

五鼎生技
Company profile

ApexBio
Taiwan

2019/5/23

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	9.97億元
董事長/總經理	沈燕士 博士
員工人數	756人 (至 3/31/2019)

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)

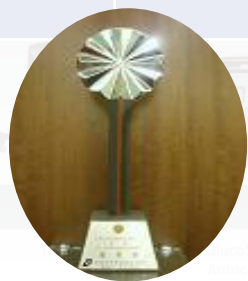
2017 取得美國Omnis
過半股權
取得巴西認證
2018 iCGM生產線建置
完成

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

歷年產品獲獎

獎項	年份與產品
竹科創新產品獎	-1999 GlucoSure Plus 第二代血糖機 -2000 尿酸測試儀 -2003 創新產品獎 -2006 AgriPro農藥殘留快速檢測套組 -2011 A1C糖化血色素測試儀 -2015 血糖/血酮雙功能套組(寵物/人用)
國家生技醫療品質獎	-2001 血糖/尿酸雙功能測試儀
經濟部科技發展獎	-2002 優等獎-血糖/尿酸雙功能測試儀
台北國際醫療展	-2008 創新產品獎---A1C糖化血色素測試儀



企業獲獎

年份	獎項與產品
2007	經濟部科技發展獎 - 傑出創新企業獎
2012	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

富比士亞洲前200強中小企業
2006/2007/2008/2012



卓越中堅企業獎
2013



品質系統

區域	主管機關	符合法規
台灣	TFDA	GMP
歐盟	CE	ISO 13485:2016 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
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



血糖快速檢測儀 GlucoSure系列

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■ 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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2017
th

血糖免校正檢測儀

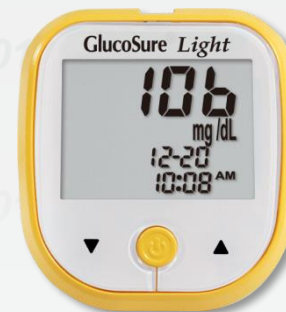
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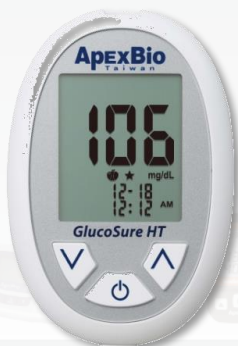
GlucoSure Vivo
欣活語音血糖測試儀



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



1997



SENSOROCK
(Touch Panel)



UA Sure



Lactate Sure



ApexBio II



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure



GlucoSure

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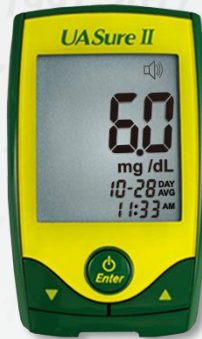
2017
th

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

SENSEBOX
(Touch Panel)

UA Sure II

Lactate
Analyzer

UA Sure II

HemoSmart
GOLD

Glucose
AutoCode

Eclipse A1c

PF-1

AutoSure
HT

AutoSure
HC

AutoSure
HC

AutoSure
HC

AutoSure
HC

AutoSure
HC

AutoSure
HC

AutoSure
HC

AutoSure
HC

AutoSure
HC

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

Recon

FormaSmart
GLU-D

Measure
AutoCode

Eclipse A1c

PF-1

ApoSure
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

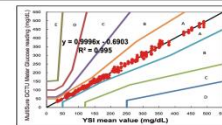
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MultiSure® GCTU Glucose, Cholesterol, Triglycerides and Uric Acid monitoring system

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



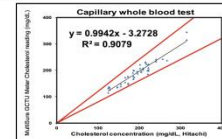
Measurement Range : 20 - 600 mg/dL
Sample Volume : $\geq 0.5 \mu\text{L}$
Quick Testing Time : 5 seconds
Hematocrit : 10% - 70%
Operating Temperature : 5 ~ 45°C
Memory : 500 test results

ISO 15197:2015		
Samples <100mg/dL		
$\pm 5\text{mg/dL}$	$\pm 10\text{mg/dL}$	$\pm 15\text{mg/dL}$
143/186	180/186	186/186
76.9%	96.8%	100.0%
Samples $\geq 100\text{mg/dL}$		
$\pm 5\%$	$\pm 10\%$	$\pm 15\%$
324/414	406/414	414/414
78.3%	98.1%	100.0%

Cholesterol



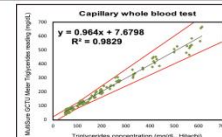
Measurement Range : 100 - 400 mg/dL
Sample Volume : $\geq 3.6 \mu\text{L}$
Quick Testing Time : 60 seconds
Hematocrit : 30% - 55%
Operating Temperature : 10 ~ 40°C
Memory : 200 test results



Triglycerides



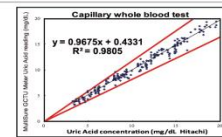
Measurement Range : 50 - 650 mg/dL
Sample Volume : $\geq 1.2 \mu\text{L}$
Quick Testing Time : 60 seconds
Hematocrit : 30% - 55%
Operating Temperature : 18 ~ 38°C
Memory : 100 test results



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

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

創新產品_GlucoSure VIVOLink

ApexBio
Taiwan



GlucoSure VIVOLink
Blood Glucose Monitoring System

ISO 15197:2015

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

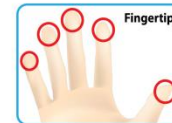
ApexBio Taiwan

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

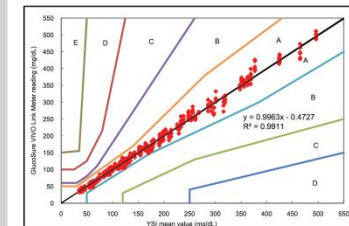


Specifications

- 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%	

ApexBio
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

創新產品_Eclipse PLUS

ApEXBio
Taiwan

Eclipse PLUS POC Analyzer

Easy to use //

HbA1c



Collect only 1 µL of blood



Insert reagent container into reaction cartridge



Insert cartridge into cartridge compartment



Result will appear on the screen

Albumin/Creatinine Ratio • Microalbumin • Creatinine



Collect 3µL of urine sample



Insert reagent container into reaction cartridge



Insert cartridge into compartment



Result will appear on the screen

Peripherals (Optional) //



- Printer
- Barcode Reader
- USB Cable

ApEXBio
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.9/16



Albumin/Creatinine Ratio (ACR)



Microalbumin



Creatinine



4in1



Fully automatic



Quick result



Small Sample



USB connection



Direct to printer



Barcode scanner

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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

1997



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Taiwan
2017
th

健康照護情境

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Taiwan



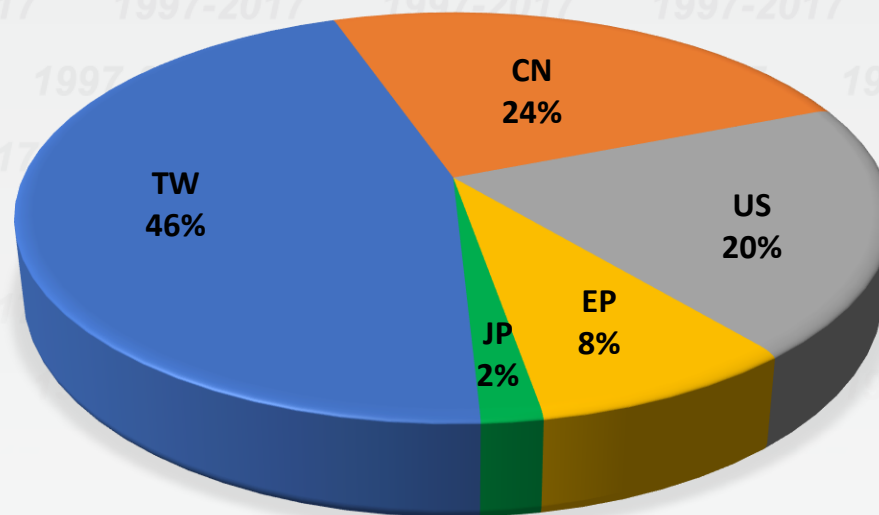
客製化開發專案

- 與客戶共同合作開發「重症別護理連續性
血糖監控系統」
 - 已進入第二里程開發階段

1997



專利分佈區域



	TW	CN	US	EP	JP	Total
Grant number	71	38	31	13	3	156
Percentage , %	45.5%	24.4 %	19.9 %	8.3 %	1.9 %	100 %

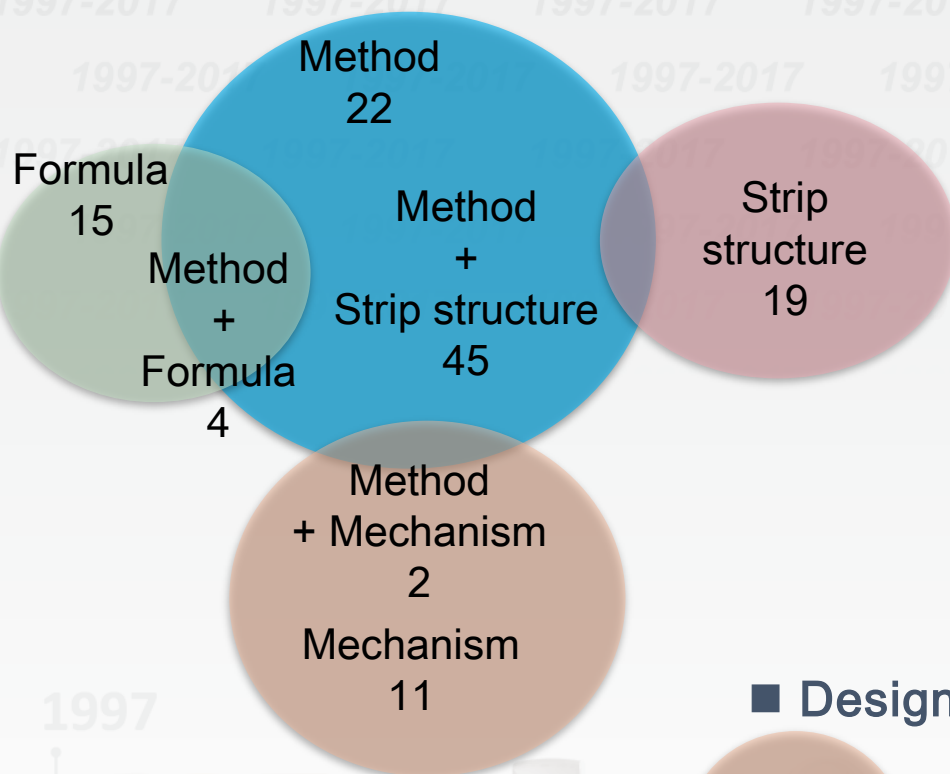
1997

2017
th

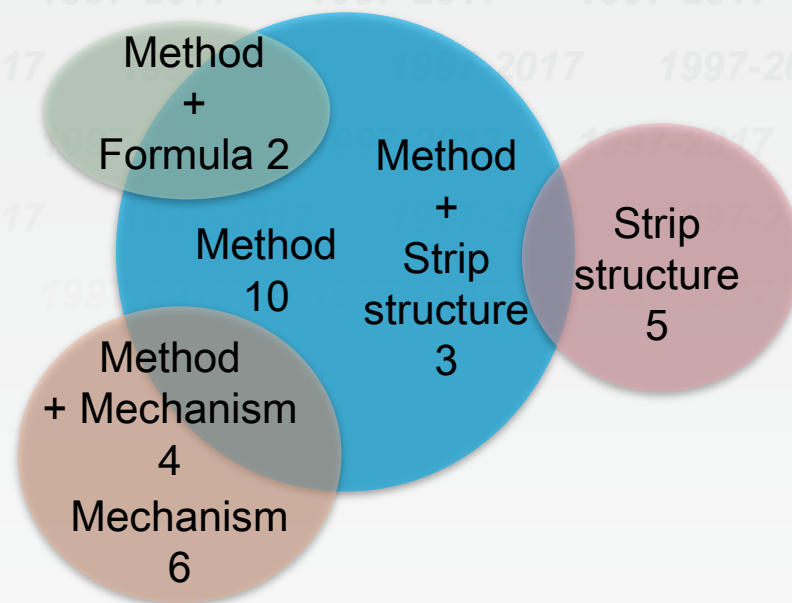


研發專利保護

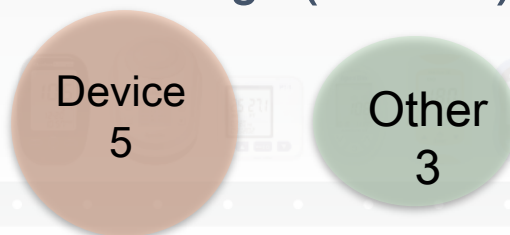
■ Electrochemical system (118 cases)



■ Optical system (30 cases)



■ Design (8 cases)



1997



全球市場銷售佈局

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洲別	2016	2017	2018	1Q19
美洲	54%	48%	43%	45%
歐洲	32%	40%	46%	46%
亞洲	13%	11%	10%	8%
非洲	1%	1%	1%	1%

1997



SENSEBOX
(Touch Panel)

UA-Sure

Lacta-Pro CI

ApexBio

Relevo

PrimeSmart

Glucose

Eclipse Kit

HT

BC

AK

POC

ALCOHOL II

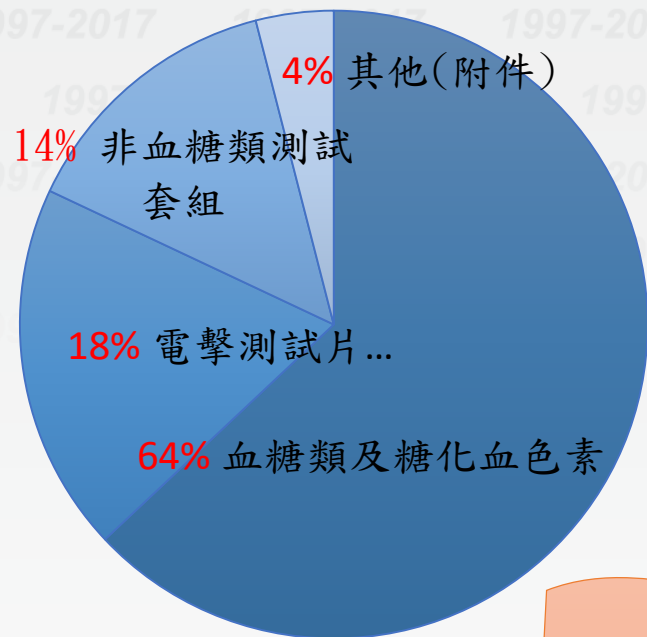
財務分析

	2015	2016	2017	2018	1Q19
營收	1,847,454	1,763,284	1,795,300	2,043,614	524,934
毛利	547,135	476,843	431,514	560,102	121,959
營業利益	300,795	245,889	160,999	227,352	34,660
稅後淨利	261,538	2,956	82,397	93,658	21,532
每股盈餘	2.66	0.03	0.86	0.95	0.22
毛利率	29%	27%	24%	27%	23%
營業利益率	16%	14%	9%	11%	7%
淨利率	14%	0.2%	4%	5%	4%
儀器出貨量	1,063K	1,287K	1,475K	1,638K	473K
試片出貨量	965M	901M	936M	1,034M	272M

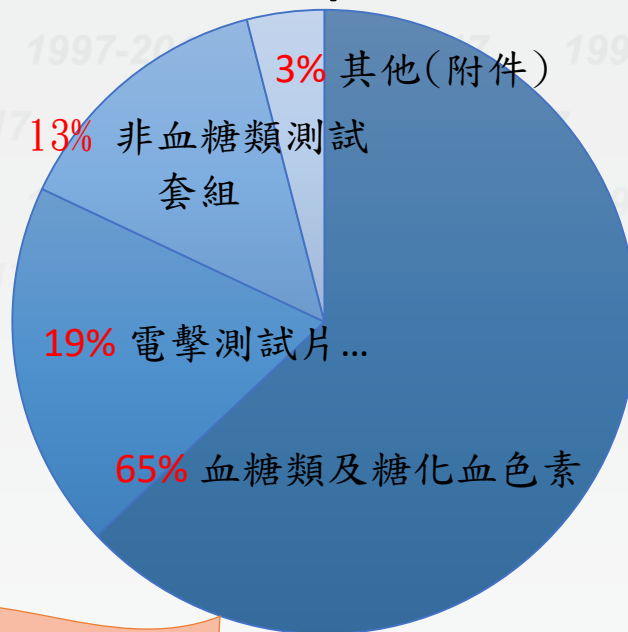
產品占比

ApexBio
Taiwan

2018



1Q/2019



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

1997



SENSEBOX
(Touch Panel)

UA-Sure

Lactate-CU
Ac

Agilent II

Re...

GG-D

Alco...

BT



Glucose
POC



Glucose
ACCU-CHIE II

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2017
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Thank you

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