



五鼎生技
Company Profile

APEXBIO
T a i w a n

2019/12/12

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： 1309 Elm Hill Pike, Nashville, TN 37210 ,USA
成立日期	12/02/1997
上市日期	06/13/2000(4101上櫃) 09/17/2001(1733上市)
實收資本額	10億元
董事長/總經理	沈燕士 博士
員工人數	751人 (至 10/31/2019)

公司沿革

1997 五鼎設立
1998 血糖套組取得FDA 510K
1999 尿酸專利取得
2000 上櫃掛牌
2001 轉上市掛牌

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 優質企業通過海關認證(AEO)

2017
• 取得美國Omnis過半股權
• 取得巴西認證
2018
• iCGM 生產線建置完成
• Ket-1 取得FDA 510K

1997-2001

2002-2005

2006-2011

2012-2015

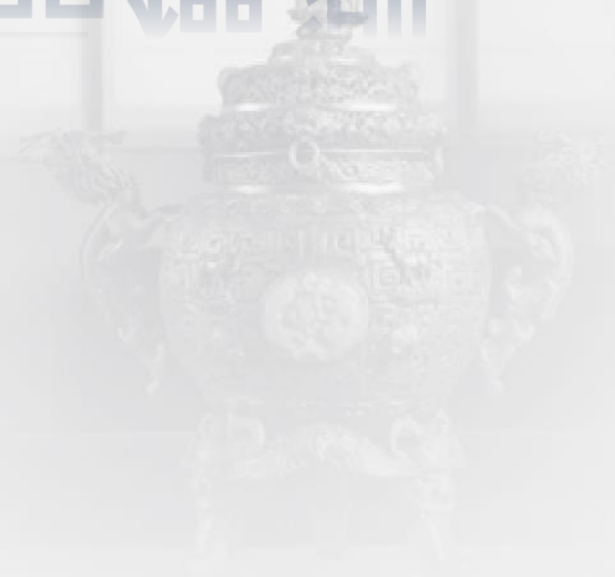
2016-2018

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

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
• 取得ISO14001/OHSAS18001認證

區域	主管機關	符合法規
台灣	TFDA	GMP
歐盟	CE	ISO 13485:2016 CE mark number:CE0197 EN 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
日本	PMDA	
巴西	ANVISA	2017 查廠通過並取得認證

全方位健康產品檢測



創新產品-GlucoSure A1c

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GlucoSure A1c HbA1c ANALYZER



1-Step Testing without Buffer
Portable/Handheld Operation
Enzymatic Electrochemistry
Dry Reagent Strip, No Refrigeration Required
Large Display
Bluetooth

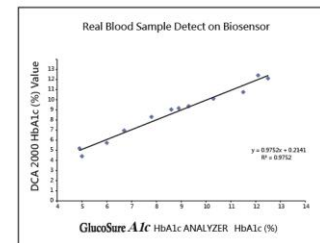
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GlucoSure A1c HbA1c ANALYZER

Glycated hemoglobin (HbA1c) is a form of hemoglobin chemically linked to glucose. It indicates one's blood glucose level over the past 60 to 90 days.

APEXBIO's hand-held GlucoSure A1c HbA1c Analyzer is first in the industry of one-step (no buffer solution required) to test accurately from a fingerstick with enzymatic electrochemistry based method dry reagent strips. It offers a fast and simple way to measure HbA1c in a professional setting and at home. Integrated Bluetooth connectivity to upload data for cloud storage and remote analysis, it's an all-around device benefits both physicians and patients.

HbA1c Testing Performance



Specifications

Methodology:	Enzymatic Electrochemistry	Power Supply:	1.5V AAA x 4
Sample Volume:	≥ 15µl	Display:	57L x 50W (mm)
Sample Type:	Capillary Whole Blood	Dimension:	93L x 96W x 26H (mm)
Testing Time:	≤ 6.5 Minutes	Weight:	123g w/o Battery
Testing Range:	4~14% 20~130 mmol/mol	Operating Condition:	Temperature 12~32°C Humidity ≤ 85%
Calibration:	Code Card	Storage Condition:	Temperature -20~50°C (Meter) 4~30°C (Strip) Humidity ≤ 85%
HCT Range:	20~60%		
Precision:	CV ≤ 4%		
Correlation:	≥ 95%		
Data Storage:	250 Tests		
Data Transfer:	USB, BLE		



APEX BIOTECHNOLOGY CORP.
No. 7, Li-Hsin 5th Rd., Hsinchu Science Park,
Hsinchu, Taiwan
Tel: 886-3-5641952 / Fax: 886-3-5678302
E-mail: info@apexbio.com / Website: www.apexbio.com



創新產品-Eclipse PLUS

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Eclipse MULTI-PURPOSE ANALYZER **PLUS**

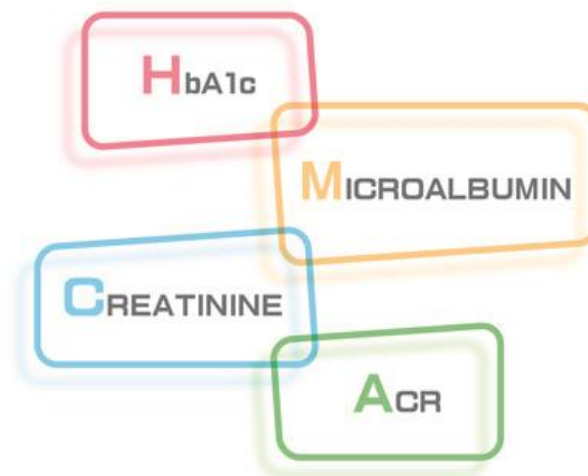
- Hemoglobin A1c
- Microalbumin
- Creatinine
- Albumin Creatinine Ratio (ACR)



Specifications

- Display: 5" Full Color LCD
- Display Unit:
HbA1c: %, mmol/mol, eAG
Microalbumin: mg/dL
Creatinine: mg/dL, mmol/L
ACR: mg/g, mg/mmol
- Operating/User Interface: Touch Panel Screen
- Data Port: Type-A USB
- Power Supply: 100~240V, 50/60Hz
- Dimension: 290L x 206W x 137H (mm)
- Weight: 1.6kg
- Operating Condition:
Temperature: 18~35°C/Humidity: <80%
- Analyzer Storage Condition:
Temperature: 4~50°C/Humidity: <80%
- Cartridge Storage Temperature:
HbA1c: 2~8°C
Microalbumin: 4~30°C
Creatinine: 4~30°C
ACR: 4~30°C
- Accessories: Optical Control Cartridge,
Barcode Scanner, Printer, USB Cable, Power Adaptor

Eclipse MULTI-PURPOSE ANALYZER **PLUS**



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創新產品-MultiSure GCTU

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MultiSure® GCTU

Blood Glucose, Cholesterol, Triglycerides and Uric Acid Monitoring System

4 in 1



Small Blood Sample



Hct Correction



Strip Ejector



LCD Backlight



Bluetooth



PC Link

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.

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

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MultiSure® GCTU

Glucose, Cholesterol, Triglycerides and Uric Acid Monitoring System

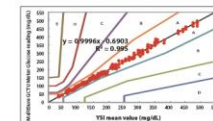
The MultiSure GCTU Monitoring System features a large backlit LCD screen designed for easy reading and requires very little blood sample as compared to standard laboratory testing. The wireless Bluetooth feature enables testing results to transmit seamlessly into a smart device for cloud storage, analysis, 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.



◀Glucose

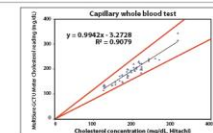
Measurement Range: 20~600 mg/dL
Test Time: 5 Seconds
Sample Size: $\geq 0.5 \mu\text{L}$
Hematocrit Range: 10%~70%
Operating Temperature: 5~45°C
Memory: 500 Test Results

ISO 15197:2013		
Sample < 100mg/dL		
+/-5mg/dL	+/-10mg/dL	+/-15mg/dL
143/186	180/186	186/186
76.9%	96.8%	100.0%
Sample $\geq 100\text{mg/dL}$		
+/-5%	+/-10%	+/-15%
324/414	406/414	414/414
78.3%	98.1%	100.0%



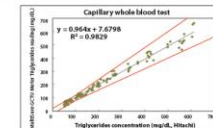
◀Cholesterol

Test Range: 100~400 mg/dL
Test Time: 60 Seconds
Sample Size: $\geq 3.6 \mu\text{L}$
Hematocrit Range: 30%~55%
Operating Temperature: 10~40°C
Memory: 200 Test Results



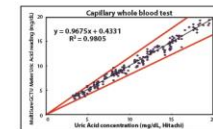
◀Triglycerides

Test Range: 50~650 mg/dL
Test Time: 60 Seconds
Sample Size: $\geq 1.2 \mu\text{L}$
Hematocrit Range: 30%~55%
Operating Temperature: 18~38°C
Memory: 100 Test Results



◀Uric Acid

Test Range: 3~20 mg/dL
Test Time: 10 Seconds
Sample Size: $\geq 1.5 \mu\text{L}$
Hematocrit Range: 20%~60%
Operating Temperature: 10~38°C
Memory: 200 Test Results



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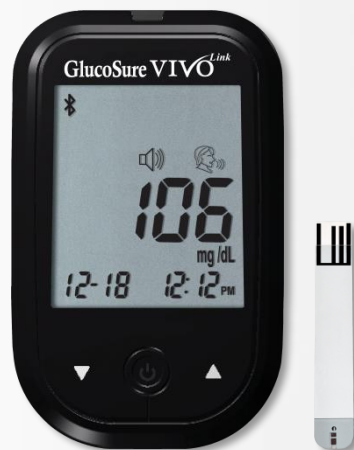


血糖免校正檢測儀

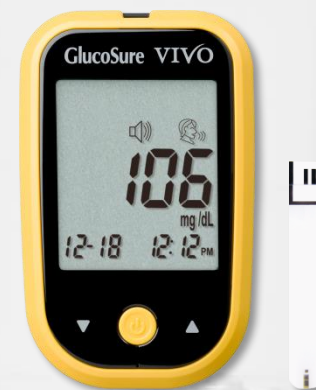
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欣活藍牙語音血糖測試系統
GlucoSure VIVO^{Link}



欣活語音血糖測試儀
GlucoSure VIVO



欣巧血糖測試儀
GlucoSure Light



新速利測血糖測試儀
GlucoSure HT



欣瑞二代血糖測試儀
GlucoSure ADVANCE II



專業快速檢測系列

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■ 血酮

欣酮血酮測試儀
KET-1



■ 尿酸

優速尿酸檢測儀
UA Sure II^{Link}



■ 尿酸

優速尿酸檢測儀
UA Sure II



■ 乳酸

競速乳酸測試系統
THE EDGE



■ 血紅素

益紅測血紅蛋白分析儀
HemoSmart GOLD



■ 糖化血色素

五鼎糖化血色素檢測儀
Eclipse A1c



多功能檢測儀MultiSure系列

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■ 血糖 + 尿酸

MultiSure必立康
血糖/尿酸雙功能測試儀



■ 血糖 + 血酮

必立康GK 血糖/血酮雙功能測試儀
MultiSure GK



■ 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



居家安心檢測系列 農藥殘留檢測

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■ 農藥殘毒快速檢驗

AgriPro



■ 農藥檢測系統

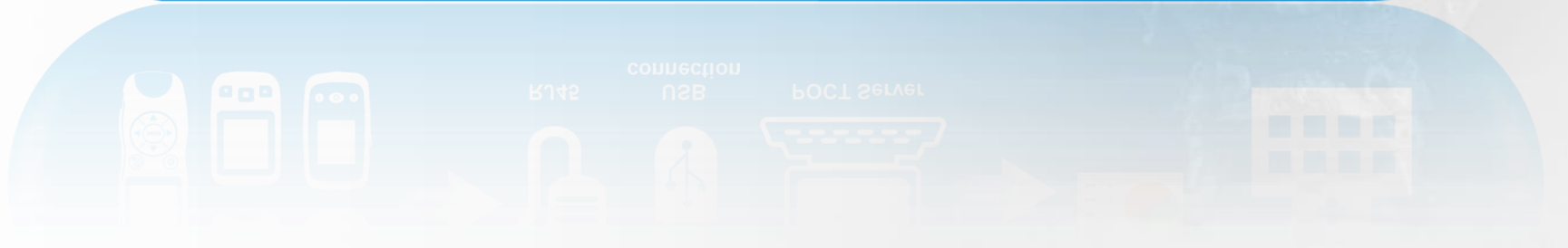
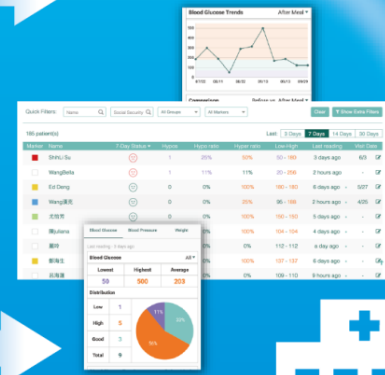
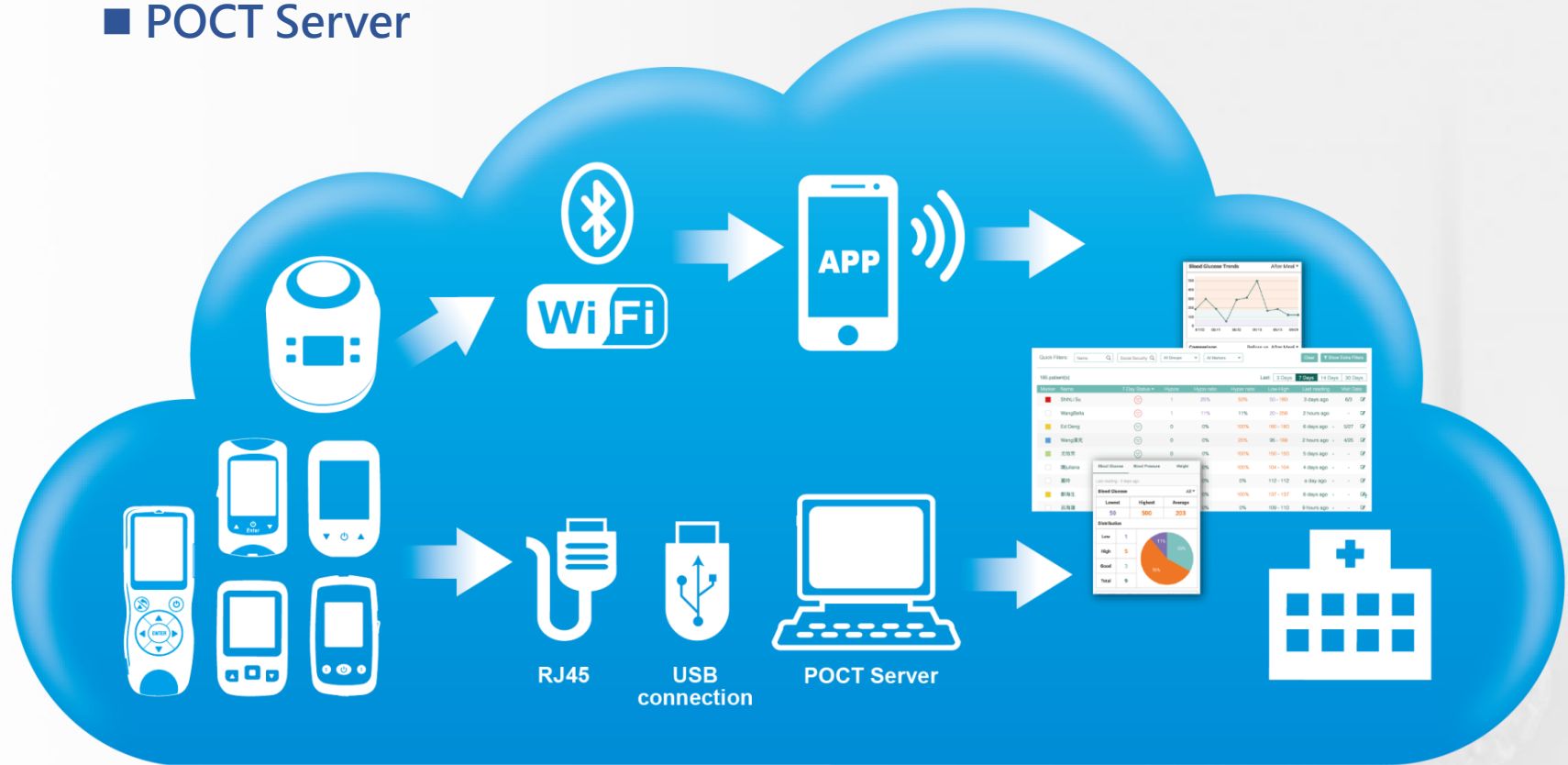
AgriPro II



蔬菜/水果
農藥殘留快速檢測

遠距健康照護情境

POCT Server





與國內外客戶共同合作開發產品

1. 新技術領域的創新產品
2. 利用五鼎技術平台衍生更多檢測產品並持續優化核心技術能力
3. 結合醫療物聯網與各醫院及醫療服務機構進行雲端整合

全球市場銷售佈局

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Taiwan



洲別	2017	2018	3Q19
美洲	48%	43%	45%
歐洲	40%	46%	45%
亞洲	11%	10%	9%
非洲	1%	1%	1%

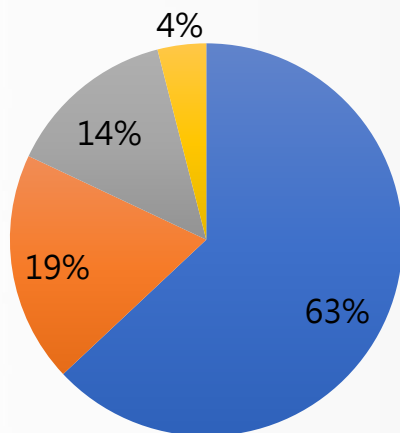
財務分析

	2017	2018	1-3Q19
營收	1,795,300	2,043,614	1,532,452
毛利	431,514	560,102	357,522
營業利益	160,999	227,352	289,591
稅後淨利	82,397	93,658	32,431
每股盈餘	0.86	0.95	0.33
毛利率	24%	27%	24%
儀器出貨量(台)	1,475K	1,638K	1,287K
試片出貨量(片)	936M	1,034M	819M

2018

產品占比

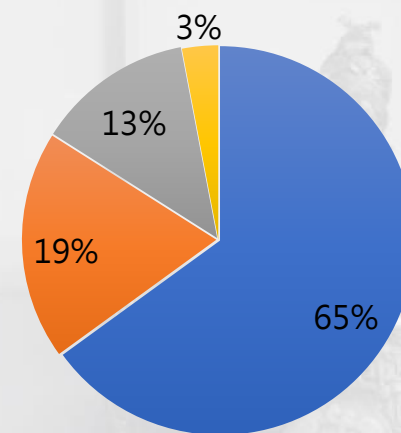
- 血糖類及糖化血色素
- 電極測試片
- 非血糖類測試套組
- 其他(附件)



1-3Q/2019

產品占比

- 血糖類及糖化血色素
- 電極測試片
- 非血糖類測試套組
- 其他(附件)



非血糖類測試套組

血紅素/血酮/尿酸/乳酸/膽固醇/農藥檢測 等



Thank You

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