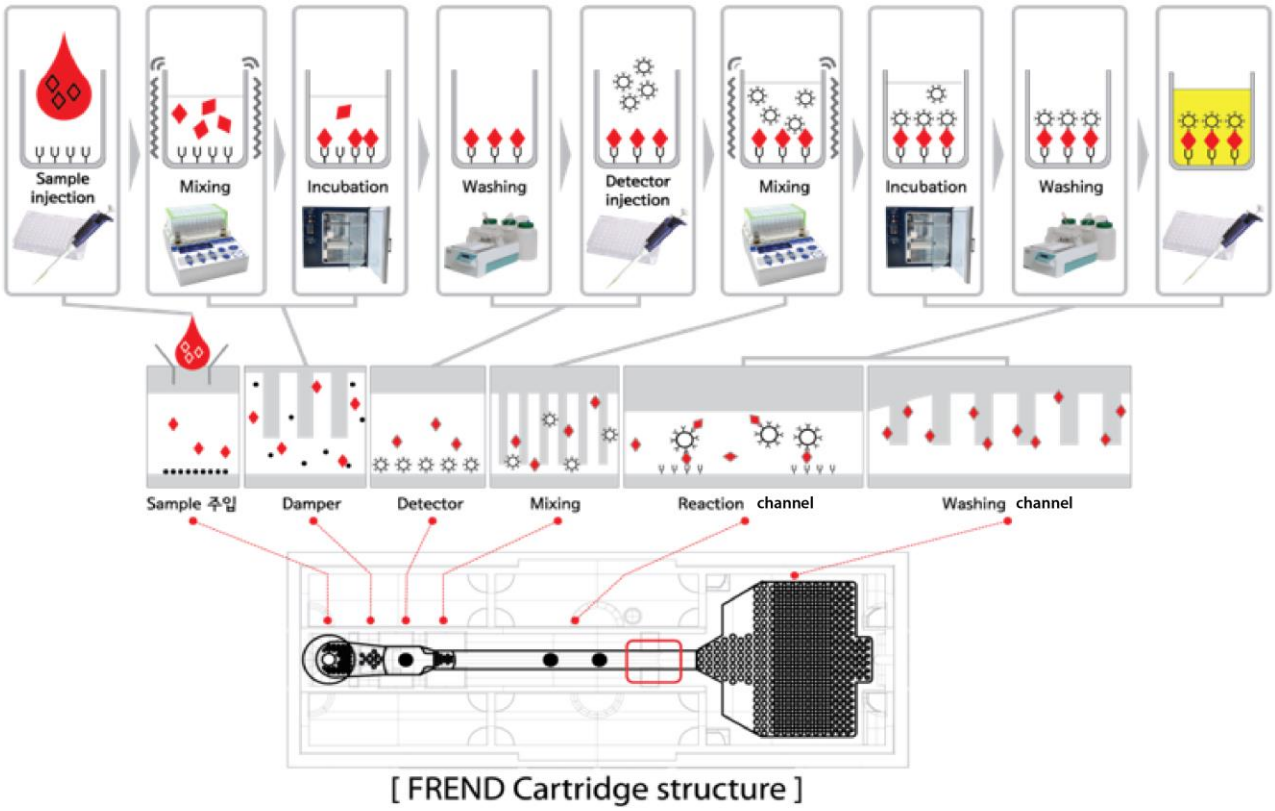
Thyroid	TSH	Free T4	Total T3	Thyroid Duo(TSH/FT4)
AMR	0.06 ~ 25mIU	0.40 ~ 6.00 ng/dL	0.25 ~ 8.00 ng/mL	TSH: 0.06 ~ 25mIU FT4: 0.40 ~ 6.00 ng/dL
Sample Type	Serum/Plasma (Lithium heparin)	Serum/Plasma (Lithium heparin)	Serum/Plasma (Lithium heparin)	Serum/Plasma (Lithium heparin)
Sample volume	Cartridge : 35 µL	Pretreatment Tube: 70µL Cartridge loading : 35µL	Pretreatment Tube : 70µL Cartridge : 35µL	Pretreatment Tube : 70µL Cartridge : 35µL
Reaction Time	< 3 min.	Incubation Time: 5 min. Cartridge reaction: < 3 min.	Incubation Time: 5 min. Cartridge reaction: < 3 min.	Incubation Time: 5 min. Cartridge reaction: < 3 min.
1 Box	25	20	20	20
Storage	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)

Urology	PSA Plus	Testosterone
AMR	0.05 ~ 25ng/ml	20 ~ 1500 ng/dL
Sample Type	Serum/Plasma (Lithium heparin/EDTA)	Serum/Plasma (Lithium heparin/EDTA)
Sample volume	35µL	Pretreatment Tube: 70µL Cartridge : 35µL
Reaction Time	< 3 min.	Incubation Time: 5 min. Cartridge reaction: < 3 min.
1 Box	25	20
Storage	2 ~ 8 ˚C (35 ~ 46 ˚F)	2 ~ 8 ˚C (35 ~ 46 ˚F)

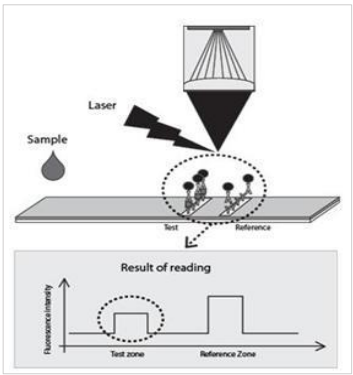
Vitamin	Vitamin D
AMR	10 ~ 110 ng/mL
Sample Type	Serum/Plasma (Lithium heparin)
Sample volume	Dilution Tube: 35 µL Pretreatment Tube: 70µL Cartridge loading : 35µL
Reaction Time	Incubation Time: 15min. (AP) Cartridge reaction: < 3 min.
1 Box	20
Storage	2 ~ 8 ˚C (35 ~ 46 ˚F)

FREND™ Principle of Measurement

Lap-on-a-Chip Technology



[FREND Cartridge structure]



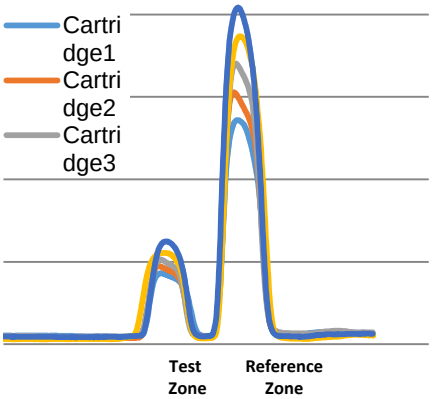
• One or multiple analytes are quantified by measuring laser-induced fluorescence on the Cartridge.

• The Concentration of the analyte in an unknown sample is calculated with the ratio of the fluorescent intensity of the Test zone and the Reference zone.

FREND™ QC Material

Quality Control – 1. Test to Test Variations

Example : Graph related to Fluorescence intensity on the detection area

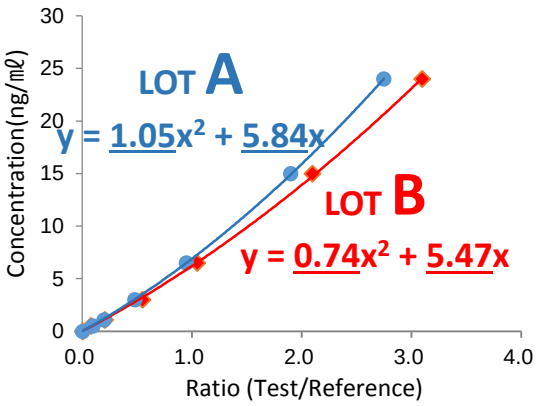


	Fluorescence Intensity		Ratio (Test/Reference)
	Test Zone	Reference Zone	
Cartridge 1	32557	112542	0.289
Cartridge 2	24603	84160	0.292
Cartridge 3	26133	93322	0.280
Cartridge 4	30427	104619	0.291
Cartridge 5	21302	74288	0.287
AVERAGE	27004	93786	0.288
S.D.	4516	15348	0.005
CV%	**16.7**	**16.4**	**1.7**

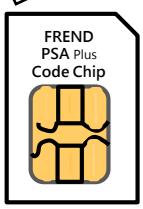
Ratio
Correct Test-to-Test variations

Quality Control – 2. Lot to Lot Variations

Example : Calibration Curve



The code chip which saved lot-dependent parameter of calibration curve is provided with each cartridge Box



Code chip
correct Lot-to-Lot variations

FREND™ Quality Control

Verification of Value Difference among Sites Tests Performed

Bio-Rad Liquicheck™ Immunoassay Plus Control

CLINIQA Liquid QC™ Tumor Marker Control

Users are able to verify the normality of FREND reagents by External Control.

Package Insert of External Control

BIO-RAD

Liquichek™ Immunoassay Plus Control
Levels 1, 2 and 3

	Level1	Level2	Level3	LOT	EXP
TSH (mIU/L)	0.77 (0.64~0.90)	7.26(6.03~8.37)	>25	40860	2016-08-31
	0.35(0.23~0.46)	4.67(4.08~5.25)	>25	40860	2016-08-31
PSA (ng/mL)	0.32(0.21~0.42)	4.21(3.69~4.71)	>25	40850	2016-03-31
	0.35(0.23~0.47)	5.26(4.26~6.48)	>25	40840	2015-11-30

Liquid QC™ Immunoassay Control Tri-Level

CE 0050 REF 94104 LOT 1210176 2015-10

	Level1 (LOT 1208182A)	Level2 (LOT 1208183A)	Level3 (LOT 1208184A)	EXP
TSH (mIU/L)	1.50(0.738~2.26)	16.2(13.0~19.5)	>25	2015-10-31
PSA (ng/mL)	1.61(1.29~2.41)	16.1(12.9~19.3)	>25	2015-10-31

QCNet™ www.qcnet.com

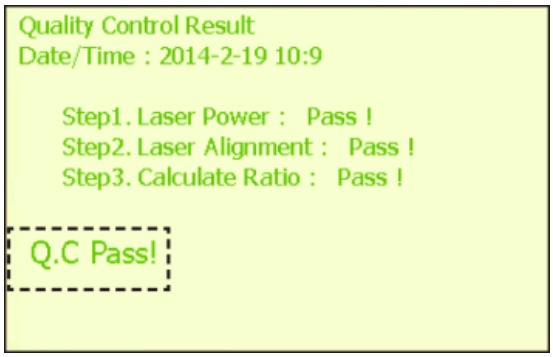
CLINIQA www.cliniqa.com

FREND™ Quality Control

FREND™ System Quality Control

When to be performed?

- ✓ When FREND System is initially installed.
- ✓ The day patients' specimens are tested.
- ✓ After relocating or re-installing FREND System.
- ✓ When FREND System has a certain error
- ✓ When users judge Quality Control is needed.



What is checked?

- ✓ Laser Power Check
- ✓ Optical Structure Check
- ✓ S/W Check

FREND™
Normal Reference Value

FREND™ Normal Reference Value

Item	Normal Reference Value
PSA	<4 ng/mL
Testosterone	2.219 to 9.925 ng/mL
TSH	0.35~4.94 mIU/L
FT4	0.71~2.16 ng/dL
TT3	0.6~1.6 ng/mL
Myoglobin	< 120 ng/ml
CK-MB(Mass)	6 ng/ml
Troponin I	0.4 ng/ml
BNP	< 100 pg/ml
PCT	*Lower respiratory disease : < 0.1 ng/mL : Normal 0.1 ≤ value < 0.25 ng/mL : Doubtful 0.25~0.5 ng/mL : Minor degree ≥ 0.5 ng/mL : Diseased *Bacterial infection < 0.5 : Normal 0.5 ≤ value < 2 ng/mL : Systemic sepsis 2 ≤ value < 10 ng/mL : Severe sepsis ≥ 10 ng/mL : Sepsis shock
Vitamin D	< 10 ng/mL : Deficient 10~30 ng/mL : Insufficient 31~100 ng/mL : Sufficient > 101 ng/mL : Toxic

**FREND System was developed with reference to a particular central lab machine.
The normal reference value provided above is based on the machine's reference value.

FREND™ Literature

DE GRUYTER DOI 10.1515/cclm-2013-0545 — Clin Chem Lab Med 2013; aop

Hae-il Park, Seungok Lee*, Yonggoo Kim, Dong-Yeok Shin, Changseop Lee, Sunmi Han, Chanil Chung, Jun Keun Chang and In Bum Seo

Analytical performance of a new one-step quantitative prostate-specific antigen assay, the FREND™ PSA Plus

Abstract

Background: We evaluated the analytical performance of a new one-step rapid quantitative sandwich immunoassay for total prostate-specific antigen (tPSA), the FREND™ PSA Plus (FREND PSA) (NanoEnTek Inc., Seoul, Korea).
Methods: The imprecision, linearity, hook effect, detection limit (LoD), and interference were evaluated and trueness verification and matrix validation were performed. For method comparison, 79 patient specimens were analyzed with FREND PSA and two comparative tPSA assays (Architect® total PSA and cobas® total PSA assay).
Results: Total CVs of the imprecision for low (0.208 ng/mL), medium (4.051 ng/mL), and high PSA levels (5.469 ng/mL) were 15.9%, 6.4%, and 9.1%, respectively. Linearity was observed from 1.01 to 19.15 ng/mL and the hook phenomenon was absent up to 171.48 ng/mL. The LoD was 0.094 ng/mL. The regression equations between FREND (y) and Architect or cobas were as follows: y=0.0133+1.054x (r=0.973), y=−0.2144+1.066x (r=0.977), respectively. Differences between FREND PSA and the comparative methods at a medical decision level of 4.0 ng/mL were less than the optimum specification bias (9.3%). The percentage biases from the trueness verification and interference test were less than the desirable specifications for bias (18.7%). The plasma tPSA level measured with lithium heparin or K2EDTA was comparable to that in the serum.
Conclusions: The FREND PSA provided reliable analytical performance and test results in comparison to two widely used tPSA assays. It is a simple and rapid test for tPSA and can be applied in point-of-care testing.

Keywords: FREND™ PSA Plus; rapid quantitative immunoassay; total prostate-specific antigen.

*Corresponding author: Seungok Lee, Department of Laboratory Medicine, Incheon St. Mary's Hospital, The Catholic University of Korea, 56 Dongsu-ro, Bupyeong-gu, Incheon, 403-720, Republic of Korea, Phone: +82 32 2805512, Fax: +82 32 2805520, E-mail: lsok@catholic.ac.kr

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Seungok Lee: Department of Laboratory Medicine, The Catholic University of Korea, Seoul, Republic of Korea
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Dong-Yeok Shin: Department of Laboratory Medicine, Incheon St. Mary's Hospital, The Catholic University of Korea, Incheon, Republic of Korea
Changseop Lee, Sunmi Han, Chanil Chung and Jun Keun Chang: Immunoassay Team, R&D Division, NanoEnTek, Inc., Seoul, Republic of Korea
In Bum Seo: Department of Laboratory Medicine, Kangwon National University Hospital, Choonchun, Republic of Korea

Introduction

Total prostate-specific antigen (tPSA) is the most useful tumor marker for early detection, staging, prognosis prediction, and monitoring of prostate cancer [1, 2]. Although tPSA levels increase in patients with benign prostatic diseases such as prostatic hyperplasia and prostatitis as well as in those with prostate cancer and can be influenced by age and race [2], tPSA measurements and digital rectal examination are widely used to detect prostate cancer in men above 50 years of age [3]. tPSA ≥ 4 μg/L is generally accepted as the cut-off value for prostatic biopsy, although this threshold remains the subject of debate [1, 2, 4]. There are two forms of PSA in the circulating blood: free PSA (fPSA) and complexed PSA (cPSA) containing α1-antichymotrypsin (ACT), which is the major form of macroglobulin [2, 5]. tPSA is the sum of fPSA and cPSA, and can be measured by immunoassay [2, 5]. Two WHO reference materials for PSA, 96/670 (90:10) and 96/668, were introduced in 2000

FREND™ PAPER

Performance Evaluation of a New One-Step Quantitative Prostate-Specific Antigen assay, the FREND™ PSA Plus

Hae-il Park[1], Seungok Lee[1,2], Dong Wook Jekarl[1,2], Yonggoo Kim[1], Changseop Lee[3], Sunmi Han[3], Chanil Chung[3], Jun Keun Chang[3]

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Introduction

- Total prostate-specific antigen (tPSA) is the most widely used serum biomarker for early detection and monitoring of prostate cancer.
- The aim of this study was to evaluate a new one-step quantitative total prostate- specific antigen (tPSA) assay, the FREND™ PSA Plus (NanoEnTek Inc, Seoul, Korea) that has been developed for point-of-care testing.
- The principle of FREND™ PSA Plus is a rapid sandwich immunoassay for determining PSA concentration on a test cartridge by measuring laser-induced fluorescence in FREND™ system (Figure 1).

Meterials and methods

- The imprecision, linearity, hook effect, detection limit, and method comparison of the FREND™ PSA Plus (FREND PSA) were evaluated according to Clinical and Laboratory Standard Institute (CLSI) guidelines, EP-05-A2, EP-06-A and EP-17-A2.
- For the method comparison, Aliquots of 79 clinical serum samples over the AMR claimed by manufacturer's instruction (0.1-25.0 ng/mL) were measured in duplicate during 5 days with FREND PSA and two comparative PSA assays as follows: Architect® Total PSA assay (Architect PSA) using Architect i2000 SR (Abbott Diagnostics); cobas® total PSA assay (cobas PSA) using cobas e 601 analyzer (Roche Diagnostics).
- The results was analyzed by using StatisPro™ version 2.00.00 (Analyses-it® Software Ltd. and CLSI®, USA).

Results

- Total CVs of the imprecision for low (0.208 ng/mL), medium (4.051 ng/mL), and high PSA levels (15.469 ng/mL) were 15.9%, 6.4%, and 9.1%, respectively.
- The linearity was observed from 1.01 to 19.15 ng/mL.
- The limit of detection was 0.094 ng/mL.
- Hook phenomenon did not appear up to 171.48 ng/mL.
- In the comparison study, the regression equations of the FREND PSA (y) with Architect PSA, and cobas PSA were obtained as follows: y = 1.054x + 0.0133 (r=0.973), y =1.066x -0.2144 (r=0.977), respectively (Table 1 and Figure 2).

Differences between FREND PSA and both of two comparative assays at a medical decision level of 4.0 ng/mL were less than optimum specification bias (9.3%).

(a) (b)

Figure 1. Principle of the FREND™ PSA Plus

(a) The FREND™ PSA Plus consists of a single-use disposable, FREND™ test cartridge and a portable, automated FREND™ system. (b) The concentration of analyte in an unknown sample is calculated by comparing test/control line ratio with a calibration curve obtained from different concentration of analyte (ng/mL).

Table 1. Methods comparison

Comparative method	Architect	Cobas
Measuring interval	0.01 ~ 100	0.005 ~ 100
n	79	79
r	0.973	0.977
Constant intercept (95% CI)	0.0133 (-0.1777, 0.2043)	-0.2144 (-0.3102, -0.1186)
Proportional slope (95% CI)	1.054 (0.998, 1.110)	1.066 (1.018, 1.114)
$S_{y/x}$	0.253	0.192
Difference (95% CI)		
at 4 ng/mL	0.109 (-0.077, 0.295)	0.048 (-0.087, 0.183)
at 10 ng/mL	0.409 (-0.065, 0.883)	0.347 (-0.047, 0.741)

(a) (b)

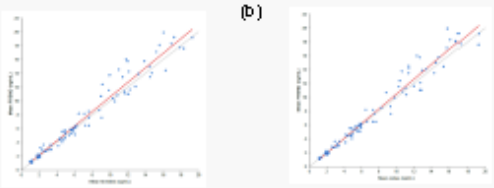

Figure 2. Scatterplot of PSA (a) between FREND (y) and Architect (x) and (b) between FREND (y) and cobas (x). Gray line represents the line of identity and red line does linear regression equation. Each blue cross symbol represents the average of duplicate measurements.

Conclusion

- The FREND PSA showed a reliable performance and results overall comparable to those of two widely accepted PSA assays.
- In practice, the FREND PSA was easy to perform and the software of FREND™ system showed user-friendly. It had attractive benefits such as small sample volume (30μL), rapid analytic time (6min) and portable. It seems to be useful for one-stop monitoring post-treatment status of prostatic cancer patients and point-of-care testing.

Reference

1. Comparison of 6 automated assays for total and free prostate-specific antigen with special reference to their reactivity toward the WHO 96/670 reference preparation. Clin Chem 2006;52:1968-74.
2. Westgard QC. http://westgard.com/biodatabase1.htm. Accessed: 25, April, 2013.

Clin. Lab. 2016;62:XXX-XXX

SHORT COMMUNICATION

Performance Evaluation of the FREND™ Cardiac Triple Cartridge on the FREND™ System

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SUMMARY

Background: **We evaluated the performance of the FREND™ Cardiac Triple cartridge on the FREND™ system in the detection of cardiac markers-myoglobin, cardiac troponin I (cTnI), and creatine kinase-MB (CK-MB).**
Methods: **Quantitative immunoassays were performed using the FREND™ system (NanoEnTek, Seoul, Korea) and its cartridge. The precision, detection limits, linearity, and correlation with the Siemens Dimension Vista® 500 (Siemens Healthcare Diagnostics, Deerfield, IL, USA) were evaluated. The cutoff value for each marker was calculated in healthy individuals (men and women, n = 138 each).**
Results: **The coefficients of variation for imprecision were less than 19.0% at low and high serum concentrations. The lower limits of quantification for myoglobin, cTnI, and CK-MB were 3.11, 0.073, and 0.70 ng/mL, respectively. Acceptable linearity was achieved for each marker (R^2 < 0.99). The results from the FREND™ system were in good agreement with those from the Siemens Dimension Vista (correlation coefficients > 0.9). The cutoff values in male and female individuals (n = 138 each) were 104.3 and 98.9 ng/mL, respectively, for myoglobin, and 4.35 and 5.37 ng/mL, respectively, for CK-MB. The cutoff value for cTnI was 0.073 ng/mL.**
Conclusions: **The FREND™ Cardiac Triple cartridge exhibited good precision, clinically acceptable linearity, and reliable correlation with the Dimension Vista.**
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Short Communication accepted September 15, 2015

KEY WORDS

analytical performance, cardiac biomarker, cardiac troponin, creatine kinase-MB, myoglobin

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of adult mortality globally; an estimated 17.5 million people died from CVD in 2012, representing 31% of all global deaths. Of these deaths, an estimated 7.4 million were caused by coronary heart disease and 6.7 million were caused by stroke [1].
Appropriate medical intervention in the acute setting is closely related with prognosis, and cardiac biomarkers likely play important roles in patients with atypical

FREND™ PAPER

GP-206 *Thyroid – Translational &Clinical*

FREND™ Thyroid Duo: a new way of Helping patients with subclinical thyroid dysfunction

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OBJECTIVES

To evaluate the analytical performance a FREND™ Thyroid Duo immunoassay on FREND™ system

METHODS

The analytical performance studies (sensitivity, precision, linearity, interference and accuracy) were performed according to the CLSI protocols (EP17, EP05, EP06, EP07 and EP09). For the method comparison, serum TSH and free T4 were assayed by FREND™ and Architect i1000 (Abbott Diagnostics, Abbott Park, IL).

RESULTS

The FREND™ Thyroid Duo demonstrated acceptable imprecision of %CV (<10%) in low, intermediate, and high level samples for both analytes. The linearity of the assay was found to be acceptable in the range of 0.06~25 mIU/L for TSH and 0.4~6 ng/dL for FT4. Method comparisons between Abbott Architect's assays and NanoEnTek's FREND Thyroid Duo assay were made and no significant deviation from linearity was found. No significant interference was observed for both analytes from bilirubin, Intra-lipid and total protein up to concentrations of 20 mg/dL, 3 g/dL, and 12 g/dL respectively.

PRECISION

TSH	Mean (mIU/L)	Repeatability SD	Repeatability CV(%)	Between-run SD	Between-run CV(%)	Between-day SD	Between-day CV(%)	Within-laboratory SD	Within-laboratory CV(%)
Low	0.49	0.038	7.6	0.020	4.0	0.012	2.4	0.045	8.9
Med	5.07	0.247	5.0	0.031	0.6	0.038	0.8	0.252	5.1
High	28.11	1.144	3.7	0.313	2.0	0.121	0.6	1.259	6.5

Free T4	Mean (ng/dL)	Repeatability SD	Repeatability CV(%)	Between-run SD	Between-run CV(%)	Between-day SD	Between-day CV(%)	Within-laboratory SD	Within-laboratory CV(%)
Low	0.77	0.047	6.0	0.029	3.6	0.010	1.3	0.056	7.1
Med	1.84	0.079	4.4	0.068	0.4	0.048	2.7	0.093	5.2
High	4.05	0.188	4.7	0.056	1.4	0.057	1.4	0.205	5.1

INTERFERENCE

	% Recovery							
	Hemoglobin		Bilirubin		Triglycerides		Total Protein	
	TSH	Free T4	TSH	Free T4	TSH	Free T4	TSH	Free T4
Low	96.2	101.2	99.4	102.9	98.7	103.0	101.9	100.0
Med	102.4	97.0	103.8	95.3	104.6	97.4	100.4	95.4
High	99.9	100.2	106.1	98.9	95.6	98.2	99.1	104.5

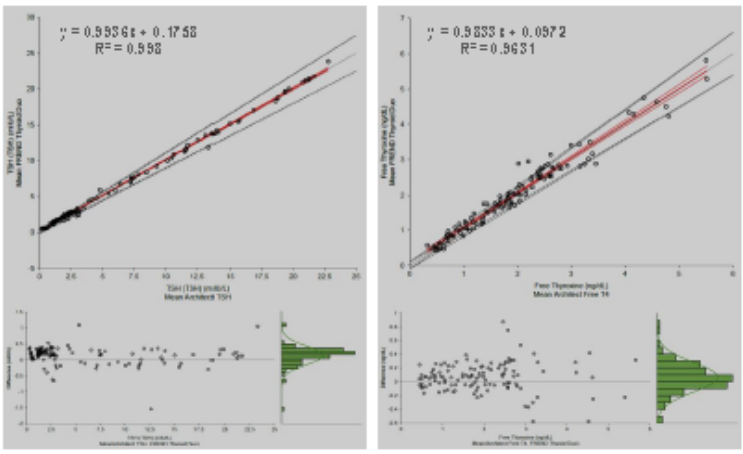
CROSS-REACTIVITY

Cross-Reactants	Final conc.	TSH (% Recovery) Low	TSH (% Recovery) Med	TSH (% Recovery) High	Free T4 (% Recovery) Low	Free T4 (% Recovery) Med	Free T4 (% Recovery) High
1. Follicle-stimulating hormone (FSH)	500 mIU/mL	97.9	97.7	100.7	96.8	101.9	102.1
2. Luteinizing hormone (LH)	500 mIU/mL	96.2	102.2	99.9	95.2	101.1	97.1
3. Human chorionic gonadotropin (HCG)	200,000 mIU/mL	102.8	99.6	100.1	101.7	104.1	100.3
4. Diiodotyrosine, T2 (3IX)	5 μg/dL	99.3	101.9	105.6	96.9	100.7	99.6
5. Tetraiodothyroacetic Acid (3CH)	10 μg/dL	102.6	100.6	102.6	94.6	94.7	98.3
6. Triiodothyroacetic Acid (2XH)	1 μg/dL	98.7	100.7	102.6	101.4	97.9	99.2
7. Triiodothyropropionic Acid (3CH)	5 μg/dL	101.3	98.7	103.8	102.7	98.1	102.5
8. Diiodotyrosine, DIT (3CH)	1,000 μg/dL	101.3	101.1	97.6	100.4	94.6	100.5
9. L-Triiodothyronine, T3 (2XH)	5 μg/dL	98.7	104.1	98.0	98.8	95.4	97.6
10. Monoiodotyrosine (3CH)	1,000 μg/dL	105.2	101.8	98.7	96.8	103.6	104.4
11. Reverse T3 (3CH)	10 μg/dL	97.6	100.4	100.1	99.3	103.8	105.6

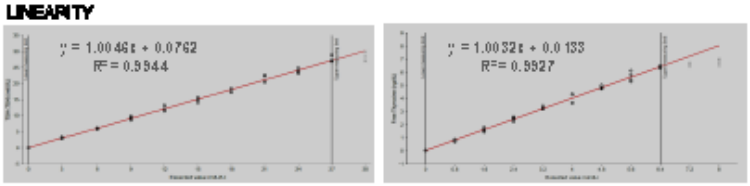
DETECTION LIMIT

	LoB (Limit of Blank)	LoD (Limit of Detection)	LoQ (Limit of Quantitation)
TSH (mIU/L)	0.03	0.04	0.06
Free T4 (ng/dL)	0.24	0.31	0.40

METHOD COMPARISON



LINEARITY



CONCLUSIONS

Conclusion: The NanoEnTek's FREND™ Thyroid Duo assay represents a rapid, accurate and convenient mean of measuring TSH and FT4 quantities in human serum on FREND™ system. The subclinical thyroid dysfunction may be screened or monitored in a clinic or physician's office using this microfluidic 2-in-1 thyroid assay with ease and comfort.

References

1. Gharib et al., *J. Clin. Endocrinol Metab.* (2005) 90:581-585
2. Astles et al., CLSI guideline EP19, *2nd ed.* June 2015.

FREND™ PAPER

Analytical evaluation of a procalcitonin assay on the new point-of-care platform FREND™ and managed by EzerCloud™, cloud quality control service

Jeong Su Park[1], Sunmi Han[2], Chanil Chung[2], Sangjo Han[3], Sung Gon Yi[3], Kyoung Un Park[1], Junghan Song[1], Kyoung Chan Park[4]

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[4]Medical Sciences Research Institute, Seoul National University Bundang Hospital, Seongnam-si, Korea

Introduction

- A point-of-care (POC) testing immunoassay (FREND system, NanoEnTek, Seoul, Republic of Korea) has recently become available for the quantitative and rapid measurement of procalcitonin (PCT). This system recently introduced cloud based quality control system (EzerCloud QC service, SK Telecom, Seoul, Republic of Korea). In this study, we examined the analytical performance and the correlation with automated chemistry analyzer in central lab.

Materials and Methods

- Samples: Randomly selected serum specimen (n = 40)
- FREND™ PCT

- Limit of Detection : CLSI EP17-A
- Interference : CLSI EP7-A2
- Cross Reaction : CLSI EP7-A2
- Precision : CLSI EP5-A2
- Correlation
  - Central Laboratory Method
    - ✓ Analyzer : Cobas e170 (Roche)
    - ✓ Reagent : ELECSYS® B·R·A·H·M·S PCT
  - VIDAS PCT (bioMérieux)
- Remote Cloud Based Quality Control : EzerCloud QC service

Results

- Limit of Detection

LoB (Limit of Blank)	LoD (Limit of Detection)	LoQ (Limit of Quantitation)
0.05 ng/mL	0.07 ng/mL	0.07 ng/mL

- Interference

Material	Conc.	Recovery rate (%)		
		0.50 ng/mL	2.00 ng/mL	15.00 ng/mL
Hemoglobin	500 mg/dL	101.7	101.9	100.8
Bilirubin	40 mg/dL	103.4	98.5	100.4
Triglycerides	2218 mg/mL	103.4	107.1	101

Drugs	Conc.	Recovery rate (%)		
		0.50 (ng/mL)	2.00 (ng/mL)	15.00 (ng/mL)
Infliximab	0.5 mg/mL	97.4	97.1	98.2
Ceftriaxone	150 mg/dL	105.5	100.2	105
Vancomycin	5 mg/mL	106.4	102	104
Dopamine	25 mg/dL	100.7	97.2	102.2
Roncuronium	4 μg/mL	100.7	102.7	100
Dobutamine	25.4 μg/mL	95.5	103.2	104.2
Heparin	15,000 U/L	100.2	100.7	102.2
Furosemide	4 mg/dL	96.7	102.2	97.1

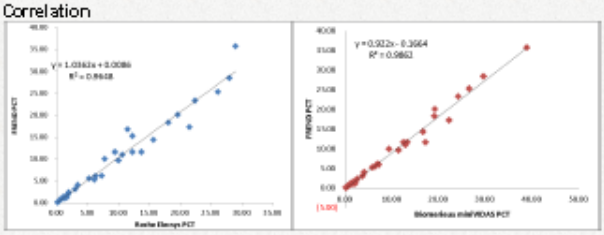
- Cross Reaction

Reactor	Conc.	Recovery rate (%)		
		0.50 (ng/mL)	2.00 (ng/mL)	15.00 (ng/mL)
Albumin	4 g/dL	96	99.7	105.4
Human calcitonin	60 ng/mL	106.2	101	102
Human katacalcin	10 ng/mL	100.7	100.6	106.2
Human α-CGRP	10 μg/mL	105.5	95.5	97.2
Human β-CGRP	10 μg/mL	102.1	103	104.2

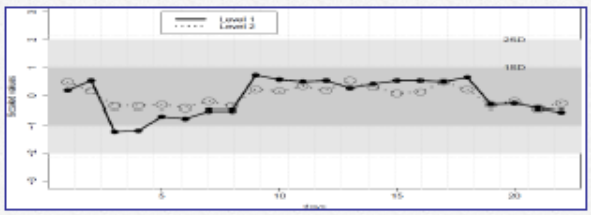
- Precision

Reference material	Mean (ng/mL)	Within-run		Between-run		Between-day		Within-laboratory	
		S.D.	CV (%)	S.D.	CV (%)	S.D.	CV (%)	S.D.	CV (%)
B	0.1	0.01	9.7	0.002	2.2	0.004	3.9	0.011	10.6
C	0.503	0.027	5.5	0.005	0.9	0.012	2.2	0.03	6
D	2.025	0.113	5.6	0.025	1.4	0.009	0.4	0.117	5.8
E	15.06	0.752	5.2	0.054	0.6	0.273	2.5	0.273	5.8
F	35.002	1.255	5.2	0.065	0.2	0.255	1.1	1.257	5.4

- Correlation



- Remote QC service



Conclusion

- The developed PCT test fulfils the basic requirements for the performance parameters defined above. The test's sensitivity was in the performance range of laboratory analyzer PCT tests. Cloud based QC system worked properly. This is the first extensive proof of concept of the FREND PCT system.

FREND™

Heating Block / AP

& Software Update Guide

FREND™ Heating Block
Instructions for Use

FREND™ Heating Block
Operation Procedure

1 Press "**POWER**" button to turn on the heating block.

Select test item in "**HEATING TASK**", and press the button.

"**Preparing**" is displayed on the screen during warming up. After completing warming up "**Ready**"is displayed on the screen. The Heating Block is ready to be used.

2 **Prepare the pretreatment tube** after the Heating Block is ready.

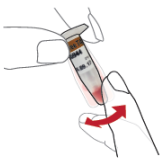
Testosterone
Free T4
Total T3
Thyroid Duo

Transfer 70µL (Two 35µL) of specimen to Pretreatment tube. Lay it on its side for 30 seconds.

Vitamin D

Transfer 35µL of specimen to the dilution tube and mix vigorously by vortexing or inverting.
Transfer 70µL (Two 35µL) of diluted sample to the pretreatment tube. Lay it on its side for 30 seconds.

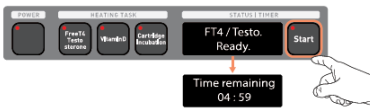
3 **Firmly Thump/Flick the pretreatment tube** to ensure mixing using the index finger or thumb. Move downward with a snap so the sample will collect at the bottom of the tube.



⚠ **CAUTION**
Pellet in the tube bottom should be completely dissolved.
Do not upside down the tube at a time of tapping.

4 **Place cartridge** on the Heating Block, and **insert pretreatment tube** into the hole in the Heating Block.

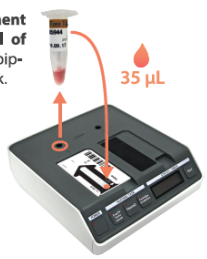
5 Press "**Start**" button to initiate the pretreatment tube incubation.



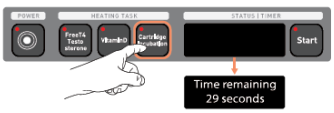
Remaining time is displayed on the screen. When the incubation is completed, "Tube heating finished" will be shown on the screen.

※ **NOTE**
Free T4, Testosterone: 5 min. / Vitamin D: 30 min.

6 **Take out the pretreatment tube,** and transfer **35µl of mixture** to cartridge by pipette on the Heating Block.



7 Press "**Incubation button**" for another 30 seconds. After incubation, **take out cartridge from the Heating Block.**



⚠ **CAUTION**
You may take out the cartridge from the Heating Block and place it on the desk when the cartridge incubation (30sec.) is done. The result may be influenced otherwise.

8 Insert the cartridge into FREND™ System for analysis.

FREND™ AP
Operation procedure

1 Turn on the FREND™ AP.

2 Press the "**Item type**" button and wait to warm up.

Type I
Vitamin D

Type II
Testosterone
Free T4

3 When FREND™ AP is ready to use, Press "**NEXT**" ⊕ button and place a cartridge.

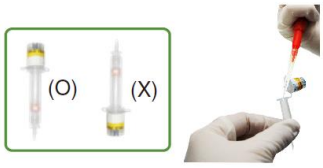
4 Press "**NEXT**" ⊕ button again. Cartridge tray is in-position and pretreatment tube tray automatically comes out.

5 **Step 5 is for Vitamin D test only. If you select the Testosterone or Free T4, please skip step 5.**

Drop 35µL specimen in the Dilution tube. Mix the specimen and buffer in the tube by vortexing or inverting.

6 Transfer 70µL [mixture (Type I) / specimen (Type II)] to the pretreatment tube.

⚠ ***Caution***
Once sample is added in the pretreatment tube, Do not invert the tube.



7 Insert the pretreatment tube in the tube hole.

8 Press "**NEXT**" ⊕ button to get the pretreatment tube tray in-position. Incubation will be started and time remaining is displayed on the screen.

9 When all the incubation steps are done, press "**NEXT**" ⊕ button to take out the FREND™ Cartridge. Then insert the cartridge into FREND™ System.

Instruction for Software Update

Please check FREND firmware version first

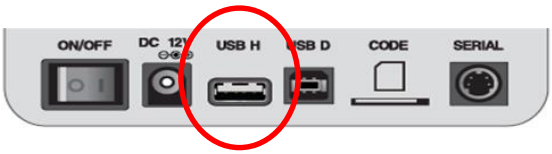
1. Click ‘SETUP’ and then ‘System view’ button to check firmware version.
2. Only 1.1.2.3 firmware version can be used.

* If FREND F/W is not 1.1.2.3, please contact to sales team (sales@nanoentek.com).

Software Update Guide

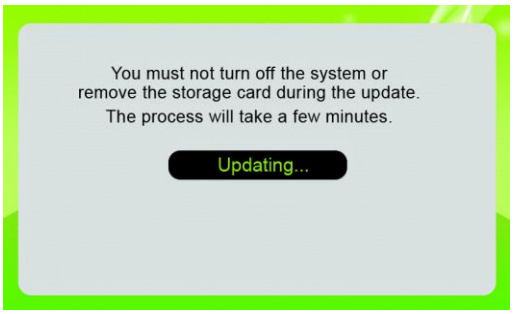
* If FREND S/W is lower than 1.1.0.6, please back up the data first.

1. Connect USB flash drive to the USB H port on the back of the FREND.



2. Click ‘SETUP’ and then ‘S/W Update’ button.

3. It start software update automatically



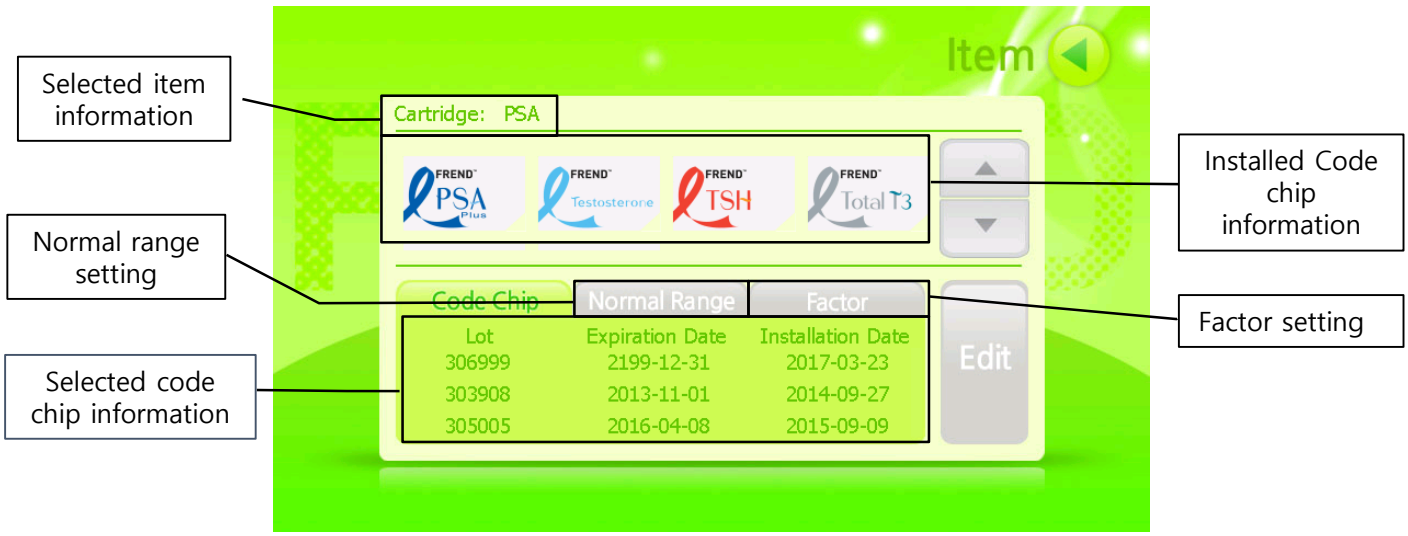
4. Reboot FREND by turning off after the update is done.

※ Latest software version: 1.3.7

Software Added Functions

Ver.1.3.1

Display Plan

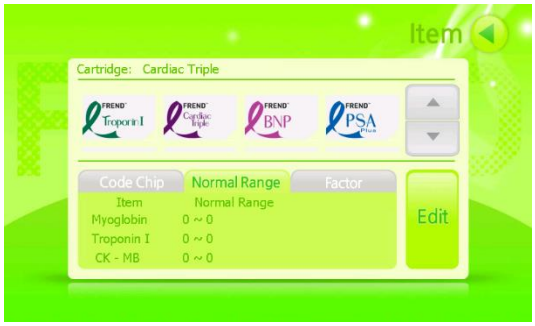


Software Added Functions

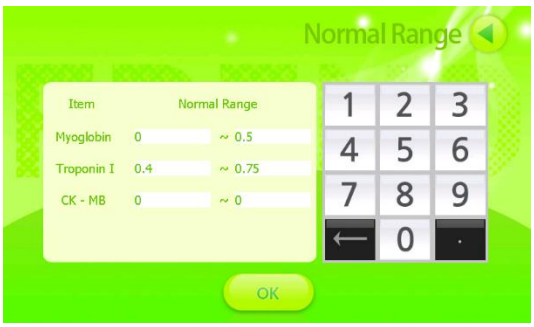
Ver.1.3.1

1. Instruction of Setting ‘Normal Range’

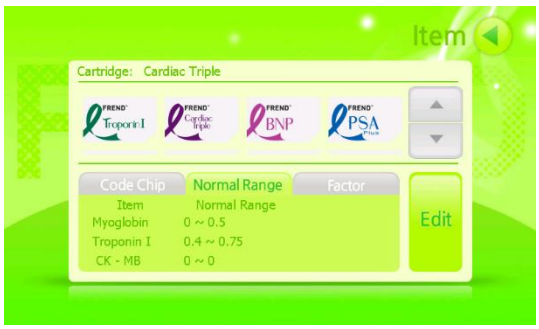
Go to ‘Data’ page and click ‘Result’ button to check the detailed test result.



Go to ‘Item’ page and click ‘Normal Range’ button.



Input the range.



Verify if set range is applied.

Go to ‘Item’ page again to final confirmation

Software Added Functions

Ver.1.3.1

2. Instruction of Setting ‘Factor Value’

Go to ‘Item’ page and
click ‘Factor’ button.

For a trial, modify the basic factor
value ‘1’ into ‘0.5’.

Verify if Factor value is modified into 0.5

※ Caution

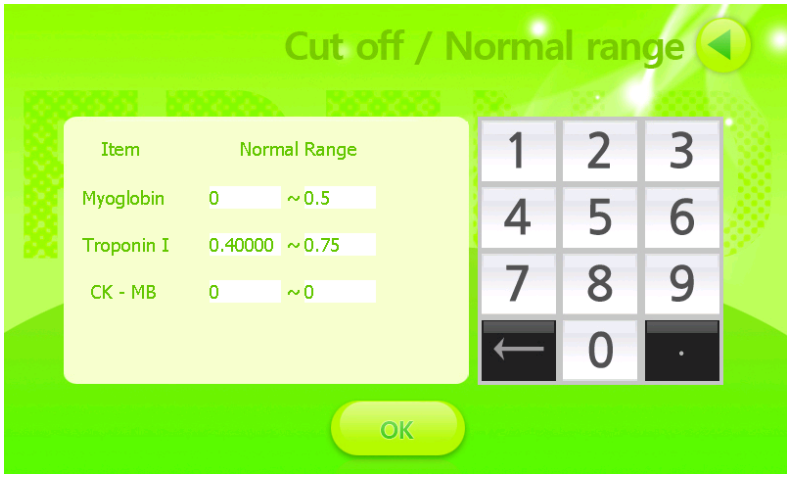
- Factor value doesn’t apply to the results that have already saved.
  Please modify Factor value before test.

Software Added Functions

Ver.1.3.1

1. Normal Range Setting

Select ‘Normal Range’ button in ‘Item’ page



Ex) Cardiac Triple

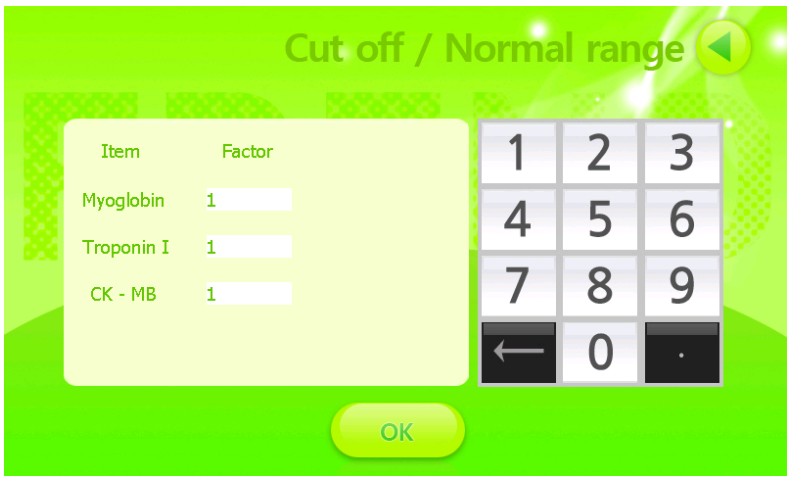
1. If ‘Normal Range’ setting is not necessary,
- **Input ‘0 ~ 0’.**

2. If ‘Cut off’ setting is necessary,
- **Input ‘0 ~ Cut off value’.**

3. If ‘Normal Range’ setting is necessary,
- **Min. Value ~ Max. Value**

2. Factor Value Setting

Select ‘Factor’ button in ‘Item’ page



Ex) Cardiac Triple

Factor Value
: Displayed Result
= Original Result value x Factor value
*** Basic factor value = 1**

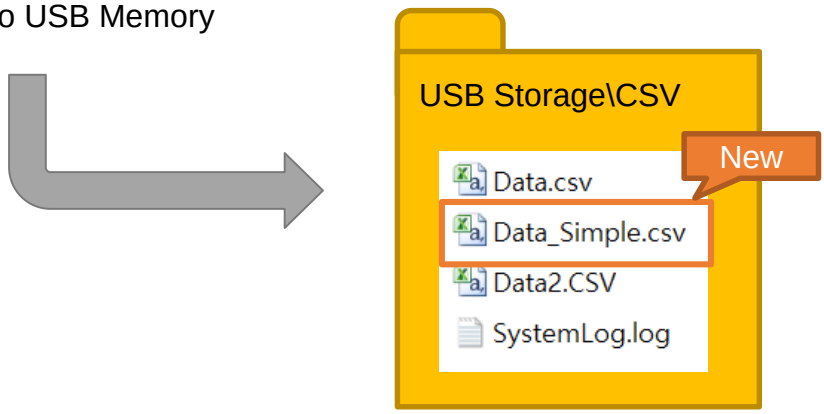
Software Added Functions

Ver.1.3.1

Simpler Format of Saved Data

- Previous format of saved data was comparatively complicated for users to check.
- Features of Simpler Format of Saved Data
  - Same format as the data displayed in ‘Data’ page.
  - Unnecessary information deleted.
  - Measurement unit added
- Instruction of saving data

Backup to USB Memory



Operation Manual of

FREND mini-pipette

Pipette

General Description

These fixed volume micropipettes are Medical devices used for dispensing fixed quantity of fluids of liquids.

FREND pipette setting

General Setting and Operation

- ✓ Fix a compatible tip on the 'tip cone'.
- ✓ The pipette is now ready for pipetting.
- ✓ It is highly recommended to understand and practice the 'plunger' operation which has two stages.
- ✓ The first stage is to fill-in and dispense the solution whereas the second stage is used only to dispense the last drop out of the tip.
- ✓ For the first stage operation, depress the 'plunger' gently until it stops by itself (never depress the 'plunger' with jerk). Give a pause at this stage and then depress the ‘plunger' further down applying little force to achieve the second stage.

Ready Position

First Stage

Second Stage

Reverse Technique

1. Depress the 'plunger' all the way to the second stage, dip the tip in the solution.
2. Release the 'plunger' slowly to fill the tip.
3. Depress the 'plunger' to the first stage. Required amount of liquid is dispensed.
4. Discard the liquid remaining in the tip or pipette it back in the original container.

Second Stage

Ready Position

First Stage

Ready Position

*** If you want to reduce the occurrence of air bubbles, please use the ‘Reverse Technique’ It is not essential.**

FREND™
Trouble Shooting Guide

FREND procedure to use

Lab. Protocol: 10 min. 3000~4000rpm

FREND: 2~3 min. > 4000rpm

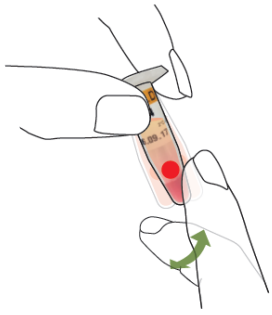
In case EMTF 02, 04

- How to use Block Reagent buffer

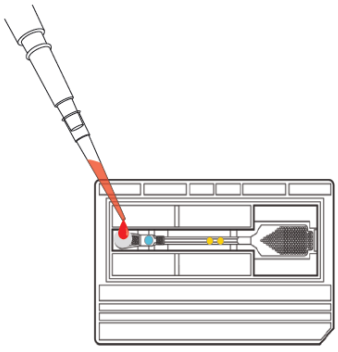
PSA Plus/TSH/Cardiac Triple/Troponin I/BNP/PCT

01 Using a sterile tip, add **70µℓ (two drops of 35µℓ sample)** of a patient sample in the tube. Leave the tube for 30 seconds.

02 Use a finger to gently tap the tube to mix the sample (approx. 15 times).



03 Load **35µℓ** of the sample mixture (one drop of **35µℓ** sample) on the FREND cartridge.



Caution: Pay attention to avoid the formation of bubbles when using a pipette.

04 Insert the FREND cartridge into FREND System.

Why EMTF 02, 04 Might Happen?

1. The sample from a patient who get a treatment with monoclonal mouse antibodies may contain human anti-mouse antibodies(HAMA). In this case, there may be a possibility that test result may be abnormal or no results come out.

2. Heteroantibody in human serum may interfere with IVD immunoassay and may interact with immunoglobulins reagent. In case the patient sample has heteroantibody, test result many be abnormal. Additional information may require.

3. FREND system is designed to get less effect from HAMA and heteroantibody. But if there is a big difference in test result between FREND system and laboratory equipment, additional tests to verify is recommended.

4. Every immunoassay equipment available in the market has same issue and FREND system has the same.

EMTF 02, 04

- In case Block Reagent buffer has no effect

1

Click ‘TEST’ button

2

Type ‘BIO0915’ Patient ID

3

Clik ‘OK’ button

4

Touch left top screen

5

Check the graph

6

Take the photo or screen shot and e-mail to ivdst@nanoentek.com

NanoEnTek

www.nanoentek.com