



五鼎生技
Company profile

ApexBio
Taiwan

2019/06/13

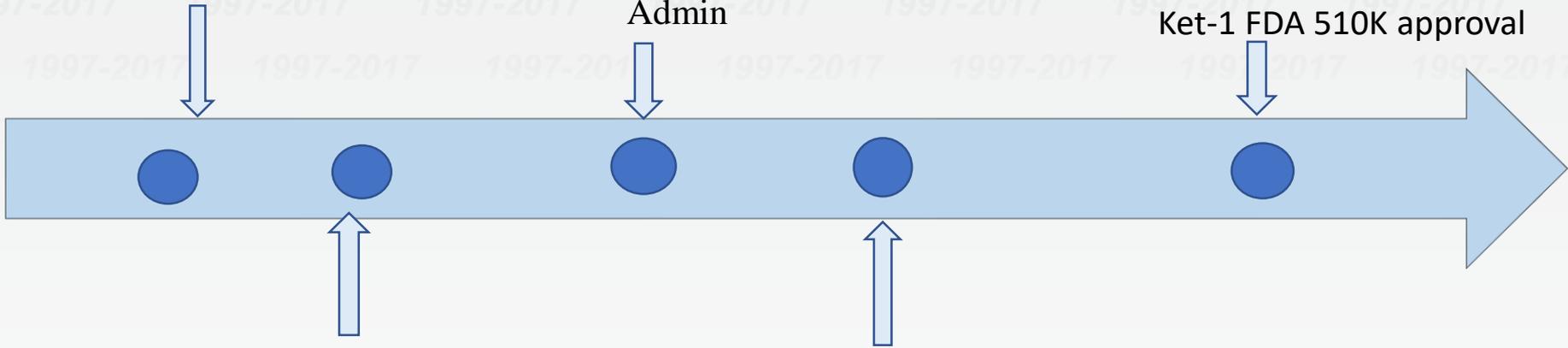
Company profile

ApEXBio
Taiwan

Stock #	TSEC 1733
Industry	IVD Medical Device
Operation Locations	Head quarter: No. 7, Li-Hsin 5 th Rd., Hsinchu Science Park, Hsinchu, Taiwan Tao Yuan Factory: No. 180, Lane 70, Wuqing Rd., Dayuan Dist., Taoyuan City 337, Taiwan Suzhou Corp.: Room 106, No.2, Kecheng Road, SIP, Suzhou, China Omnis Health LLC : 1309 Elm Hill Pike, Nashville, TN 37210 , USA
Started	12/02/1997
IPO	06/13/2000(4101 OTC) 09/17/2001(1733 TSEC)
Capital	NTD997 Million
Chairman/CEO	Thomas Shen PhD
Employees	756 people (upto 03/31/2019)

Milestone

- 1997 ApexBio set-up
- 1998 BGM FDA 510K approval
- 1999 Uric Acid patent granted
- 2000 IPO listed to Taiwan OTC
- 2001 Transit IPO listed to TSEC
- 2007 Lactate launch
- 2008 Voice BGM launch
- 2009 Taoyuan factory set-up
- 2010 Tele-health tech build-up
- 2011 AEO certified by Customs Admin
- 2017 Acquired Omnis Health LLC 98%
Pass Brazil INMETRO on-site audit
- 2018 iCGM production line set-up
Ket-1 FDA 510K approval



- 2002 ISO 9001/13485 notified
- 2003 CE IVDD notified
- 2005 Pesticide residues check product launch
- 2012 ApexBio Suzhou Corp set-up
- 2013 1st Taiwan MITTELSTAND Award from MOEA
- 2015 HbA1C/MultiSure GK products launch
APEA Award Outstanding Category
ISO14001/OHSAS18001 notified



Product Awards

Award	Year and products
HsinChu Park Innovation	-1999 GlucoSure Plus Glucose Monitoring System -2000 Uric Acid Monitoring System -2003 R&D Accomplishment Awards -2006 AgriPro -2011 HbA1C -2015 Multisure GK (for Human/Animal)
National Biotech & Medical Care Quality Award	-2001 Multisure GU
National Industrial Innovation Award	-2002 Multisure GU
Taipei MediPharma Innovation Award	-2008 HbA1C



Company Awards

Year	Award
2007	15 th National Industrial Innovation Award -- Outstanding Enterprise Innovation Award
2012	Forbes Asia's 200 Best Under A Billion-- 2006/2007/2008/2012
2013	The 1st Taiwan Mittelstand Award

Forbes Asia's 200 Best Under A Billion



The Taiwan Mittelstand Award



Quality system

Region	The Authority	Regulatory compliance
Taiwan	TFDA	GMP
EU	CE	ISO 13485:2016 CE mark number:CE0197 ISO 15197:2015
USA	FDA	510K's FDA on-site audit w/o 483 citations 2001/2006/2011/2016
China	CFDA	Medical Device Class II
Japan	PMDA	
Brazil	ANVISA	2017 passed on-site audit

Product profile

1997



Blood Glucose Monitoring Systems

■ Simple

GlucoSure Plus
速利測血糖測試儀



■ Professional

GlucoSure ADVANCE
欣瑞血糖測試系統



■ Voice

GlucoSure Voice
欣聲語音血糖測試儀



1997



Blood Glucose Monitoring Systems

ApexBio
Taiwan

GlucoSure Vivo
欣活語音血糖測試儀



GlucoSure Light
欣巧血糖測試儀



No coding series

GlucoSure HT
新速利測血糖測試儀



GlucoSure ADVANCE II
欣瑞二代血糖測試儀



1997



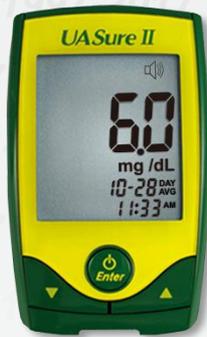
ApexBio
Taiwan
2017
th

Professional Monitoring System

ApexBio
Taiwan

■尿酸 Urine Acid

UA Sure II 優速尿酸檢測儀



■乳酸 Lactate

THE EDGE 競速乳酸測試系統



■血紅素 Hemoglobin

HemoSmart GOLD

益紅測血紅蛋白分析儀



■糖化血色素 A1C Hemoglobin

Eclipse A1c

五鼎糖化血色素檢測儀



1997

SINSONEX
(Touch Panel)

UA Sure II
ApexBio

HemoSmart
GOLD

MAXIMUM
Automatic

Eclipse A1c

PHI

ApexBio
HT

MAXIMUM
GC

17

Multi-functional System

ApexBio
Taiwan

■ 血糖+尿酸 Glucose & Urine Acid

MultiSure 必立康

血糖/尿酸雙功能測試儀



■ 血糖+血酮 Glucose & Ketone

MultiSure GK 必立康GK

血糖/血酮雙功能測試儀



■ 血糖+膽固醇 Glucose & Cholesterol

MultiSure GC 必立康GC

血糖/膽固醇雙功能測試儀



■ 血糖+血酮 Glucose & Ketone

GlucoSure POC (for Hospital)

欣舒測專業型連線測試儀



1997

MultiSure
(Touch Panel)

MultiSure
GC

MultiSure
GK

New product - MultiSure GCTU

ApexBio
Taiwan

MultiSure® GCTU

Blood Glucose and Cholesterol, Triglycerides and Uric Acid Monitoring System



GLU/
CHO/
TG/
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

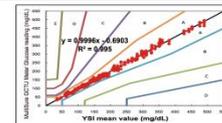
ApexBio
Taiwan

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



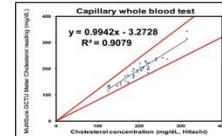
Measurement Range : 20 - 600 mg/dL
Samples : $\geq 0.5 \mu\text{L}$
Quick Testing Time : 5 seconds
Hematocrit : 10% - 70%
Operating Temperature : 5 ~ 45°C
Memory : 500 test results

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

◀ Cholesterol



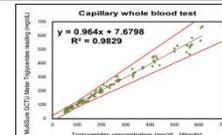
Measurement Range : 100 - 400 mg/dL
Sample Volume : $\geq 3.6 \mu\text{L}$
Quick Testing Time : 60 seconds
Hematocrit : 30% - 55%
Operating Temperature : 10 ~ 40°C
Memory : 200 test results



◀ Triglycerides



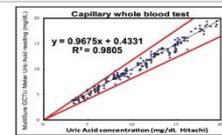
Measurement Range : 50 - 650 mg/dL
Sample Volume : $\geq 1.2 \mu\text{L}$
Quick Testing Time : 60 seconds
Hematocrit : 30% - 55%
Operating Temperature : 18 ~ 38°C
Memory : 100 test results



◀ 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

New product-GlucoSure VIVO^{Link}

ApEXBio
Taiwan

GlucoSure VIVO^{Link} Blood Glucose Monitoring System

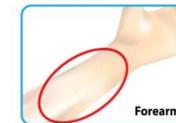
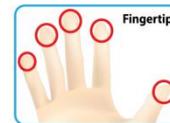
- Autocoding
- Talks in 2 languages
- Result in 6 seconds
- Bluetooth
- PC link
- Alternate site testing

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

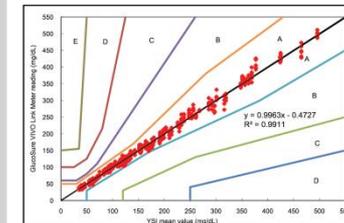


Specifications

- **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

New Product - Eclipse PLUS

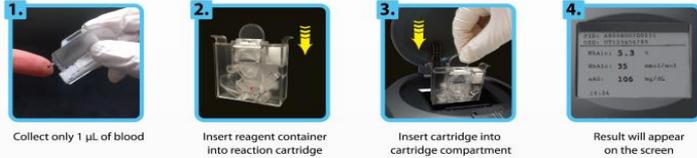
ApexBio
Taiwan

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)



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



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

ApexBio
Taiwan

Telehealth care network



Point of Care

APP

POCT Server

Quick Filters: Name | Social Security | All Data | All Names | Clear | Show Extra Filters

185 patient(s)	7 City Status	Hypert	Hypert ratio	Diabet ratio	Low-Hgt	Last recding	Visi Days
SHIH Su	1	25%	52%	35-180	3 days ago	623	Q
WangBella	1	11%	11%	35-256	2 hours ago	-	Q
Est Deng	0	0%	100%	180-180	6 days ago	527	Q
WangWei	0	0%	25%	35-180	2 hours ago	425	Q
文怡	0	0%	100%	150-150	5 days ago	-	Q
Wyllana	0	0%	100%	134-134	4 days ago	-	Q
陳昇	0	0%	0%	112-1	-	-	Q
郭慶生	0	0%	100%	137-1	-	-	Q
总数量	50	500	203	3%	0%	139	

Blood Glucose
 Lowest: 50 | Highest: 500 | Average: 203
 Distribution: Low (1), High (5), Good (3), Total (9)

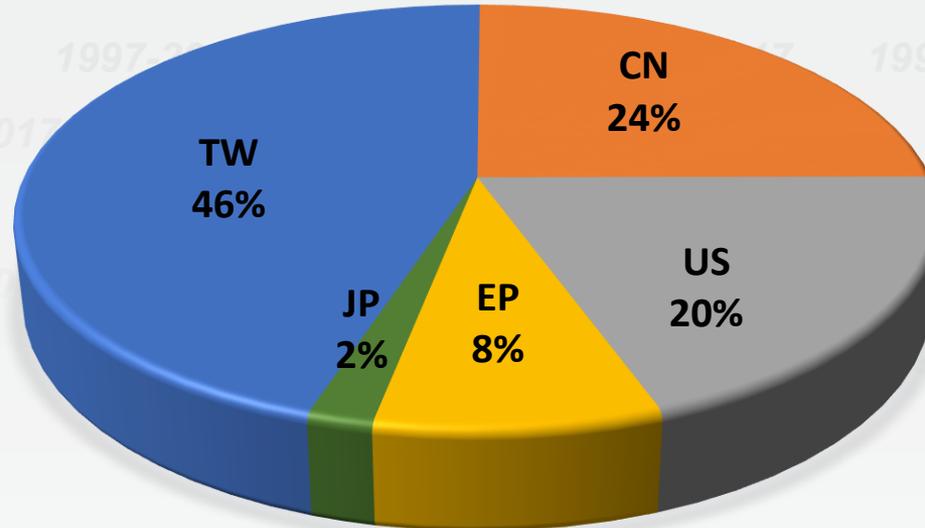
NRE projects with customers

- Continuous Glucose Monitoring System for intensive care
-- into 2nd milestone stage

1997



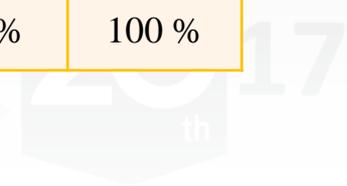
Patent Distribution By Region



	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 %

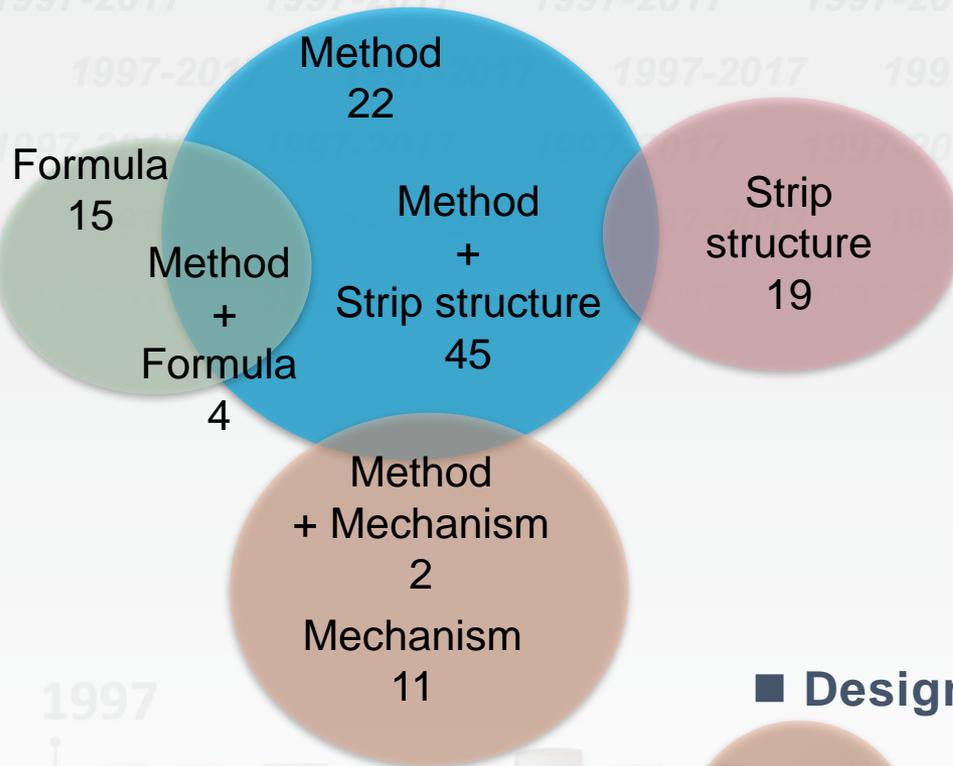
區域

1997

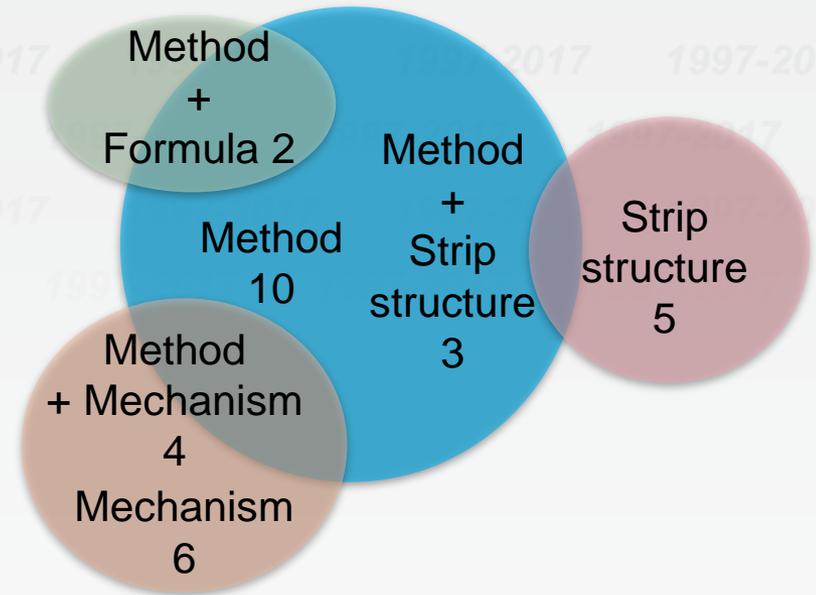


Patent granted

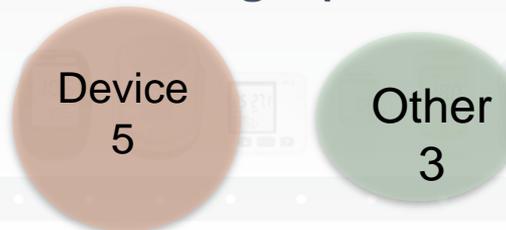
■ Electrochemical system (118 cases)



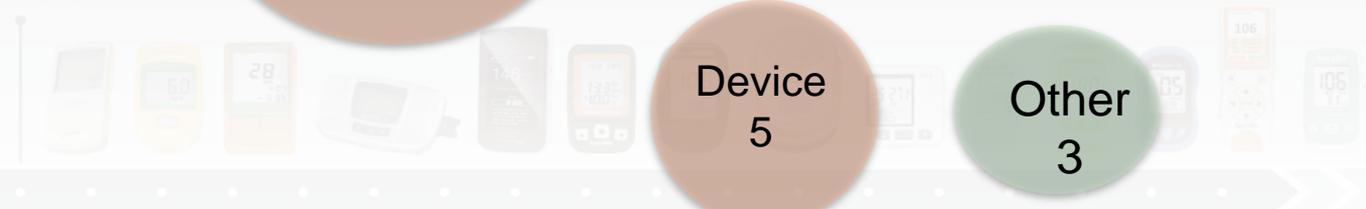
■ Optical system (30 cases)



■ Design (8 cases)



1997



Global sales distribution



Territory	2016	2017	2018	1Q19
USA	54%	48%	43%	45%
EU	32%	40%	46%	46%
Asia	13%	11%	10%	8%
Africa	1%	1%	1%	1%

1997



Finance Performance

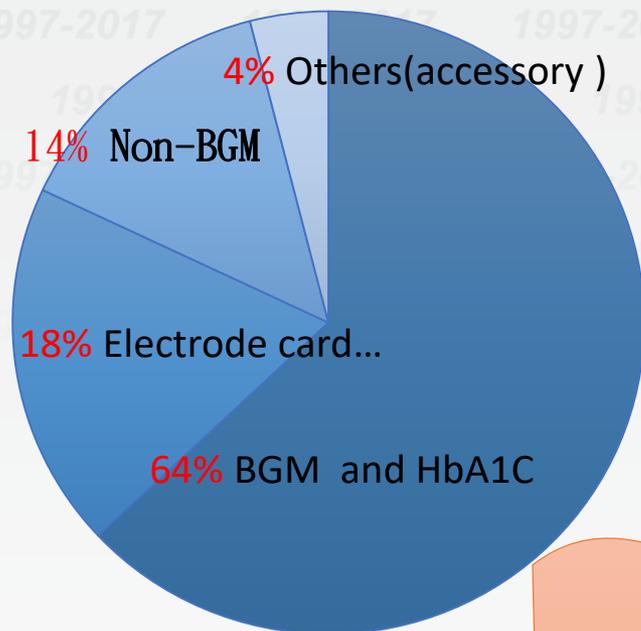


(NT\$ 1,000)

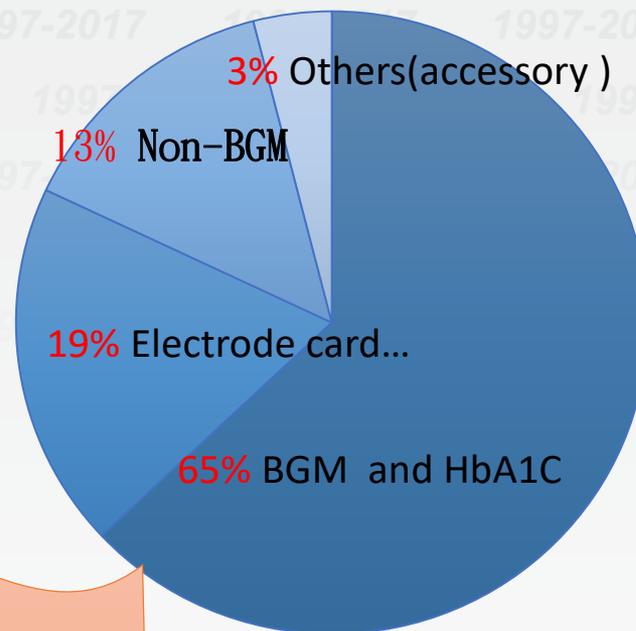
	2015	2016	2017	2018	1Q19
Revenue	1,847,454	1,763,284	1,795,300	2,043,614	524,934
Gross margin	547,135	476,843	431,514	560,102	121,959
Operation profit	300,795	245,889	160,999	227,352	34,660
Profit after tax	261,538	2,956	82,397	93,658	21,532
EPS	2.66	0.03	0.86	0.95	0.22
G/M ratio	29%	27%	24%	27%	23%
Operation profit ratio	16%	14%	9%	11%	7%
Net profit ratio	14%	0.2%	4%	5%	4%
Shipped Meter Qty	1,063K	1,287K	1,475K	1,638K	473K
Shipped Strip Qty	965M	901M	936M	1,034M	272M

Products ratio

2018



1Q/2019



Non-BGM systems
Hemoglobin/Ketone/UricAcid/
Lactate/Cholesterol/
Pesticide residues
quick check etc..

1997





Thank you

ApEXBio
Taiwan
