



GIVE CONCERNS TAKE HEALTH


Fast and accurate
ultrasensitive multiplex
diagnostic solution

ezDiatech

GIVE CONCERNS, TAKE HEALTH

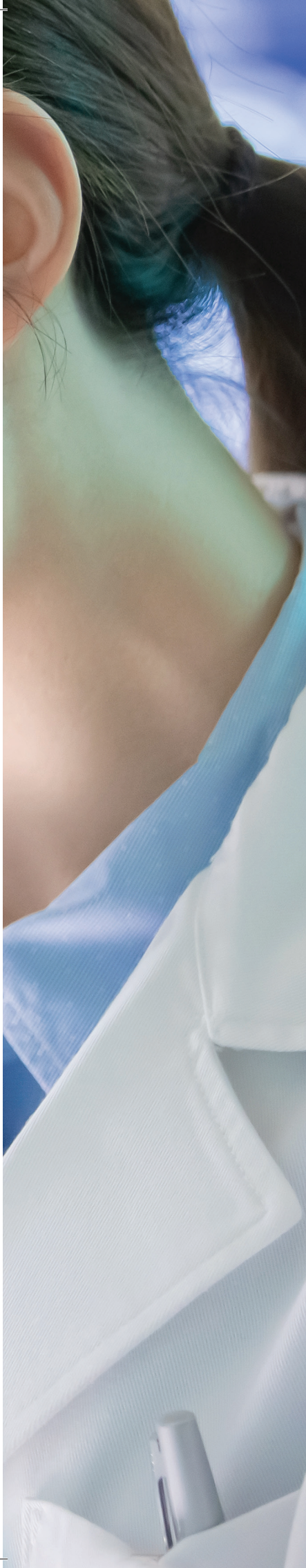
www.ezdiatech.com

ALL-3201-R2



EzDiatech Inc. creates health and happiness
for humanity with our fast and accurate
ultrasensitive multiplex diagnostic solution.

ezDiatech
GIVE CONCERNS, TAKE HEALTH



EzDiatech Inc.
is based on
three core values.



Think to open

Open mind to learn new fields
for progress with endless passion



Decide to challenge

Challenge spirit to change the world by
learning and applying new technologies
with creative thinking



Act to serve

The spirit of social service to
contribute to human health and happiness.

Leading the IVD field through ceaseless R&D and conversion source technology.

This is the road
EzDiotech
has traveled.



2016

- Nov. • Booth display at MEDICA in Germany
 - Venture Business Certification and policy funding from the Korea Technology Finance Corporation
- Oct. • Certificate for the R&D Department
- Jul. • Established

2017

- Dec. • Creative & Innovative Enterprise Certification (Chungnam Creative Economy Innovation Center)
- Nov. • Booth display at the American Association for Clinical Chemistry (AACC) conference
- Oct. • Selected for R&D funding by Industry-University-Research Institute Collaboration (Ministry of SMEs and Startups in Korean government)
- Jun. • Policy funding from the Korea SMEs and Startups Agency of the Korean government

2018

- Nov. • Booth display at MEDICA in Germany
- May • License obtained for medical device manufacturing
- Mar. • Funded by VC (Seoul Investment Partners)
 - GMP Certification
- Feb. • Booth display at MEDLAB in United Arab Emirates
 - Certification of in-house R&D center

2019

- Aug. • Booth display at the American Association for Clinical Chemistry (AACC) conference
- Jul. • Selected for TIPs (Tech Incubator Program for Startup) with Funding (Government R&D Grant)
- Apr. • Funded by VC (KB Investment Co., Ltd.)
- Feb. • Funded by Boditech Med Inc.

2020

- Dec. • Selected as an IPO Candidate Company of Korea Credit Guarantee Fund
 - GMP Certificate
 - Selected for funding by the Korea Government R&D fund (SME's Technology Innovation Development Project, 600 million KRW)
- Nov. • Selected as the First Penguin Company of Korea Credit Guarantee Fund
- Jul. • Selected as BIG3 Company (Innovative Startup Package Support Project)
- Secured Series A Funding (KB Investment, Samho Green Investment, KDB Capital, MAGNA Investment)
- Jun. • Selected for Startup Leap Package Support Project



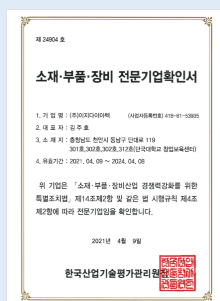
EzDiatech has accumulated technological know-how through steady research activities.



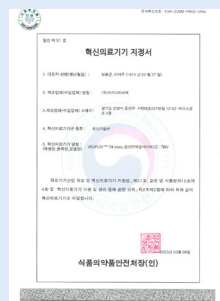
GMP Certificate



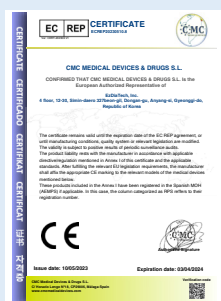
ISO 13485



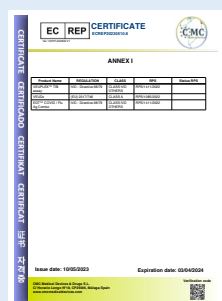
Confirmation of a specialized company for materials, parts and equipments



VEUPLEX™ TBI assay - Designation of Innovative Medical Device



CE Certificate of VEUDx-IVDR



CE Certificate of VEUPLEX™ TBI assay



Letter of a patent
A novel POCT diagnostic system for traumatic brain injury and infectious diseases



Letter of a U.S. patent
Automated immunoassay device and method using large magnetic particle complex

2021

- Dec. • Ministry of the SMEs & Startups Award of the Korean government
- Sep. • Booth display at the American Association for Clinical Chemistry (AACC) conference
- Jun. • Series B Funding from an investment-association company (T-investment Inc.)
- Certification of Innovation Business company
- Certification of the VEUDx IVD device manufacturing
- Apr. • Selected for funding by the Korea Government R&D fund for Medical Device Development (~2.0 billion KRW)
- ISO 13485 Certification
- Certification of the Material, Parts and Equipment Specialist Company

2022

- Nov. • Booth display at MEDICA in Germany
- Aug. • Booth display at the Medical Fair Asia 2022 Singapore
- Jul. • Booth display at the American Association for Clinical Chemistry(AACC) conference
- May. • KFDA Certification of IVD medical device manufacturing of the VEUPLEX™ TBI assay for export
- Apr. • CE certificate of VEUDx, a full automation device
- CE certificate of VEUPLEX™ TBI assay, the blood diagnostic kit for traumatic Brain Injury (Concussion)

2023

- Dec. • Selected as a partner organization for Kyung Hee University's industry, academia, and research institute.
- Certificate of conformity with in vitro diagnostic medical device manufacturing and quality control standards (Certificate of GMP)
- Sep. • Booth display at the Medica Fair Thailand 2023
- Jul. • VEUPLEX™ PCT test - License obtained for medical device manufacturing
- Booth display and poster presentation at 2023 AACC conference
- Jun. • VEUPLEX™ TBI assay - Certification approval of Thailand FDA
- May. • CE IVDR certificated : VEUDx analyzer
- Apr. • MOU signed with Korea Brain Research Institute
- Mar. • Abstract presentation of International Brain Injury Association (Dublin)
- Designation of Innovative Medical Device for VEUPLEX™ TBI assay by Korea Ministry of Food and Drug Safety
- Feb. • Booth display at the MEDLAB in United Arab Emirates

2024

- Feb. • Booth display at the MEDLAB in United Arab Emirates



POCT diagnostic technology

VEUS is a fully automated ALL-IN-ONE diagnostic system for rapid and accurate immunoassays and molecular diagnostics within 15~50 minutes.

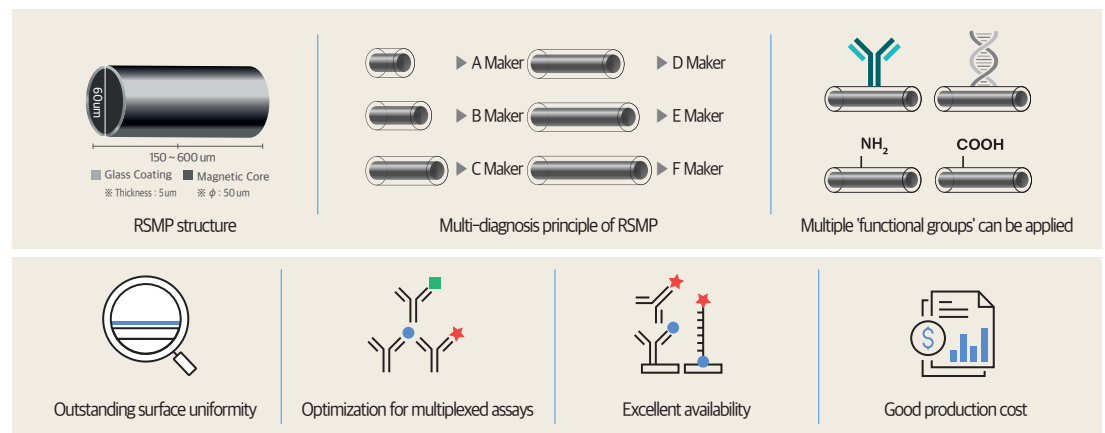
1. Rod Shaped Magnetic Particles - RSMP

The ingenious magnetic particle with outstanding performance and reproducibility

Magnetic particles are usually used in the current IVD field to derive quick and accurate diagnostic results. However, conventional magnetic particles, with low reproducibility and availability, have a drawback of requiring expensive imaging system. To solve this problem, we have developed an original magnetic particle, the Rod Shape Magnetic Particles (RSMP), that can be used for multiplexed diagnostics with high reproducibility and low production cost.

RSMP has superior strengths in all aspects such as productivity, reproducibility, precision, availability and cost compared to conventional magnetic particles.

Features



2. The reaction principle of VEUS, Fast Reaction Technology

Magnetic Particles Moving Reaction Technology

Conventional immunochemical reactions use a method of exchanging liquid such as reaction solution and washing solution in the well containing magnetic particles, so there are various disadvantages such as accuracy and reproducibility of results, time and cost. VEUS overcomes the shortcomings with a rapid response technology using the RSMP up & down and well-to-well moving technology to produce good diagnosis within 15 - 50 minutes.

Features

The rapid reaction and washing technology through RSMP's up & down / well-to-well movement can reduce running time for diagnosis, experimental waste and device size.







3. The imaging technology to perform ultra-sensitive detection

Ultra-Sensitive Fluorescence Analysis System

The ultra-sensitive fluorescent imaging module has been optimized and manufactured for RSMP, and the technology to image the whole well area at a time has been secured. Further, a remarkably improved signal for low noise ratio and high-sensitive fluorescent assay has been achieved.

Features

The entire well area can be imaged at a time with 100-times better fluorescent sensitivity and lower signal/noise ratio than those of conventional fluorescent microscopes, enabling economical and efficient ultra-sensitive tests.

 <p>RSMP-specialized 1x lens</p>	 <p>Ultra-sensitive fluorescent signal detection</p>	 <p>Field of View → 50mm²</p>	 <p>100-times better fluorescent sensitivity and S/N ratio</p>
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4. The multi-detection result analysis with A.I. Multiplexed Diagnostics Analysis

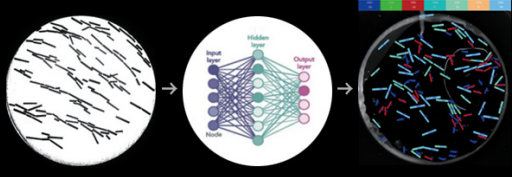
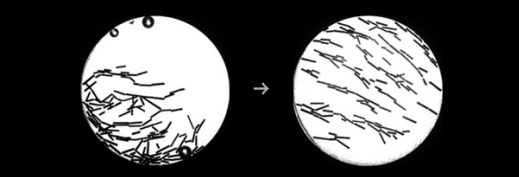
A.I Imaging Analysis Technology

NVIDIA GPU is used to improve the RSMP size detection and the multi-detection is conducted with the optimized AI model. More than 99% accuracy of multiplex detections has been secured and the results can be conveniently produced by calculating data.

Features

The high accuracy result can be obtained based on our patented AI-based multi-detection technology.

method	Accuracy of multi-detection (3 plexed assay)	method	Accuracy of multi-detection (3 plexed assay)
Analysis utilizing AI-combined software → CV image processing technology	~99%	Demagnetization of magnetic particles	~80%

Multi-detection through the AI technology	Multi-detection existing method
	



VEUS, the abbreviation of **Versatile, Easy, and User-friendly IVD System**, is an innovative diagnostic system: Versatile - almost all in vitro diagnostic items are applicable; Easy - the system is entirely automated enabling easy testing with no pretreatment required; User-friendly - anyone can use the system easily. Further, the system realizes high sensitivity (below 1 pg/ml), multiplexed diagnostics (simultaneous testing of several biomarkers) and rapid results (within 40~50 minutes) with high accuracy (above 95%).

VEUDx



VEUDx Analyzer

- Model : VI-01A-2
- Principle : Fluorescence coding/analysis
- TAT : 40~50 minutes
- Size : 530 mm(L) X 485 mm(D) X 465 mm(H)
- Weight : 33.8 kg
- Cartridge slots: up to 6 cartridges Desorption Tray type
- Power Supply : AC 100-120V, 50/60Hz or AC 200-240V, 50/60Hz
- Display : 7 inch Touch LCD, 1024 x 600

Four differentiated technologies of VEUS

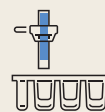
We have developed the world's first diagnostic product that provides hypersensitive and high-accuracy diagnosis in 40~50 minutes.

Features



No warming time

With no warming time required, the system enables immediate testing as it can reach 37°C within 4-5 min., reducing test preparation time.



Efficient mixing / washing

The up&down / well to well movement technology of magnetic particles makes reaction and washing easy and reduces both waste generation and automatic device size, enabling economical and eco-friendly use.



Multiplex assay

Based on the magnetic particle size-based coding system, the VEUS system allows multiplexed diagnostics.



ALL-IN-ONE system

With the reaction and optical modules integrated as a unit, the VEUS system allows easy operation.

VEUS Application & Product - Immunoassay

VEUPLEX™ TBI assay

TBI multiple diagnosis

VEUPLEX™ TBI assay

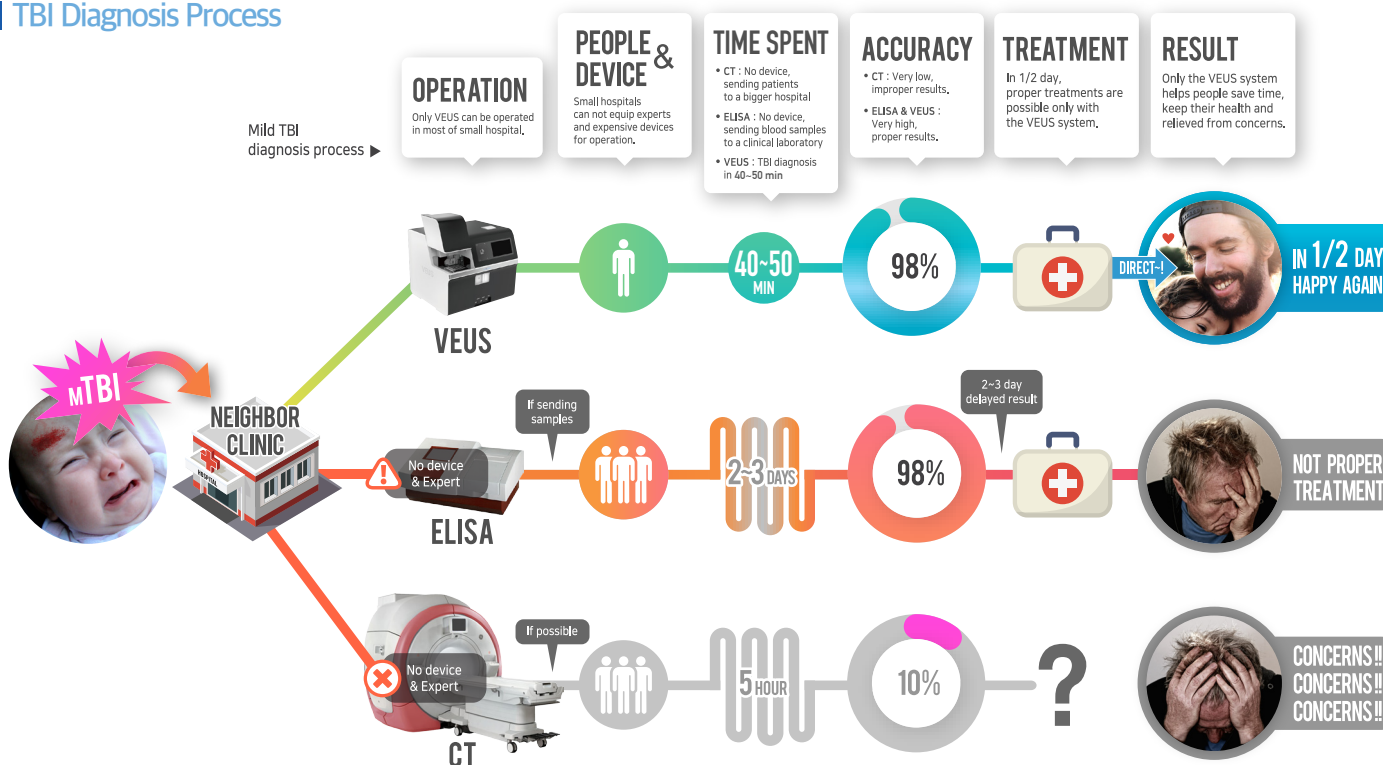
- Package : 60 Test/Kit
- Composition : Test Cartridge, User Manual
- Indication : Traumatic Brain Injury
- Sample : Serum
- Target : GFAP, UCH-L1
- TAT : 40 min
- Cut-off
 - GFAP : 24 pg/ml
 - UCH-L1 : 138 pg/ml

A common incident worldwide, TBI (Traumatic Brain Injury) is an injury to the brain caused by an external force and can be classified as mild, moderate and severe TBI cases. TBI is mostly diagnosed by CT scan or MRI, but in case of mTBI, less than 10% are normally detected by the conventional methods. So while remaining 90% of mTBI patients are not properly treated. If it is neglected, mTBI can progress to severe depending on the patients. Therefore, accurate diagnosis of mTBI is necessary. In general, patients suspected with mTBI go to small or mid-sized hospitals that usually are not equipped both the equipment and manpower for TBI diagnosis, so their samples are sent to clinical laboratories. From then, 3-4 days are spent to produce final diagnostic results, disabling fast and effective treatment for mTBI. Our VEUPLEX™ TBI assay can provide rapid and accurate the TBI diagnostic result in 40 minutes for fast and proper treatment.

Price 50% Less	Time Spent 40 min	VEUPLEX™ TBI assay is a remarkable solution for TBI test results in terms of cost (less than a half), convenience, speed (check results within 40~50 min.) and accuracy (95% accuracy) compared to previous examinations.
Expert Not needed	Accuracy 95%	Consequently, the only effective TBI diagnostic / treatment method in existence is VEUPLEX™ TBI assay. * Patent registration : 10-2272915 (2021.06.29)

		Clinical diagnosis			Clinical sensitivity (%) [95% confidence interval]	Clinical specificity (%) [95% confidence interval]
		Patient group	Normal group	Total		
UCH-L1	Positive	71	1	72	76.34 [66.4 - 84.5]	98.97 [94.4 - 100.0]
	Negative	22	96	118		
	Total	93	97	190		
GFAP	Positive	81	1	82	87.1 [78.5 - 93.2]	98.97 [94.4 - 100.0]
	Negative	12	96	108		
	Total	93	97	190		
VEUPLEX™ TBI assay	Positive	88	1	89	94.62 [87.9 - 98.2]	98.97 [94.4 - 100.0]
	Negative	5	96	101		
	Total	93	97	190		

TBI Diagnosis Process



Application & Product - Immuno assay

Multiplexed diagnostics of brain diseases (Neurology)

The rapid increase of patients with brain diseases, due to rapidly ageing population worldwide, is expected to incur two trillion USD medical care costs from 75 million patients by 2030. As population ageing in Korea is progressing 4.5 times faster than that of other OECD countries, it is evident that brain diseases such as dementia, Alzheimer's, and cerebral infarction will become a more serious social issue. Traditionally, for diagnosis of dementia, Alzheimer's and other brain diseases, combined tests including tests on brain blood vessel disease / brain atrophy through MRI and Alzheimer's Disease Assessment Scale (ADAS) are conducted. However, these diseases can be detected only when brain atrophy or other diseases have early progressed. Therefore, active R&D is underway for using biomarkers to determine the exact cause of diseases and perform early treatment through early diagnosis before symptoms appear.

Price
1/5 Less

Time Spent
40~50 min

Our multiplexed diagnostics of brain diseases (Neurology) using VEUS, a multiplex immuno-assay system, does not only enable diagnosis before patients are symptomatic by accurately and rapidly investigate various brain disease-specialized biomarkers, but also provide accurate solutions for proper treatments.

Expert
Not needed

Accuracy
90%

Our brain disease (Neurology) multiplexed assay kit can investigate 3~4 biomarkers simultaneously, providing more than 90% accurate results.

Biomarkers of brain diseases (Neurology)

Blood Biomarker / Gene	Concussion	Alzheimer's disease	Parkinson's disease	Multiple sclerosis	Lou Gehrig's disease
GFAP	○	○	○	○	○
UCH-L1	○				
Total Tau	○	○			
pTau 181		○			
pTau 231		○			
Neurofilament Light	○	○	○	○	○
Amyloid β (40, 42)		○			
α-synuclein			○		

VEUPLEX™ multiplex assays for Neurological Diseases

1.VEUPLEX™ Neuro 1p-A(NfL) (for RUO)

- ▷ Species reactivity : Human
- ▷ Limit of Detection(LOD) : 0.47 pg/ml
- ▷ Dynamic Range : 1.25 pg/ml -640 pg/ml
- ▷ Sample type : plasma(recommend), Serum, Cell culture supemates

2.VEUPLEX™ Neuro 1p-B(GFAP) (for RUO)

- ▷ Species reactivity : Human
- ▷ Limit of Detection(LOD) : 0.384 pg/ml
- ▷ Dynamic Range : 3.125 pg/ml -400 pg/ml
- ▷ Sample type : Serum(recommend), Plasma, Cell culture supemates

3.VEUPLEX™ Neuro 1p-C(UCH-L1) (for RUO)

- ▷ Species reactivity : Human
- ▷ Limit of Detection(LOD) : 0.788 pg/ml
- ▷ Dynamic Range : 6.25 pg/ml -800 pg/ml
- ▷ Sample type : Serum(recommend), Plasma, Cell culture supemates

4.VEUPLEX™ Neuro 2p-A(GFAP, UCH-L1) (for RUO)

- ▷ Species reactivity : Human
- ▷ Limit of Detection(LOD)
 - GFAP : 0.384 pg/ml
 - UCH-L1 : 0.788 pg/ml
- ▷ Dynamic Range
 - GFAP : 3.125ml - 400 pg/ml
 - UCH-L1: 6.25 pg/ml - 800 pg/ml
- ▷ Sample type : Serum(recommend), Plasma, Cell culture supemates

5.VEUPLEX™ Neuro 3p-A(pTau 181, pTau 231, Total Tau) (for RUO)

- ▷ Species reactivity : Human
- ▷ Limit of Detection(LOD)
 - pTau 181 : 1.88 pg/ml
 - pTau 231 : 1.48 pg/ml
 - Potal Tau : 0.59 pg/ml
- ▷ Dynamic Range
 - pTau 181, pTau 231 : 2.5 pg/ml - 320 pg/ml
 - Total Tau : 0.625 pg/ml - 160 pg/ml
- ▷ Sample type : Serum(recommend), Plasma, Cell culture supemates

Instruction

- These products are for RUO(Research Use Only) and have been developed for the purpose of quantitative testing of specific biomarkers in specimen.
- In order to set the cut-off, first need to select a indication and analyze the quantitative results between the test group and the control group in corresponding indication.
- Therefore, it is not appropriate to provide cut-off in our ROU product, which is before confirming indication for each ROU product.

VEUPLEX™ Neuro 2p-A (GFAP, UCH-L) (for RUO)

- As a RUO product, it cannot be marked as a TBI assay, and should not be used to TBI(Traumatic Brain Injury)diagnosis(IVD). It can be used for various neurological RUO purposes such as Stroke, Alzheimer's and Parkinson's disease.

Application & Product - Sepsis diagnostics (VEUPLEX™ PCT test)

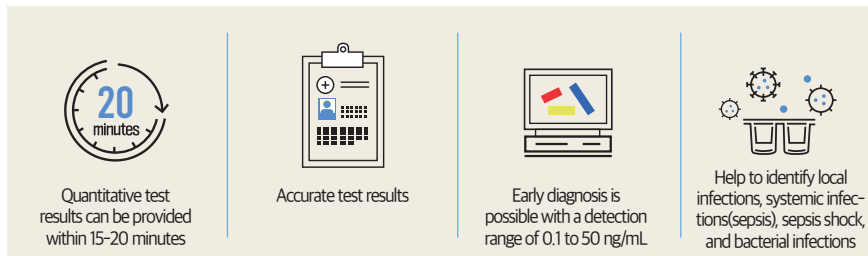
Procalcitonin (PCT) is a protein produced by thyroid C cells and is used as a biomarker for diagnosing sepsis. When inflammatory reactions such as bacterial infection or sepsis occur, Procalcitonin increases rapidly in the first two to six hours and reaches peak levels in six to 24 hours in the body. Therefore, it is a useful indicator to distinguish whether sepsis is caused by bacteria or another cause such as viral or fungal, and to prescribe appropriate antibiotics accordingly.

In the case of CRP, an inflammatory indicator, it takes about three to four days to reach the highest concentration, whereas procalcitonin reaches its peak concentration within a day, so it is possible to quickly determine whether to prescribe antibiotics.

The Cut-off concentration of procalcitonin is 0.5 ng/mL, which is less likely to result in infection, so antibiotic use is generally not recommended and antibiotic prescription decisions are required by combining the results of other infection markers and clinical findings of physicians.

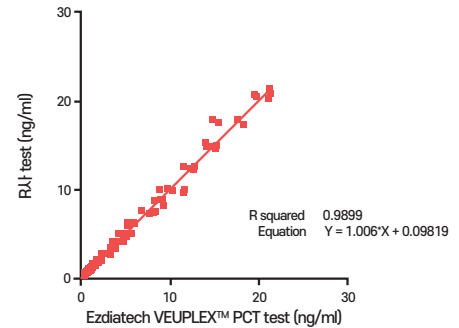
A medium concentration of 0.5 to 2 ng/mL implies a possibility of infection, in which case the use of antibiotics can be prescribed at the discretion of the physician. High levels above 2 ng/mL are at high risk of sepsis and indicate the possibility of severe infection, so early treatment with antibiotics may be necessary.

The VEUPLEX™ PCT test is an in vitro diagnostic medical device that quantifies procalcitonin (PCT) present in a person's serum with Fluoroimmunoassay (FIA) to help diagnose bacterial infections and sepsis.

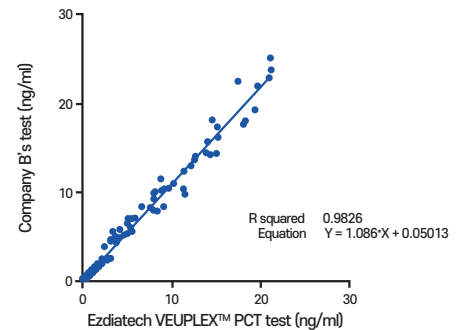


Performance

Correlation of Ezdiatech VEUPLEX™ PCT test with Company R's test



Correlation of Ezdiatech VEUPLEX™ PCT test with Company B's test



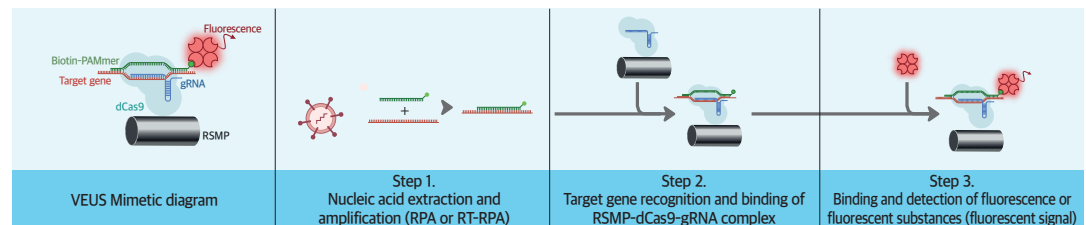
High accuracy: VEUPLEX™ PCT test highly correlated with comparative products.

Application & Product - Molecular diagnostics

From nucleic acid extraction to the multiplexed assay result, all-in-one

VEUS Molecular diagnostics Technology

Principle of the VEUS multiplexed molecular assay



Genetic scissor technology has been hailed as an innovative technology applicable to gene therapies, as a technology for recognizing and arbitrarily editing specific base sequence of genes within cells and has constantly evolved through several generations. The recent efforts to develop a new molecular diagnostic technology using genetic scissor technology are gaining attention. We have developed a molecular diagnostic assay that can perform the whole molecular assay process from nucleic acid extraction to the multiplexed molecular assay result within 50 minutes through applying our magnetic particles, RSMPs and genetic scissor technology (CRISPR-Cas) for multiplexed assays. Further, sensitivity and specificity can be increased due to reduction of the false positive rate that occurs often in rapid molecular diagnostic tests.

* Patent registration : 10-2021-0146635 (2020.11.02) / 10-2022-0073702(2022.06.16)

Multiplexed molecular diagnostics of respiratory viruses

Optimized for multiplexed assays	Time Spent 50 min	The VEUS multiplexed molecular assay is performed an all-in-one process from nucleic acid extraction to the multiplexed assay result, more than 95% accurate diagnostic results of COVID-19, Influenza A and B within ~ 50 minutes without experts required for operation.
Expert Not needed	Accuracy 95%	



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