NanoEnTek

CE IVD

FREND™ Vitamin D

Total 25-Hydroxy Vitamin D

Intended use

The FREND™ Vitamin D test is a rapid indirect competitive fluorescent immunoassay designed for the quantitative measurement of 25-Hydroxy vitamin D and related hydroxylated metabolites in human serum and plasma (K_3EDTA, lithium-heparin and citrate) specimens using the FREND™ system, and the FREND™ AP System. Measurements of total 25-hydroxy vitamin D and related hydroxylated metabolites are used to aid in the assessment of vitamin D sufficiency.

The FREND™ Vitamin D microfluidic flow cartridge is designed for use in the FREND™ System fluorescent immunoassay reader, and the FREND™ AP System. The FREND™ Vitamin D Test System is intended for use in clinical laboratories. For in vitro diagnostic use only. The test is not intended for use in point-of-care settings.

Summary and explanation of test

Vitamin D is a fat-soluble prohormone known for its role in regulating calcium and phosphorus levels in bone mineralization[1, 2].Sunlight exposure produces vitamin D via photochemical conversion of 7- dehydrocholesterol in the epidermis and is the primary source of vitamin D [3, 4]. Seasonal changes, amount of exposure, sunscreen use, and skin pigmentation can cause variation in the amount of vitamin D produced in the body. A minor source of vitamin D can be absorbed from food and vitamin supplements, with an estimated 10-20% absorbed by the body in this manner [5, 6].

In circulation, 25-OH vitamin D is bound to vitamin D binding protein (VDBP) or albumin at 1000 times higher concentrations than the active form 1,25-(OH)2-vitamin D [7]. Additionally, the 25-OH form has a half-life of 2-3 weeks, as compared to the less stable 1,25-(OH)2 form, which has a half-life of a few hours[8]. 25-OH vitamin D exists as D2 (ergocalciferol) and D3 (cholecalciferol) isomers, with supplements available for both. Often, total 25-OH vitamin D is measured to assess the sufficiency in a patient and make appropriate clinical decisions [9].

Principle of the assay

The FREND™ Vitamin D test cartridge is a single-use rapid "competitive" immunoassay utilizing fluorescent nanoparticles in microfluidic flow to capture and quantify total 25-OH vitamin D in serum and plasma specimens. A 35 µL specimen is placed into a Dilution Tube and 70 µL of the diluted sample is placed into the FREND™ Vitamin D Gold Antibody pretreatment tube, which contains proprietary reagents. The pretreatment tube is processed in the FREND™ AP (Advanced Preparing) device. The AP device mixes and incubates the sample and loads the correct volume onto the FREND™ Vitamin D cartridge.

During the incubation labeled 25-OH vitamin D-antibody immune complexes are formed and the AP device transfers a 35 µL sample to the FREND™ Vitamin D cartridge. Vitamin D conjugated fluorescent nanoparticles in the cartridge compete with the 25-OH vitamin D-antibody immune complexes from the pretreatment tube for binding to antibodies immobilized in the test zone. The intensity of fluorescence is inversely proportional to the amount of 25-OH vitamin D in the sample. The FREND™ system measures the fluorescence and calculates, displays, stores and optionally prints the 25- OH vitamin D concentration.

Material provided

Contents		Catalogue number
20	FREND™ Vitamin D cartridges	FRVDAP 020
20	FREND™ Vitamin D Gold Antibody pretreatment tubes	
20	Sample Dilution tubes	
30	Disposable pipette tips	

01 FREND™ Vitamin D Code chip
01 FREND™ Vitamin D Package Insert

One cartridge contains:

Monoclonal mouse anti-vitamin D	1.6 ± 0.16 ng
25-hydroxyvitamin D	136 ± 13.6 ng
Fluorescent particles	2.4 ± 0.24 μg

One Sample Dilution tube contains:

Perfluorohexanoic Acid	9.5 ± 0.95 μg

One Gold Antibody pretreatment tube contains

Gold nano-particle conjugation antibody	7.0 ± 0.7 μg

Materials required but not provided

- The FREND™ AP
- The FREND™ System
- Micro-pipette capable of delivering 35 and 70 μL
- Personal protective equipment and biohazard waste equipment

Warning and Precautions

⚠ Caution: In the United States, federal law restricts this device to sale by or on the order of a physician.

- The FREND™ Vitamin D cartridges are intended for in vitro diagnostic use only.
- Vitamin D cartridges are only to be used on the FREND™ System.
- Vitamin D cartridges are disposable, single use devices. Do not reuse them under any circumstances.
- Allow sealed cartridges to come to room temperature for approximately 15~30 minutes prior to use.
- Cartridges and Gold Antibody pretreatment tubes should not be frozen.
- Assure the humidity in the laboratory is in the 10~80% range when tests are run.
- Assure the room temperature remains in the range of 64 ℉~77 ℉ (18~25 ℃) when tests are run.
- Avoid cross-contamination between samples by using a new pipette tip for each new specimen.
- Avoid high humidity, direct sunlight or heat in the area used for cartridge storage.
- Inaccurate results are possible if the sample used is contaminated in any way.

- Using specimens containing clotted fibrin could result in erroneous results.
- Over or under loading the cartridge with sample may cause inaccurate results.
- Human specimens are not used in the preparation of this product. However, since human specimens will be used for samples, and since other quality control products in the lab may be derived from human materials please practice Universal Precautions when handling all specimens and controls.
- Do not use the cartridges, pretreatment tubes or dilution tubes beyond the expiration date on the pouch.
- Do not use the cartridge and pretreatment tubes if the pouch is damaged or the seal is broken.
- Perform testing as specified in the Package Insert and User Manual.
- Keep the cartridge and Gold Antibody pretreatment tube sealed in the pouch until ready for use.
- Use the cartridge and Gold Antibody pretreatment tube immediately after opening the pouch.
- Wear disposable gloves when handling the cartridges, pretreatment tubes and the samples.
- Wash hands thoroughly and often after handling reagent cartridges or samples.
- Do not ingest the silica gel package found in the cartridge pouch.
- The FREND™ Vitamin D assay has been evaluated and no high dose hook effect was observed for Vitamin D concentrations up to 1600 ng/mL.
- Handle specimens in accordance with the OSHA Standard on Bloodborne Pathogens. [10]

Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at the specified temperature. Reagent stability has been demonstrated for twelve months from the date of manufacture.

The expiration date is clearly indicated on the product box and the cartridges.

Materials	**Catalogue number**
Refrigerator temperature storage (36~46 °F or 2~8 ℃)	
FREND™ Vitamin D cartridges, pouched (20)	FRVDAP 020
FREND™ Vitamin D Gold Antibody pretreatment tubes, pouched (20)	None Sample
Sample Dilution Tubes (20)	None

Room temperature storage

Pipette tips None

Specimen collection and handling

Human serum and plasma (lithium-heparin, K_3EDTA and citrate) samples are suitable for use with FREND™ Vitamin D cartridges.

Follow instructions detailed in this package insert as well as the specimen collection tube manufacturer's instructions for specimen collection and preparation (including manufacturer's instructions for centrifugation time and speed.)

For serum, a blood sample is collected aseptically without additives by venous puncture. After allowing the sample to clot for 30 minutes at room temperature, the collection tube should be centrifuged for 10 minutes at 3,000 rpm.

For plasma (lithium-heparin, K_3EDTA and citrate), a venous blood sample is collected aseptically with the designated additive. After allowing the specimen to sufficiently mix with anticoagulant at room temperature, centrifuge the tube for 10 minutes at 3,000 rpm.

Samples may be stored at 36~46 °F (2~8 °C) for up to 6 hours prior to analysis. If the analysis is scheduled to be done at some later time, the serum or plasma sample should be separated from the red cells and stored frozen at -4 °F (-20°C) or below for future use.

Repeated freeze-thaw cycles should be avoided. Prior to assay, slowly bring frozen samples to room temperature (64~77 °F or 18~25 °C) and mix gently but thoroughly before testing.

For optimal results, avoid grossly hemolytic, lipemic, or turbid specimens. Specimens should be free of aggregated fibrin, red blood cells, or other particulate matter.

Procedure

Calibration

There is no need for calibration to be performed by the end user as is generally required on other automated laboratory equipment. All calibration statistics and information have been electronically stored on the FREND™ Vitamin D Code chip included in each box of FREND™ Vitamin D cartridges. The FREND™ Vitamin D Code chip is specific for each lot of FREND™ Vitamin D cartridges.

Calibration information should always be checked by running external quality control samples to verify that the results obtained for Vitamin D on the FREND™ System using the FREND™ Vitamin D cartridges meet the laboratory criteria for acceptability.

Code chip installation

Please refer to the FREND™ System user manual for more detailed instructions relative to the Code chip installation. Abbreviated instructions follow here:

1) Insert the FREND™ System electrical cord into an appropriate outlet.
2) Insert the Code chip into the Code chip slot at the rear of the FREND™ System following the arrows.
3) Press the 'Setup' button on the 'Main' screen.
4) Press the 'Code chip' button on the 'Setup' screen.
5) The information embedded on the FREND™ Vitamin D Code chip is automatically saved on the FREND™ System.
6) When the Code chip installation is completed, press the 'OK' button to go to the 'Setup' screen.
7) Press the 'Item' button on the 'Setup' screen.
8) Check the FREND™ Vitamin D cartridge lot number and the installation date of the Code chip.
9) Press the 'Home' button to go to the 'Main' screen to begin running external quality control and patient samples.

Quality control

• FREND™ System QC cartridges

The FREND™ QC Cartridge contains multiple controls that check the optics of the system. By testing the QC Cartridge, the integrity of the laser power, alignment and mechanical components of the system are confirmed.

For each day of patient testing perform QC Cartridge testing. Refer to the quality control procedures section in the User Manual of the FREND™ System. In brief, perform QC Cartridge testing for the following conditions:

- Upon initial setup of the system,
- Each day of patient testing,
- When the system has been transported or moved,
- Whenever there is uncertainty about the performance of the system,
- Whenever required by your laboratory's quality control requirements.

• Internal procedural controls

The FREND™ Vitamin D test cartridge contains a built-in control feature. Fluorescence signal in the reference zone of each cartridge shows: (1) that enough volume is added, (2) that proper flow is obtained, and (3) that the antibody is reactive. If this reference zone signal is missing or lower than threshold, the FREND™ System considers it an incorrect or failed test and produces an error message instead of a test result. In addition, with each cartridge run, the system monitors for (1) flow of sample, (2) speed of sample flow, (3) shelf-life of cartridge components, (4) function of internal barcode scanner, and (5) function of scanner's mechanical components.

• External quality control testing

Commercially available controls from a variety of manufacturers are available that contain 25-OH Vitamin D as a measured analyte. It is recommended that a minimum of two (2) levels of controls be run once per day on days when assaying patient samples on the FREND™ Vitamin D Test. Or another QC option may be adopted – Individualized Quality Control Plan (IQCP) [11] is an all-inclusive approach to assuring the quality of the entire testing process. An IQCP includes practices, data and information that each laboratory already uses to ensure quality testing and meet CLIA, beyond testing a certain number of QC materials at a designated frequency. To ensure that these control procedures are equivalent to CLIA QC regulations and suitable for each laboratory,

it is required to establish and document the QC that is appropriate for the test system, testing environment and testing personnel.
Controls should be run according to local, state, federal regulations or accreditation requirements for quality control frequency. If any external quality control sample values are out of the acceptable range, it will be necessary to investigate the problem before reporting patient results to assure there is not an instrument or software malfunction. Do not assay patient samples on the FREND™ System using FREND™ Vitamin D if quality control results do not fall within the acceptable ranges.

Specimen processing

• Preparation

Remove sufficient FREND™ Vitamin D cartridges, Sample dilution tubes, and Gold Antibody pretreatment tubes from the refrigerator to test the number of patient samples and required external quality control materials. Allow the tubes and the sealed pouches containing the cartridges to come to room temperature for approximately 15~30 minutes prior to the start of the testing sequence.

When using refrigerated patient samples, remove those from the refrigerator and allow them to come to room temperature prior to testing. If frozen samples will be utilized, be sure these are removed from the freezer, thawed at room temperature and then mixed gently but thoroughly prior to testing. Testing should not begin on previously frozen samples until they have reached room temperature (64~77 °F or 18~25 °C).

There are no other reagents or sample preparations necessary.

• Assay procedure

1) Ensure that the FREND™ Vitamin D cartridge, Gold Antibody pretreatment tube, Sample Dilution Tube and specimen are at room temperature (64~77 ℉ or 18~25 ℃). Open the pouch and place the FREND™ Vitamin D cartridge into the cartridge tray of the AP device. Press "NEXT" to close the cartridge tray and open the pretreatment tube tray.
2) Transfer 35µL of specimen into the Sample Dilution tube and mix well by vortexing or inverting.
3) Transfer a 70 µL aliquot of the diluted specimen to the FREND™ Vitamin D Gold Antibody pretreatment tube. (⚠ Caution: once the sample is added to the pretreatment tube Do not invert the tube). Insert the pretreatment tube into the tube hole in the FREND™ AP pretreatment tube tray. Refer to the FREND™ AP MANUAL for complete operating instructions.
4) Press the "NEXT" button. The pretreatment tray will close and the first incubation step (15 minutes) will begin.
5) After the first incubation is complete, 35 µL of mixed sample will be loaded onto the cartridge and the second incubation step (2 minutes) will begin.
6) When both incubation steps are completed, the cartridge tray will open and the cartridge will be ready to be inserted into the FREND™ System.
7) Press the 'Test' button on the 'Main' screen of the FREND™ System.
8) The system moves to the Patient ID screen automatically.
9) Type the Patient ID and press the 'Enter' button to begin the test.
10) Insert the cartridge into the cartridge slot using the cartridge arrow as a guide.
⚠ Caution: Check the direction of the cartridge before insertion and assure the insertion is complete.
11) When the reaction in the cartridge is completed, the FREND™ System will automatically begin the reading process.
12) When the measurements are completed, the cartridge will automatically be expelled and the results displayed.
⚠ Caution: Do not disconnect power cord or shut off power on the FREND™ System while a cartridge is in the reading chamber. This may cause a system error.
13) If the FREND™ System is connected to the optional printer, press the 'Print' button and the results will be output on the printer paper.
14) For more detailed instructions, please refer to the FREND™ System User Manual.

Procedural notes

If the Vitamin D concentration of a specimen is found to be greater than the linearity limit of the assay of 96.0 ng/mL, report any value above 96.0 ng/mL as "greater than 96 ng/mL." There is no specific diluent provided in the FREND™ Vitamin D reagent.

Calculation of results

The FREND™ System performs all sample and reagent handling operations automatically within the cartridge once the sample has been loaded into the sample in let in the cartridge and the cartridge placed into the FREND™ System. The rate of fluorescence produced by the reaction is read at various intervals during the analysis process, blank readings are subtracted after which the net rate is automatically converted to Vitamin D concentration in ng/mL based upon information stored on the FREND™ Vitamin D Code chip.

This result is then output on the screen and to the optional printer. It is also stored in memory on the FREND™ System.

Screen displayed for various concentration scenarios

Displayed result	Description
	Vitamin D concentration Less than 13.0 ng/mL
	Vitamin D concentration Not less than 13.0 ng/mL and not higher than 96.0 ng/mL
	Vitamin D concentration Higher than 96.0 ng/mL

Limitations of the procedure

1) When used for diagnostic purposes, the results obtained from this assay should be used in conjunction with other data (e.g., symptoms, results of other tests, clinical impressions, medical history, therapy, etc.)
2) The FREND™ System paired with a FREND™ Vitamin D cartridge, is programmed to report 96.0 ng/mL as the highest concentration of Vitamin D measurable. The lowest measurable concentration is 13.0 ng/mL, the assay limit of detection.
3) Specimens from patients with heterophilic antibodies, such as anti-mouse (HAMA), anti-goat (HAGA), or anti-rabbit (HARA) antibodies, may show falsely elevated or depressed values or may result in an incomplete test [12, 13]. Patients routinely exposed to animals or animal serum products can be prone to these types of heterophilic interferences.
4) Patients taking the drugs containing Paricalcitol (e.g., Zemplar) should not be tested by this assay.
5) Certain medications may interfere with assay performance. All results should be interpreted with respect to the clinical picture of the patient.
6) Although hemolysis has an insignificant effect on the assay, hemolyzed samples may indicate mistreatment of a specimen prior to assay and results should be interpreted with caution.
7) Lipemia has an insignificant effect on the assay except in the case of gross lipemia where interference with the lateral flow of the sample in the cartridge may occur.
8) The concentration of Vitamin D in a given sample determined with assays from different manufacturers can vary due to differences in assay methods, calibration, and antibody specificity.
9) Please refer to the Specimen Collection and Handling, Warnings and Precautions, Storage and Stability, and Procedural Notes sections in this insert sheet.
10) FREND™ Vitamin D has not been evaluated in point-of-care settings.
11) FREND™ Vitamin D is to be used in licensed clinical laboratories with trained technologists.

Performance characteristics

Precision

A single lot imprecision study was performed at the NanoEnTek laboratory as described in the CLSI protocol EP5-A3. Three serum pools were assayed for 20 days, 2 runs per day in duplicate using a single lot of FREND™ Vitamin D reagent cartridge. The results are summarized below:

FREND™ Vitamin D Single Site Single Lot Precision

sample Pool	Mean Vitamin D Level, (ng/mL)	Repeatability		Between-run		Between-day		Within-laboratory	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	20.1	1.76	8.7%	0.46	2.3%	0.22	1.0%	1.83	9.1%
2	50.6	2.26	4.5%	1.31	2.6%	0.59	1.2%	2.67	5.3%
3	80.5	4.53	5.6%	1.13	1.4%	0.74	1.4%	4.72	5.9%

Linearity Study

To demonstrate the linearity of the assay, a serum base pool with an elevated Vitamin D (105.6 ng/mL) was prepared and diluted to a total of 9 levels according to the dilution protocol outlined in CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach. At each dilution level, the samples were tested in quadruplet to determine the experimental value of Vitamin D. Linearity was demonstrated across a measuring interval of the FREND™ Vitamin D (13.0 ng/mL ~ 96.0 ng/mL).

Method Comparison

Method comparison studies were performed in a CLIA-certified laboratory using de-identified fresh and frozen serum specimens. The reference method was the Architect 25-OH Vitamin D assay on the Abbott ARCHITECT i System. All samples (133) analyzed in the clinical testing were split and tested by both the ARCHITECT i and the FREND™ Vitamin D test systems. Passing-Bablok regression analysis gave a slope of 1.069, a y-Intercept of -0.182 and a correlation (R) of 0.971. Comparability using CLSI guideline EP09-A3 shows that the two methods compare favorably.

Matrix Comparison

Matrix comparison study was performed according to CLSI EP14-A3. Vitamin D concentrations in 36 paired serum, lithium heparin plasma, K_3 EDTA plasma, and citrate plasma samples were measured using the FREND™ Vitamin D Test System. Passing-Bablok regression analyses of serum results (x) compared to lithium heparin plasma, K_3 EDTA plasma, and citrate plasma results (y) yielded an acceptable regression (Slope = 0.958, Intercept = 0.067, R = 0.995 for heparinized plasma, Slope = 0.991, Intercept = -0.062, R = 0.993 for K_3 EDTA plasma, and Slope = 0.937, Intercept = 0.700, R = 0.995 respectively), indicating that FREND™ Vitamin D Test System can be measured equally well in serum, Lithium heparin plasma, K_3 EDTA plasma, and citrate plasma.

Reference Interval

The normal range (reference interval) of Vitamin D measured in the FREND™ Vitamin D Test System was established from 300 unaltered serum specimens collected from geographically diverse locations in the United States in Summer (June to August) and Fall/Winter (October to February). The reference interval is provided below.

Reference Interval for the FREND™ Vitamin D Test System

Reference Interval	Lower reference limit 90% CI	Upper reference limit 90% CI
<13.0 to 48.4	<13.0 to <13.0	47.7 to 68.0

Consider these limits as guidelines only. It is important for each laboratory to establish its own reference range, representative of its typical population.

Sensitivity

The Limit of Detection (LoD) for the FREND™ Vitamin D was established according to the CLSI EP17-A2 protocol and was determined to be 6.3 ng/mL. The functional sensitivity was 9.9 ng/mL, and the measuring range was established at 13.0 ng/mL to 96.0 ng/mL.

Specificity and Interferences

Interference was defined as recovery values outside of 10% of the known specimen mean concentration. Recovery within 90% to 110% of the expected Vitamin D level was considered as lack of interference. The interference studies were performed as recommended in the CLSI EP07-A2 protocol. Results are summarized in the table below.

Interferent Type	Interferent (Level Tested)	% Recovery, Low Level Vitamin D	% Recovery, High Level Vitamin D
Endogenous Substances	Hemoglobin (500 mg/dL)	107.0	98.4
	Bilirubin conjugated (30mg/dL)	95.6	95.7
	Bilirubin unconjugated (30mg/dL)	100.0	94.9
	Triglyceride (1500 mg/dL)	99.6	94.0
	Cholesterol (500 mg/dL)	93.0	96.1
	Total protein (12 g/dL)	103.4	98.8
	Biotin (6 µg/mL)	99.9	102.7
HAMA and RF	HAMA (1000 ng/mL)	97.4	108.2
	Rheumatoid Factor (536 IU/mL)	101.4	96.8

Cross-Reactivity

The following substances were evaluated for potential cross-reactivity with the FREND™ Vitamin D at two concentrations. Testing was done according to the CLSI protocol EP7-A2. Drugs containing Paricalcitol (e.g., Zemplar) will interfere with the assay.

Cross-reactant	Conc. of cross-reactant (ng/mL)	% Cross-reactivity	
		Low	High
Vitamin D2 (Ergocalciferol)	500	0.5	0.8
Vitamin D3 (Cholecalciferol)	500	0.5	0.7
1,25-(OH)2-Vitamin D2	100	2.2	0.7
1,25-(OH)2-Vitamin D3 (Calcitriol)	100	6.9	1.9
3-epi-25-(OH) Vitamin D3	100	2.1	2.0
25-(OH) Vitamin D2	25	97.2	97.3
25-(OH) Vitamin D3	25	107.2	92.2
Paricalcitol	25	15.8	14.7

% Cross-reactivity = 100 x ((Measured value – true value)/concentration of cross-reactant), absolute value.

References

1. Holick, MF. High prevalence of vitamin D inadequacy and implications for health. Mayo Clinic Proceedings. 2006, 81 (3): 353-373.
2. Bolland, MJ et al. The effect of vitamin D supplementation on skeletal, vascular, and cancer outcomes: a trial sequential meta-analysis. The Lancet Diabetes &Endocrinology, 2014, 2 (4): 307-320.
3. Wolf, G. The discovery of vitamin D: the contribution of Adolf Windaus. Journal of Nutrition, 2004, 134 (6): 1299-1302.
4. Holick, MF. Vitamin D: importance in the prevention of cancers, type 1 diabetes, heart disease, and osteoporosis. The American Journal of Clinical Nutrition, 2004, 79 (3): 362-371.
5. Calvo, MS et al. Vitamin D intake: a global perspective of current status. Journal of Nutrition, 2005, 135 (2): 310-316.
6. Ross, AC et al. Dietary Reference Intakes for Calcium and Vitamin D. Washington DC: National Academies Press 2011, p. 435.
7. Svasti, J et al. Molecular basis for the three major forms of human serum vitamin D binding protein. Biochemistry 1979, 18 (8): 1611-1617.
8. Holick, MF et al. Vitamin D2 is as effective as vitamin D3 in maintaining circulating concentrations of 25- hydroxyvitamin D. The Journal of Clinical Endocrinology and Metabolism,2008, 93 (3): 677-681.
9. Maxmen, A. Nutrition advice: the vitamin D-lemma. Nature 2011, 475 (7354): 23-25.
10. Chao, E.L.; Henshaw, J.L. Occupational Safety and Health Administration: Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards. OSHA 3186-06R, 2003.
11. Centers for Medicare & Medicaid Services. CLIA Individualized Quality Control Plan – Considerations when deciding to develop an IQCP. CLIA Brochure #12. November 2014.
12. Schroff, R.W.; Foon, K.A.; Beatty, S.M.; Oldham, R.K.; Morgan, A.C. Human Anti-Murine Immunoglobulin Responses in Patients Receiving Monoclonal Antibody Therapy. Cancer Research. 1985, 45: 879-885.
13. Boscato, L.M.; Stuart, M.C. Heterophilic Antibodies: A Problem for All Immunoassays. Clinical Chemistry, 1988, 34 (1): 27-33.

Glossary of symbols

	Do not reuse
	Use by YYYY-MM-DD
	Lot number
	Catalog number
	Warning or Caution
	Manufactured by
	Authorized representative in the Europe Community
	*In vitro* diagnostic medical device
	Temperature limitation
	Contains sufficient for <n> tests

NanoEnTek

ivdst@nanoentek.com
www.nanoentek.com

Manufactured by

NanoEnTek Inc.
851-14, Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea
Tel : +82-2-6220-7942 Fax : +82-2-6220-7999

EC REP

MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St. Ingbert, Germany

US Branch

NanoEnTek USA Inc.
5627 Stoneridge Drive Suite 304, Pleasanton, CA 94588, USA
Tel : +1-925-225-0108, +1-888-988-0108 (Toll free) Fax : +1-925-225-0109
www.nanoentekinc.com

Revised on 2017.01.06