

PLEXENSE

Biotech Company

2021.07

Company

Company Introduction

Plexense Inc.

Since its foundation in 2012, Plexense, Inc. has specialized in the development and production of rapid and cost-effective immunoassay platform for clinical, food and life sciences testing.

Proprietary technology of ACCEL ELISA provides up to 40X increase in sensitivity compared to conventional techniques. Results can be achieved in less than 45 minutes with a simplified one-wash protocol. ACCEL ELISA provides more accurate and faster immunoassay methods than traditional ELISA, mass spectrometry, and chromatography methods.

- Company name : Plexense Inc
CEO : Gibum Kim
Address : Dongbaekjungang-ro 16beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea 13th floor
Website : www.plexense.com
- US Company name : PlexenseBio, Inc
CEO : Lon Hatamiya
Address: 4136 E. Commerce Way, Suite 300
Sacramento, CA 95834

Business Areas

➤ Diagnostic kit development and manufacture

- Develops and manufactures diagnostic kits of human and animal diseases, agricultural and environmental, etc. under its own brand.

➤ Diagnosis service business (Future Business)

- Provides total diagnostic service such as molecular diagnosis based on ELISA test.

➤ Diagnostic Product CDMO

- Produce and deliver diagnostic kits coated with third-party diagnostic markers on our ELISA platform.

➤ Supply of dedicated diagnostic equipment (Future Business)

- Development and manufacture of diagnostic equipment for on-site diagnosis/large-scale testing.

Company

Major History

2012

Foundation of Plexense Inc.

2015

No. 1 institutional investors in the Idea Marketplace held by POSCO.

2017

Acquired ACCEL ELISA® patent

July

- Signed an agreement with Mayo Clinic for joint development of urine-based bladder cancer early diagnosis kit.

2019

June

- Signed a marker sharing agreement with the Bio Health Guard Research Center.

September

- Signed a Joint Business Contract with the U.S. Department of Agriculture for an early diagnosis kit for Citrus Green Disease.

2020

February

- Signed a contract for the development of a MERS diagnostic kit with the Korea Centers for Disease Control and Prevention.

May

- Developed a product jointly with the Korea Research Institute of Bioscience and Biotechnology.

December

- Signed a technology transfer contract with K-Bio for Neutralizing Antibody.
- Acquired of certification for COVID-19 serum Antibody diagnostic kit in 8 overseas countries.

2021

January

- Applied for approval for domestic use of COVID-19 serum antibody diagnostic kit

May

- Completion of COVID-19 Saliva Antigen diagnostic kit development.
- Alzheimer's disease diagnosis kit development contract (Dandi Bio)

June

- Acquisition of exclusive license for Orange Green Disease diagnostic marker from University of California, USA
- Signed a contract with the University of Florida for the right to use orange green disease diagnostic markers.
- Acquisition Europe CE of COVID-19 Saliva Antigen Diagnostic Kit.
- Completion of COVID-19 Neutralizing Antibody diagnostic kit development.

July



- Acquisition of export license for COVID-19 Saliva Antigen diagnostic kit.
- Acquisition approval for domestic use of COVID-19 serum Antibody diagnostic kit (Expected)

Company


Intellectual Property


Registered Patents : 14

Domestic: 10 

Overseas: 4  

Patent application: 22

Domestic: 4 

Overseas: 18  

▶ Major patents status

Nº	Patent No.	Contents	Date of registration
1	10-1793074	Biosensor and method of assaying substances using thereof	Oct,27,2017
2	10-1759894	Lab-on-a-chip and a method of fabricating thereof	Jul,14,2017
3	10-1758345	Biosensor for detecting target material using localized surface plasmon resonance and method for preparing the same	Jul,10,2017
4	10-1634332	Sensor for spectroscopic analysis	Jun,22,2016
5	10-1592241	Method of fabricating a device having an array of nano particles, surface plasmon based sensor, and method of assaying substances using the sensor	Feb,1,2016
6	10-1474844	Sensor for spectroscopic analysis and method of fabricating the sensor	Dec,15,2014
7	10-1335032	Cartridge and apparatus for the quantitative analysis of sample	Nov,25,2013
8	10-1328190	Cartridge for analyzing samples by Localized Surface Plasmon Resonance and the method thereof	Nov,5,2013

Major Business Contracts

Date	Parties	Content
17.07.01	US, Mayo Clinic	Signed joint development agreement with urine-based bladder cancer early diagnosis kit.
19.09.01	US, Department of Agriculture	Development of Citrus greening disease.
19.06.25	Bionano Health Guard Research Center	Joint R&D agreement for diagnosis and monitoring in bio convergence field.
20.02.12	Korea Centers for Disease Control and Prevention	Commercialization of serological evaluation agents for new viruses such as MERS Study on advanced ELISA platform.
20.12.28.	Osong, (K-BIO)	Transferred Covid-19 neutralizing antibody technology.
21.06	US California University	Obtained exclusive license for orange green disease diagnostic marker.
21.06	US Florida University	Signed a contract for preferential use of the orange green disease diagnostic marker.

Major National Projects

▶ Total of 16 successfully completed government projects

Terms	Department	Contents
17.06.20~19.06.19	SME Administration	Development of sensors for early diagnosis of animal diseases through the fusion of surface treatment technology and homogeneous immunological analysis technology
19.07.01~21.12.31	Korea Ministry of Health	Support for joint research and development of BT-based medical products (development of fluorescence-based on-site diagnosis system for early diagnosis of bladder cancer)
20.02.12~21.12.31	Korea Centers for Disease Control and Prevention	For commercialization of serological evaluation agents for new viruses such as MERS ELISA platform advancement research

Company

Production Facility Status

Production Capacity

Classification	Production/month
	Standard working hour (5days a Week, 8 hours a day, 1 Group)
Production line	2,880,000

- ▶ Established of MES (Manufacturing Execution System)

Smart Factory



Products

Overview of Diagnostic kit and Product Line

	Name of Product	Product Overview	Business Status	Development		Customer
				Clinical/ Certification	Release	
Human Diagnosis	COVID-19					
	Serum Antibody Detection Kit	COVID-19 Infection/History and immunity are tested to ensure effective vaccination.	-Excellent performance on marker from Bio-nano Health Guard Research Center under the Ministry of Science and Technology (Superior in performance comparison test by Roche) - 92% sensitivity showed in Korea Research Institute of Bioscience and Biotechnology.	-CE/ Other countries. -US FDA EUA Submission completed -Completed 1 st complement	Completed	-Red Cross, Inexpensive mass testing. -Diagnosis of asymptomatic or pre infected patients.
	Saliva Antigen Diagnosis Kit	Preemptive quarantine, regular screening with simple saliva.	-First saliva-based mass antigen diagnostic kit -Excellent sensitivity/low cost/fast compared to rapid kit. Clinical performance shows: 91.8% sensitivity.	-Free Sales, CE/ - Preparation on KFDA and US FDA EUA	July, 2021	-General hospitals, Military bases, Schools, Enterprises.. Etc densely populated area.
	Neutralizing Antibody Diagnosis Kit	Post-vaccination testing, vaccine monitoring	-Excellent marker from Bio-nao Health Guard Research Center. -Neutralizing Antibody testing market expected to grow according to the supply of vaccines.	-Free sales, -Preparation on KFDA, CE, US FDA EUA	Oct, 2021	-Detection of immunity after vaccination. -Measurement of immunity from recovering patients.
	Human Disease					
	Bladder Cancer diagnostic kit (Urine sample)	Urethroscopy, which involves pain, can be replaced with a urine sample within 30 mins to test result.	-3 other Companies got approval of sales in Bladder cancer diagnostic kit. Sensitivity shows 60% relativity low compared to Plexense's Bladder cancer diagnostic kit. -US) Mayo Clinic developed diagnostic kit using multiple markers from Plexense's kit: sensitivity shows 84%. -Developing on-site diagnostic kit with K-Bio health.	2022	2023	-Domestic Hospitals, Mayo Clinic
	Cortisol Stress Hormone test (Saliva sample)	Prognosis and early treatment of depression by diagnosis of stress hormone (Cortisol) with saliva sample.	-Early diagnosis of depression, measurement of stress level. Cushing's syndrome test - Salimatrix's products are on sale which takes 2 hours. -Our diagnostic kit is in the clinical stage for certification	2021	2022	-Domestic Hospitals, Schools, Obstetrics & Gynecology, postpartum care center, Prison, Military bases etc..
Canine Diagnosis	Heartworm Diagnostic Kit	Early diagnosis of animal diseases with high sensitivity by using ELISA methods on samples such as blood and feces	-The domestic market is mainly composed of Bionote's Rapid Kit. But because of low accuracy it requires retesting and confirming for positive samples by foreign products. - Plexense's high-sensitivity and speed mass testing kit is capable of securing part in new markets that respond to the growing demand of the pet diagnostics market. - As of June 2021, the number of pet owners reached 14.48 million in S.Korea, demand for diagnosis of various pet diseases increased and the need as well.	-Production Available -Planning for sales in 2022	Oct, 2022	- Large domestic animal diagnosis hospitals.
	Measles Diagnostic Kit					
	Coronavirus Diagnostic Kit					
	Enteritis diagnostic kit					

Products

Overview of Diagnostic kit and Product Line

	Product name	Product overview	Business Status	Development stage status		Customer
				Clinical test/Certification	Product release	
Diagnostics of agricultural and livestock products	Crop Diagnosis					
	Early diagnosis of Citrus Greening Disease Kit - Joint development with U.S. Department of Agriculture Research Institute/University of California/University of Florida/California Citrus Research Institute	Treatment for Citrus/Cotton disease is weak, and as a way to minimize damage caused by infection, implement early diagnosis and follow-up measures after diagnosing infection.	-Lack of methods of treatment, prevention and early diagnosis of global infectious diseases in countries such as Brazil, China, USA and Mexico. -Agreement for exclusive use of diagnostic markers of the University of California. - Agreement for the Exclusive Use of Markers of the U.S. Department of Agriculture, University of Florida	Not required	December 2021	-California Citrus Farming Association, Florida/California/China/Brazil, Orange producer.
	Early diagnosis of Cotton Blue Disease Kit - Joint development with U.S. Department of Agriculture Research Institute/Cornell University	(At the time of visual confirmation, the infection may already be progressed and there is a high possibility of transmission elsewhere.)	- A viral epidemic that causes enormous damage to cotton production in the southern United States, China, and India. - Lack of treatment, prevention, and early diagnosis. (The global market size is estimated at over 600 billion won) - Exclusive joint development with U.S. Department of Agriculture is in progress. - NDA with Cornell University and agreement for exclusive use of markers in progress .	Not required	December 2021	- U.S. The Cotton Inc. - Cotton manufacture company in US . - Cotton manufacture company in China. - Cotton manufacture company in India.
	Food Safety Screening					
	Aflatoxin M1 Test Kit	Increase of raw materials for agricultural products contaminated with various mycotoxins through global distribution of agricultural products.	- Currently in the process of supplying products to the Seoul Milk Research Institute. -In the case of a domestic importer of Hazardous Substances Rapid Test Kits, the annual sales are over 2 billion won. - After strengthening regulations by the Ministry of Food and Drug Safety in 2020, Seoul Milk invested 700 million won to introduce a large-scale testing process for hazardous substances in dairy products - The domestic market size is estimated at over 10 billion won, and the global market is estimated at over 1.4 trillion won, but there are no domestic hazardous substance test kit manufacturers. - Domestic food manufacturers (Seoul Milk, CJ, Maeil Milk, Harim, SPC, etc.)	-Production available. -No need for certification.	October 2021	-Domestic food manufacturers.
	Aflatoxin B1 Test Kit					
	Zearalenone test kit					
	Deoxynivalenol Test Kit					
	Fumonisin Test Kit					
	Ochratoxin test kit					
Residual Antibiotic Test						
Streptomycin test kit	It is used for detection in the broiler, pig, and poultry industries by strengthening the testing regulations for hazardous substances in food.	-Since 2017, it has been continuously sold to the U.S. Department of Agriculture and Citrus Research Institute -Domestic food manufacturers (Seoul Milk, CJ, Maeil Milk, Harim, SPC) 등	- In the production process. -No need for certification.	December 2021	-USDA Lab, Citrus Lab -Domestic food manufacturers.	
Oxytetracycline Test Kit						
Operating equipment	Based on microplate reader (Manual testing)	- Operated for semi-automatic test of small-scale samples and full-automatic test of large-scale samples				
	Full automated equipment test Providing Dynex DS2 equipment					