

五鼎生技
Company profile

ApexBio
Taiwan

2020/08/24

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	756人 (至 7/31/2020)

公司沿革

ApexBio
Taiwan

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

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 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

1997



血糖免校正檢測儀

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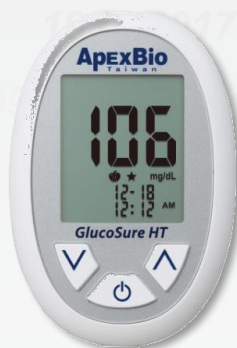


GlucoSure Vivo
欣活語音血糖測試儀

GlucoSure VivoLink
欣活藍牙語音血糖測試儀



GlucoSure HT
新速利測血糖測試儀



GlucoSure ADVANCE II
欣瑞二代血糖測試儀



GlucoSure Light
欣巧血糖測試儀



GlucoSure AutoCode
欣讚血糖測試儀



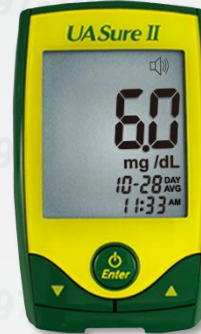
專業快速檢測系列

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■尿酸

UA Sure II 優速II尿酸檢測儀

UASure II Link 優速II尿酸藍牙檢測儀



■血紅素

HemoSmart GOLD

益紅測血紅蛋白分析儀



■乳酸

THE EDGE

競速乳酸測試系統



■血酮

KET-1

欣酮血酮測試系統



■糖化血色素

Eclipse A1c

五鼎糖化血色素檢測儀



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

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



1997

SENSEBOX
(Touch Panel)

UA Sure

Glucose

GlucoseSmart
GCU-D

GlucoseSure
AutoCode

Eclipse A1c

PF-1

Amesure
H7

Amesure
H7

MultiSure
GC

MultiSure
GK

MultiSure
GC

MultiSure
GK

MultiSure
GC

MultiSure
GK

MultiSure
GC

MultiSure
GK

創新產品_MultiSure GCTU

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MultiSure® GCTU

Blood Glucose and Cholesterol, Triglycerides and Uric Acid Monitoring System

4in1



Glucose, Cholesterol, Triglycerides and Uric Acid testing



PC link



Strip ejection



Bluetooth



Foil pack available



Back light



Glucose, Cholesterol, Triglycerides and Uric Acid testing

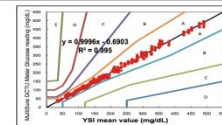
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MultiSure® GCTU Glucose, Cholesterol, Triglycerides and Uric Acid monitoring system

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



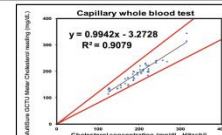
Measurement Range : 20 - 600 mg/dL
Sample Volume : $\geq 0.5 \mu\text{L}$
Quick Testing Time : 5 seconds
Hematocrit : 10% - 70%
Operating Temperature : 5 ~ 45°C
Memory : 500 test results

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 $\geq 100\text{mg/dL}$		
+/-5%	+/-10%	+/-15%
324/414	406/414	414/414
78.3%	98.1%	100.0%

Cholesterol



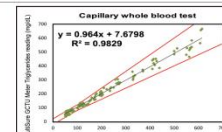
Measurement Range : 100 - 400 mg/dL
Sample Volume : $\geq 3.6 \mu\text{L}$
Quick Testing Time : 60 seconds
Hematocrit : 30% - 55%
Operating Temperature : 10 ~ 40°C
Memory : 200 test results



Triglycerides



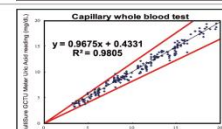
Measurement Range : 50 - 650 mg/dL
Sample Volume : $\geq 1.2 \mu\text{L}$
Quick Testing Time : 60 seconds
Hematocrit : 30% - 55%
Operating Temperature : 18 ~ 38°C
Memory : 100 test results



Uric Acid



Measurement Range : 3 - 20 mg/dL
Sample Volume : $\geq 2.5 \mu\text{L}$
Quick Testing Time : 10 seconds
Hematocrit : 20% - 60%
Operating Temperature : 10 ~ 38°C
Memory : 200 test results



ApexBio
Taiwan

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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**

HbA1c

MICROALBUMIN

CREATININE

ACR



APEXBIO



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創新產品_GlucoSure A1C

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A1c

HEMOGLOBIN A1c ANALYZER



Enzymatic Electrochemistry
Dry Reagent Strip, No Buffer Required
Portable/Handheld Operation
Voice Guidance & Bluetooth Embedded

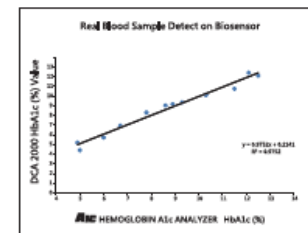
APEXBIO

A1c HEMOGLOBIN A1c 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 Hemoglobin A1c 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 voice guidance for step by step instruction and results readback, Bluetooth connectivity to upload data for cloud storage and remote analysis, it's an all-around device benefits both physicians and patients.

A1c Testing Performance



Specifications

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



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居家安心檢測系列 農藥殘留檢測

ApexBio
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■ 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

ApexBio
Taiwan

2017
th

SENSORIX
(Touch Panel)

UA-Sure

LabCheck-CL
Air

AgriPro II

ThermoPro
ECO-D

AutoScan
AutoCode

Galaxy ATx

PF-1

AquaSure
HT

MultiSure
SC

MultiSure
SK

Glucose
FUC

Glucose
ALCOHOL II

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The diagram illustrates the POCT Server architecture. It shows various devices (glucose meter, mobile phones, PDA) connecting to a central cloud. The cloud contains icons for Bluetooth, WiFi, and a mobile app. Data flows from these devices into the cloud, then to a POCT Server (laptop), which is connected via RJ45 and USB. The server outputs data to a hospital building icon. A detailed screenshot of the POCT Server interface is shown, displaying a table of patient data and a blood glucose trends graph.

POCT Server Interface Screenshot:

Monitor	Name	1 Day Change	2 Days Change	3 Days Change	4 Days Change	5 Days Change	6 Days Change	7 Days Change	8 Days Change	9 Days Change	10 Days Change	11 Days Change	12 Days Change	13 Days Change	14 Days Change	15 Days Change	16 Days Change	17 Days Change	18 Days Change	19 Days Change	20 Days Change
1	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
2	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
3	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
4	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
5	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
6	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
7	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
8	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
9	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	
10	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	

Blood Glucose Trends:

After Study 1

Before Study 1

100

80

60

40

20

0

10/10/17

10/11/17

10/12/17

10/13/17

10/14/17

10/15/17

10/16/17

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11/01/17

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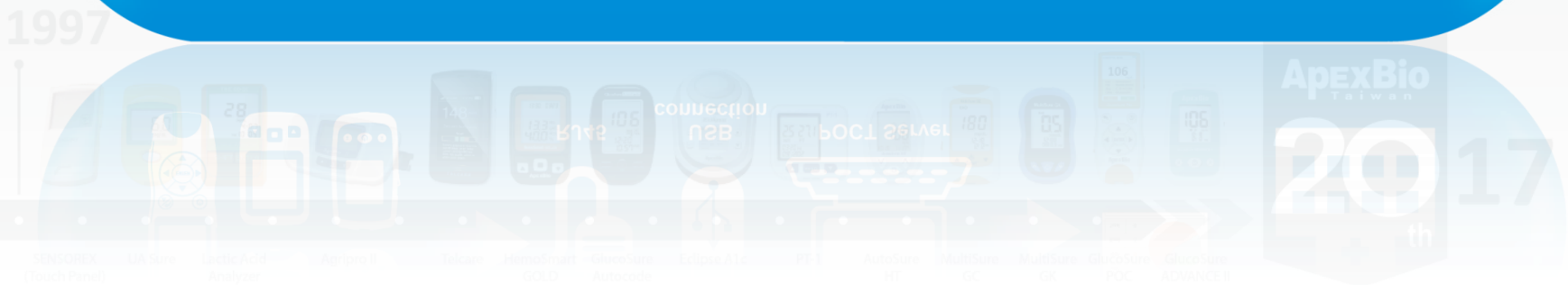
1/29/18

1/30/18

1/31/18

2/01/18

2/02/18



客製化開發產品專案

ApexBio
Taiwan



與國內外客戶共同開發產品

- 創新技術領域產品開發（電化學、光學、免疫學）
- 結合五鼎成熟技術平台衍生新產品，並持續優化產品
- 運用五鼎法規、品質、通路、臨床、製造優勢之結盟
- 結合醫療物聯網與醫院及醫療服務機構進行雲端整合

1997



ApexBio
Taiwan
2017
th

全球市場銷售佈局

ApexBio
Taiwan



洲別	2018	2019	2020/2Q
美洲	43%	41%	43%
歐洲	46%	48%	47%
亞洲	10%	10%	10%
非洲	1%	1%	0

1997



2017
th

財務分析

	2018	2019	2020/1H
營收	2,043,614	2,198,862	1,041,014
毛利	560,102	590,577	226,842
營業利益	227,352	203,276	47,129
稅後淨利	93,658	113,859	38,502
每股盈餘	0.95	1.14	0.39
毛利率	27%	27%	22%
儀器出貨量	1,638K	1,800K	879K
試片出貨量	1,034M	1,127M	536M

產品占比

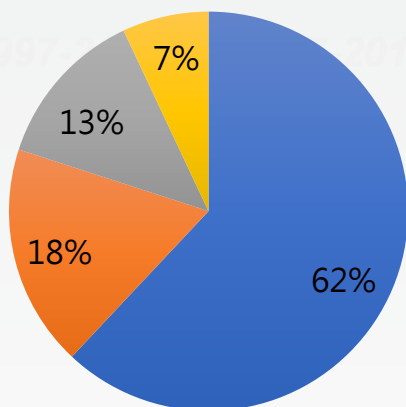
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2019

1H/2020

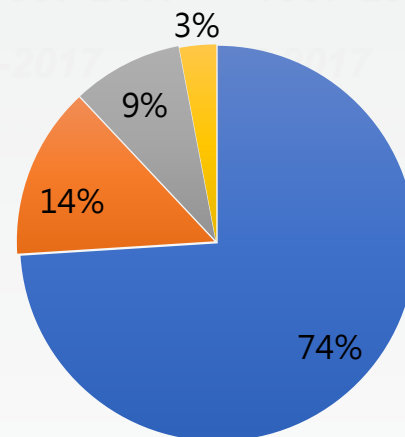
產品占比

- 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)



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

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Taiwan

2017th



Thank you

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