

1997



SENSOREX  
(Touch Panel)

UA Sure

Lactic Acid  
Analyzer

Agripro II

Telcare

HemoSmart  
GOLD

GlucoSure  
Autocode

Eclipse A1c

PT-1

AutoSure  
HT

MultiSure  
GC

MultiSure  
GK

GlucoSure  
POC

GlucoSure  
ADVANCE II

ApEXBio  
Taiwan

20<sup>th</sup> 17

五鼎生技  
ApEXBio  
Taiwan

# 法人說明會

12月 21日 ,2017



# 五鼎生技公司簡介

**ApEXBio**  
Taiwan

股票代號	上市公司 1733
產業別	醫療器材業
營運據點	總公司：新竹科學園區力行五路7號 桃園廠：桃園縣大園鄉五權村五青路70巷180號 蘇州五鼎生技醫療器械進出口貿易有限公司： 江蘇省蘇州工業園區科成路2號2樓106室 美國公司Omnis Health LLC： 505 Airpark Center Drive, Nashville, TN 37217,USA
成立日期	12/02/1997
上市日期	06/13/2000(1401上櫃) 09/17/2001(1733上市)
實收資本額	9.97億元
董事長/總經理	沈燕士 博士
員工人數	690人 (至 9/30/2017)

# 里程碑

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Taiwan

- 2002取得歐盟認證ISO 9001/13485
- 2003取得CE mark 認證
- 2005 農藥殘餘快速檢測產品上市
- 2006 FDA第二次查廠無缺失通過

- 2012 蘇州五鼎設立
- 2013 獲得經濟部第一屆中堅企業獎
- 2015 糖化血色素產品上市  
血糖/血酮雙功能套組產品上市  
獲亞太企業家精神獎
- 2016 FDA第四次查廠無缺失通過
- 2017 購買美國Omnis銷售公司

1997-2001

- 1997 五鼎設立
- 1998 血糖套組取得美國FDA 510K
- 1999 尿酸專利取得
- 2000 上櫃掛牌
- 2001 轉上市掛牌  
FDA查廠無缺失通過

2002-2006

2007-2011

- 2007 乳酸產品上市
- 2008 語音血糖產品上市
- 2009 桃園試片廠設立
- 2010 遠距雲端技術建置
- 2011 FDA第三次查廠無缺失通過
- 2011 優質企業通過海關認證

2012-2017

20<sup>th</sup> 17

# 歷年獲獎

**ApEXBio**  
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年份	獎項與產品
1999	竹科88年度創新產品獎---Glucosure Plus 第二代血糖機
2000	竹科89年度創新產品獎---尿酸測試儀
2001	國家生技醫療品質獎---血糖/尿酸雙功能測試儀
2002	第10屆經濟部科技發展獎 優等獎---血糖/尿酸雙功能測試儀
2003	竹科92年度研發成效獎
2006	竹科95年度創新產品獎---AgriPro農藥殘留快速檢測套組
2007	第15屆經濟部科技發展獎---傑出創新企業獎
2008	台北國際醫療展 創新產品獎---A1C糖化血色素測試儀

# 歷年獲獎

ApEXBio  
Taiwan

年份	獎項與產品
2009	免校正碼血糖測試儀獲得FDA 510(K)驗證並上市
2011	竹科100年度創新產品獎---A1C糖化血色素測試儀
2012	第四次榮獲富比士最佳200企業(2006/2007/2008/2012)
2013	經濟部第一屆前十大卓越中堅企業獎
2015	竹科105年度創新產品獎---血糖/血酮雙功能套組 生策會第12屆新創獎—寵物血糖/血酮雙功能套組

2017  
th

# 品質系統

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區域	主管機關	符合法規
台灣	TFDA	GMP
歐盟	CE	ISO 9001:2008 ISO 13485:2012/AC:2012 CE mark number:CE0197 ISO 15197:2015
美國	FDA	510K's FDA四次查廠無缺失通過 2001/2006/2011/2016
中國	CFDA	Medical Device Class II
加拿大	CMDCAS	ISO 13485:2003
日本	PMDA	
巴西	INMETRO	2017 查廠通過並取得認證

# 全方位健康產品檢測

1997



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# 血糖快速檢測儀 GlucoSure 系列

**ApEXBio**  
Taiwan

## ■ 簡易型

GlucoSure Plus  
速利測血糖測試儀



## ■ 專業型

GlucoSure ADVANCE  
欣瑞血糖測試系統



## ■ 語音型

GlucoSure Voice  
欣聲語音血糖測試儀



1997



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# 血糖免校正檢測儀

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GlucoSure Vivo  
欣活語音血糖測試儀



GlucoSure Light  
欣巧血糖測試儀



GlucoSure HT  
新速利測血糖測試儀



GlucoSure ADVANCE II  
欣瑞二代血糖測試儀



# 專業快速檢測系列

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## ■尿酸

UA Sure II 優速尿酸檢測儀



## ■乳酸

THE EDGE 競速乳酸測試系統



## ■血紅素

HemoSmart GOLD  
益紅測血紅蛋白分析儀



## ■糖化血色素

Eclipse A1c  
五鼎糖化血色素檢測儀



1997

17

# 多功能檢測儀MultiSure系列

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Taiwan

## ■ 血糖+尿酸

MultiSure必立康  
血糖/尿酸雙功能測試儀



## ■ 血糖+血酮

MultiSure GK 必立康GK  
血糖/血酮雙功能測試儀



## ■ 血糖+膽固醇

MultiSure GC 必立康GC  
血糖/膽固醇雙功能測試儀



## ■ 醫療專用 ■ 血糖+血酮

Glucosure POC  
欣舒測專業型連線測試儀



# 創新產品\_MultiSure GCTU

**ApEXBio**  
Taiwan

## MultiSure® GCTU

Blood Glucose and Cholesterol, Triglycerides and Uric Acid Monitoring System

**4 in 1**

ISO 15197:2015

GLU/CHO/TGI/UA  
Glucose, Cholesterol, Triglycerides and Uric Acid testing

PC link

Strip ejection

Bluetooth

Foil pack available

Back light

Glucose, Cholesterol, Triglycerides and Uric Acid testing

ApEXBio Taiwan

### MultiSure® GCTU *Glucose, Cholesterol, Triglycerides and Uric Acid monitoring system*

The MultiSure GCTU Monitoring System is a portable biosensor-based device for use at home or in a professional setting to conveniently measure the four important markers of metabolism\*; blood glucose, cholesterol, triglycerides, and uric acid all in one pocket-sized instrument.

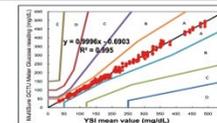
The MultiSure GCTU Monitoring System features a large backlit LCD screen designed for easy reading and requires very little blood sample as compared to standard laboratory testing. The wireless Bluetooth feature enables testing results to transmit seamlessly into a smart device for cloud storage, analysis, and record keeping. Test strips are individually packaged to minimize contamination and ensure optimal performance with every test. The MultiSure GCTU Monitoring System is one of its kind device designed with accuracy and ease of use in mind.

\*Kempf K, Martin S, and Döhning C et al. 2016. The Boehringer Ingelheim employee study (Part 2): 10-year cardiovascular diseases risk estimation. Occup Med (Lond).



#### ◀Glucose

Measurement Range : 20 - 600 mg/dL  
Sample Volume : ≥ 0.5 µL  
Quick Testing Time : 5 seconds  
Hematocrit : 10% - 70%  
Operating Temperature : 5 ~ 45°C  
Memory : 500 test results

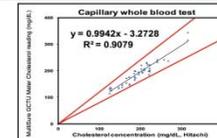


ISO 15197:2015		
Samples <100mg/dL		
+/-5mg/dL	+/-10mg/dL	+/-15mg/dL
143/186	180/186	186/186
76.9%	96.8%	100.0%
Samples ≥100mg/dL		
+/-5%	+/-10%	+/-15%
324/414	406/414	414/414
78.3%	98.1%	100.0%



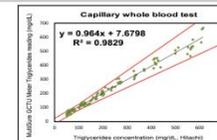
#### ◀Cholesterol

Measurement Range : 100 - 400 mg/dL  
Sample Volume : ≥ 3.6 µL  
Quick Testing Time : 60 seconds  
Hematocrit : 30% - 55%  
Operating Temperature : 10 ~ 40°C  
Memory : 200 test results



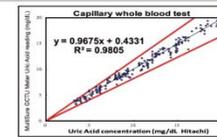
#### ◀Triglycerides

Measurement Range : 50 - 650 mg/dL  
Sample Volume : ≥ 1.2 µL  
Quick Testing Time : 60 seconds  
Hematocrit : 30% - 55%  
Operating Temperature : 18 ~ 38°C  
Memory : 100 test results



#### ◀Uric Acid

Measurement Range : 3 - 20 mg/dL  
Sample Volume : ≥ 2.5 µL  
Quick Testing Time : 10 seconds  
Hematocrit : 20% - 60%  
Operating Temperature : 10 ~ 38°C  
Memory : 200 test results



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Taiwan

No.7, Li-Hsin Rd. V, Hsinchu Science Park, Hsinchu, Taiwan, R.O.C.  
TEL: 886-3-5641952 / FAX: 886-3-5678302 / E-Mail: info@apexbio.com / Website: www.apexbio.com

Rev.10/17

# 創新產品\_GlucoSure VIVO<sup>Link</sup>

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**GlucoSure VIVO<sup>Link</sup>**  
Blood Glucose Monitoring System

ISO 15197:2015

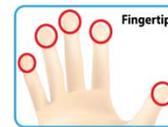
- Autocoding
- Talks in 2 languages
- Result in 6 seconds
- Bluetooth
- PC link
- Alternate site testing

ApEXBio Taiwan

## GlucoSure VIVO Link Blood Glucose Monitoring System

The GlucoSure VIVO Link Blood Glucose Monitoring System provides an easy and precise way to measure blood glucose using fresh capillary whole blood taken from fingertips, palms, or forearms. The GlucoSure VIVO Link has a large screen and talks clearly in 2 languages\* for easy understanding of operation and testing results. The GlucoSure VIVO Link's Bluetooth wireless feature enables testing results to seamlessly transmit into a smart device and share the data with healthcare providers instantly for better understanding and management of patients' condition.

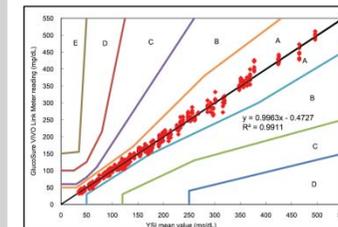
### More testing sites



### Specifications

- Measurement Range**  
20~600 mg/dL (1.1~33.3 mmol/L)
  - Coding Method**  
Automatic
  - Quick Testing Time**  
6 seconds
  - Sample Volume**  
0.6 µL
  - Operating Temperature**  
10°C~40°C
  - Memory**  
300 blood test results with date and time
  - Data Management**  
7, 14, and 30 days averaging
  - Additional Features**  
PC link  
Bluetooth  
Alternative site testing  
Talks in 2 languages\*
- \*Please inquire about language available from your local distributor.

### Precision and Accuracy performance according to ISO15197 : 2015



ISO 15197 : 2015		
Sample < 100 mg/dL		
±5 mg/dL	±10 mg/dL	±15 mg/dL
131 / 180	176 / 180	180 / 180
73%	98%	100.0%
Sample ≥100 mg/dL		
±5%	±10%	±15%
271 / 420	395 / 420	418 / 420
65%	94%	99.5%

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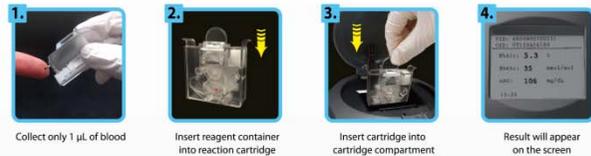
# 創新產品\_Eclipse PLUS

**ApEXBio**  
Taiwan

## Eclipse PLUS POC Analyzer

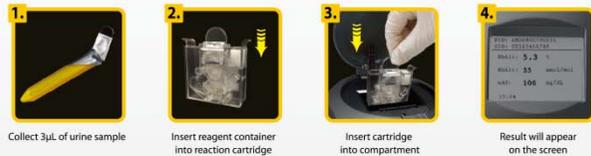
### Easy to use

HbA1c



1. Collect only 1 µL of blood  
2. Insert reagent container into reaction cartridge  
3. Insert cartridge into cartridge compartment  
4. Result will appear on the screen

Albumin/Creatinine Ratio • Microalbumin • Creatinine



1. Collect 3µL of urine sample  
2. Insert reagent container into reaction cartridge  
3. Insert cartridge into compartment  
4. Result will appear on the screen

### Peripherals (Optional)



- Printer
- Barcode Reader
- USB Cable

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Rev9/16



**4in1**



Fully automatic Quick result Small Sample USB connection Direct to printer Barcode scanner

**ApEXBio**  
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# 居家安心檢測系列 農藥殘留檢

ApEXBio  
Taiwan

測

## ■ 農藥殘毒快速檢驗

AgriPro



## ■ 農藥檢測系統

AgriPro II



1997



蔬菜/水果  
農藥殘留快速檢測

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Taiwan  
2017  
th

# 健康照護情境

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Taiwan

## Point of Care



POCT Server



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# 客製化開發專案

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- 與客戶共同合作開發「重症別護理連續性  
血糖監控系統」
- 運用現有技術平台替客戶開發肝功能檢測

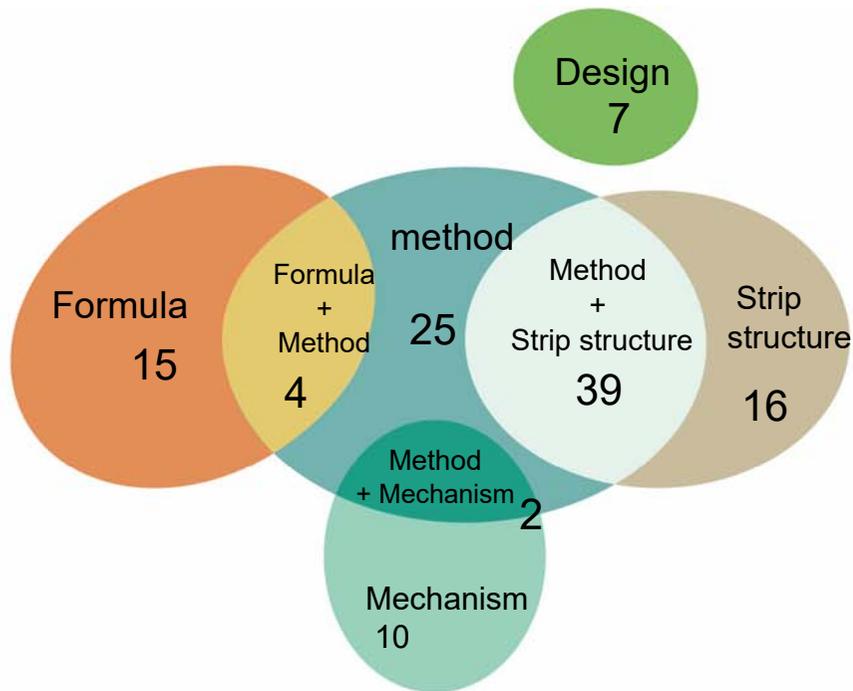
1997



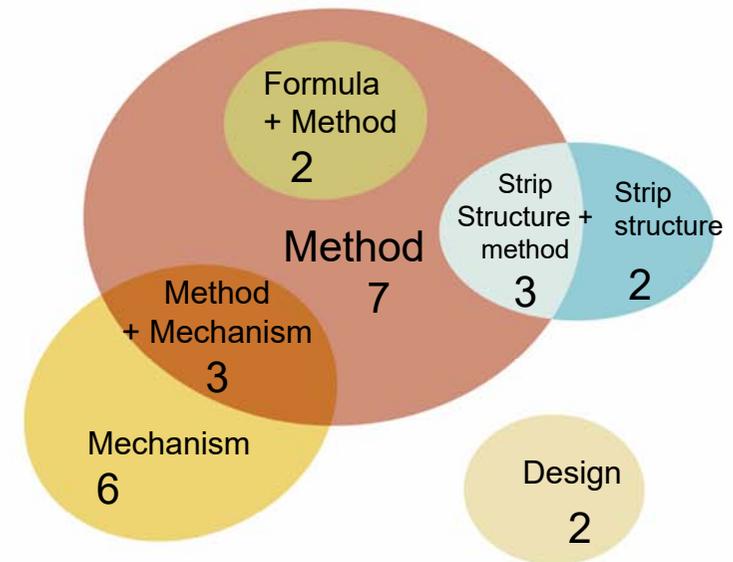
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# 研發專利保護

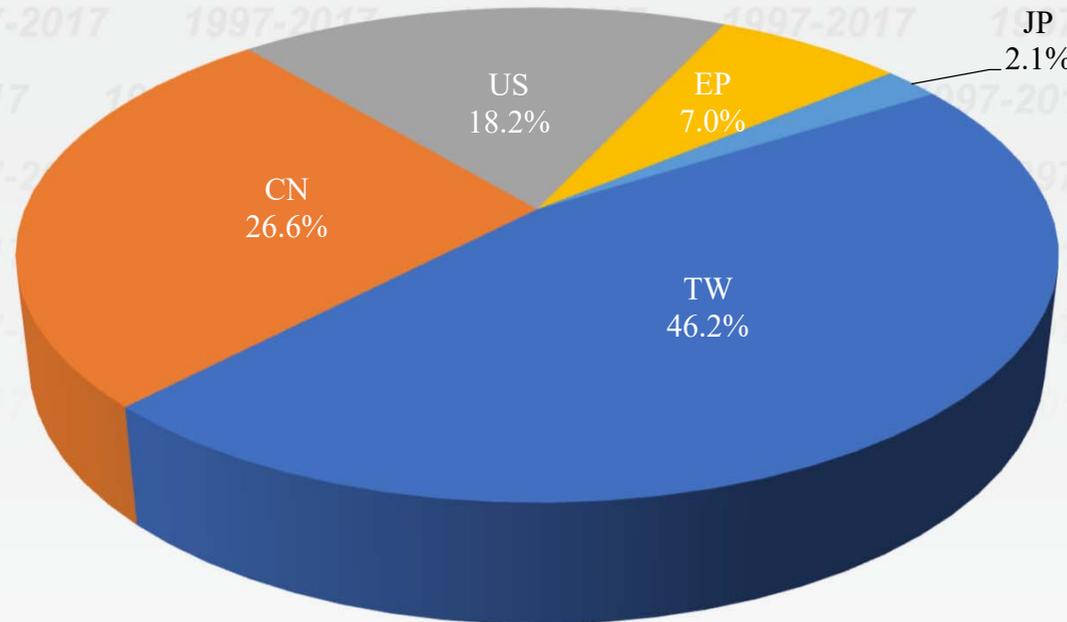
## ■ Electrochemical system (118 patents)



## ■ Non-electrochemical system (25 patents)



# 專利分佈區域



	TW	CN	US	EP	JP	Total
Grant number	66	38	26	10	3	143
Percentage , %	46.2%	26.6%	18.2%	7%	2.1%	100%

1997

2017  
th



# 財務分析

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	2013	2014	2015	2016	1-3Q / 2017
營收	1,829,221	1,788,929	1,847,454	1,763,284	1,323,240
毛利	568,443	524,673	547,135	476,843	267,751
營業利益	348,991	289,487	300,795	245,889	81,643
稅後淨利	374,464	271,010	261,538	2,956	38,786
每股盈餘	3.77	2.77	2.66	0.03	0.41
毛利率	31%	30%	29%	27%	20%
營業利益率	19%	17%	16%	14%	6%
淨利率	20%	15%	14%	0.2%	3%
儀器出貨量	705K	772K	1,063K	1,317K	1,217K
試片出貨量	832M	965M	965M	904M	718M

1997



SENSOREX (Touch Panel)

UA Sure

Lactic Acid Analyzer

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GlucoSure Autocode

Eclipse A1c

PT-1

AutoSure HT

MultiSure GC

MultiSure GK

GlucoSure POC

GlucoSure ADVANCE II

ApEXBio Taiwan

20<sup>th</sup> 17

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