



五鼎生技
Company profile

APEXBIO
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2020/08/24

Company profile

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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	NTD 1 Billion
Chairman/CEO	Thomas Shen PhD
Employees	756 people (upto 7/31/2020)

Milestone

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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 ANVISA on-site audit
2018 . iCGM production set-up
. Ket-1 FDA 510K approval

1997-2001

2002-2005

2006-2011

2012-2015

2016-2018

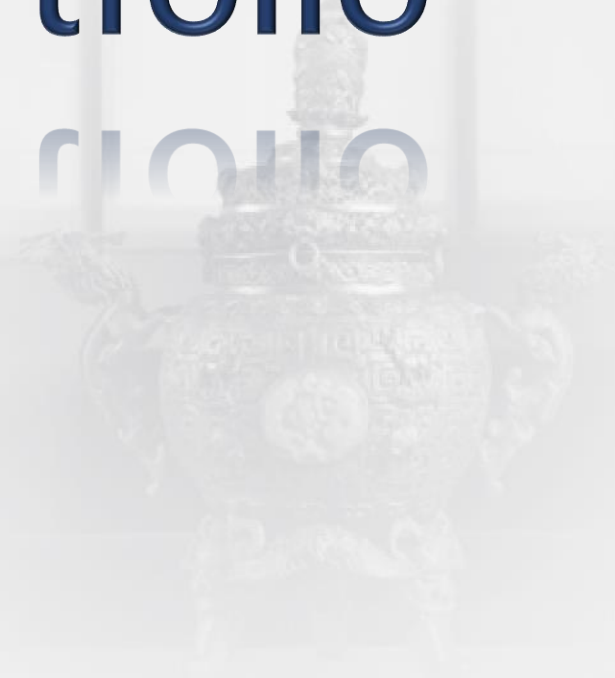
2002 ISO 9001/13485 notified
2003 CE IVDD notified
2005 Pesticide residues check product launch

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

Quality system

Region	The Authority	Regulatory compliance
Taiwan	TFDA	GMP
EU	CE	ISO 13485:2016 CE mark number:CE0197 EN 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 portfolio



Blood Glucose Monitoring system

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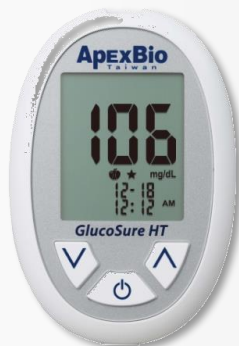


GlucoSure Vivo
欣活語音血糖測試儀

GlucoSure VivoLink
欣活藍牙語音血糖測試儀



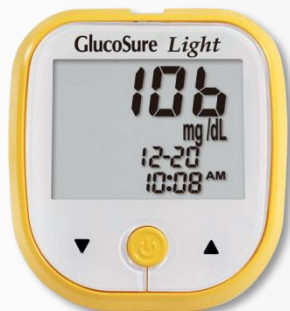
GlucoSure HT
新速利測血糖測試儀



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



Professional Monitoring System

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■尿酸Uric Acid

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Hemoglobin

HemoSmart GOLD

益紅測血紅蛋白分析儀



■乳酸Lactate

THE EDGE

競速乳酸測試系統



■血酮Ketone

KET-1

欣酮血酮測試系統



■糖化血色素HbA1C

Eclipse A1c

五鼎糖化血色素檢測儀



Multi-functional System

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■ **血糖 + 尿酸** Glucose + Uric 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



■ **醫療專用Professional**
■ **血糖 + 血酮** Glucose + Ketone
GlucoSure POC
欣舒測專業型連線測試儀



New Product - MultiSure GCTU

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MultiSure[®] GCTU

Blood Glucose and Cholesterol, Triglycerides and Uric Acid Monitoring System

4 in 1

ISO 15197:2015

Glucose, Cholesterol, Triglycerides and Uric Acid testing

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*

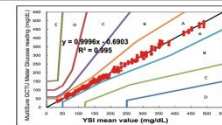
The MultiSure GCTU Monitoring System is a portable biosensor-based device for use at home or in a professional setting to conveniently measure the four important markers of metabolism*; blood glucose, cholesterol, triglycerides, and uric acid all in one pocket-sized instrument.

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

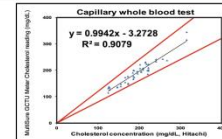
Measurement Range : 20 - 600 mg/dL
 Sample Volume : ≥ 0.5 µL
 Quick Testing Time : 5 seconds
 Hematocrit : 10% - 70%
 Operating Temperature : 5 ~ 45°C
 Memory : 500 test results



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%

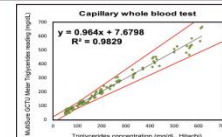
◀ Cholesterol

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



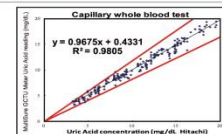
◀ Triglycerides

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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New Product - Eclipse PLUS

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Eclipse MULTI-PURPOSE ANALYZER **PLUS**

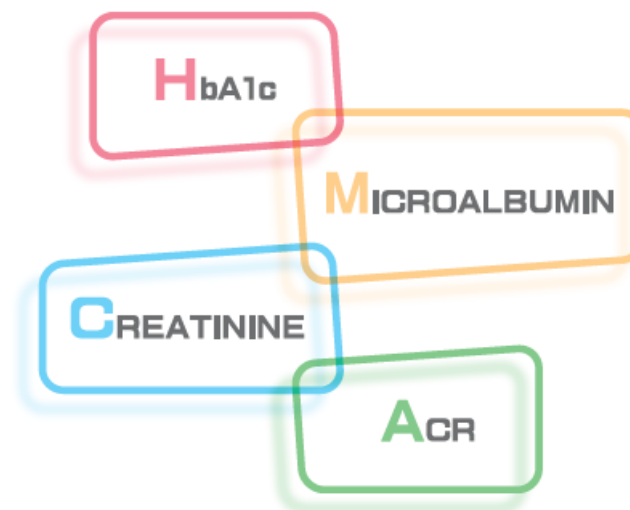
- Hemoglobin A1c
- Microalbumin
- Creatinine
- Albumin Creatinine Ratio (ACR)



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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New product– 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

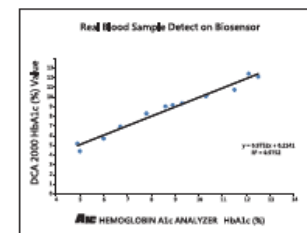
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A1c HEMOGLOBIN A1c ANALYZER

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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Pesticide residues quick check

APEXBIO
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AgriPro

AgriPro II



Fruit/Vegetable
pesticide residues
quick check



Customized projects

1. Product platform focus on electrochemistry/photometry/immunology
2. To derive new parameter tests and optimize our core platform.
3. Sharing our advantage of regulation/quality control/sales channels/clinical trails/manufacturing to alliance with partners and customers.
4. Integrate to IOT with hospitals and healthcare service centers

Global sales distribution

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Territory	2018	2019	2020/2Q
America	43%	41%	43%
EU	46%	48%	47%
Asia	10%	10%	10%
Africa	1%	1%	0

Finance Performance

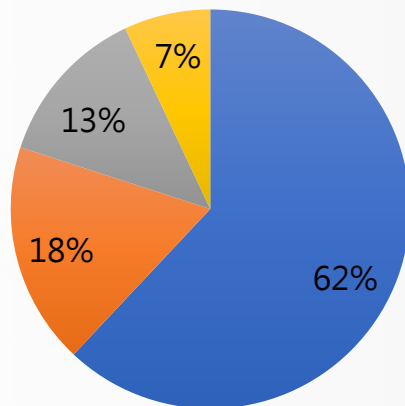
	2018	2019	2020/1H
Revenue	2,043,614	2,198,862	1,041,014
Gross margin	560,102	590,577	226,842
Operation profit	227,352	203,276	47,129
Profit after tax	93,658	113,859	38,502
EPS	0.95	1.14	0.39
G/M ratio	27%	27%	22%
Shipped Meter Qty (kit)	1,638K	1,800K	879K
Shipped Strip Qty(pcs)	1,034M	1,127M	536M

Products ratio

2019

Products ratio

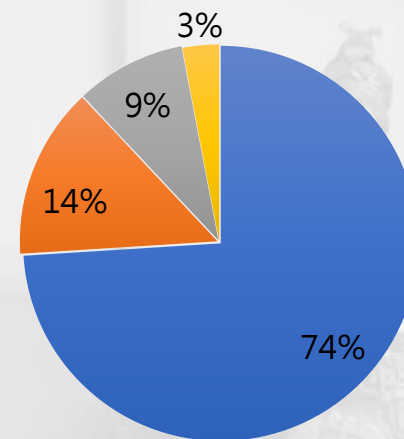
■ BGM & A1C ■ Electrode
■ Non-BGM ■ Others



1H/2020

Products ratio

■ BGM & A1C ■ Electrode
■ Non-BGM ■ Others



Non-BGM

Hemoglobin/Ketone/UricAcid/Lactate/Cholesterol/
Pesticide quick check etc



Thank you

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