

五鼎生技

APEXBIO

T a i w a n

Dec 2024



Company profile

TSEC 1733

Industry IVD Medical Device

Operation Locations

.Head quarter: No. 7, Li-Hsin 5th Rd., Hsinchu Science Park, Hsinchu, Taiwan

.Tao Yuan Factory: No. 180, Lane 70, Wuqing Rd., Dayuan Dist., Taoyuan City,
Taiwan

.Suzhou Corp.: Room 106, No.2, Kecheng Road, SIP, Suzhou, China

.Omnis Health LLC : 1736 River Hills Dr Suite 6, 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 695 people (upto 9/30/2024)

Milestone

1997-2001

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

2002-2006

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

2007-2011

2007 Lactate launch
2008 oice BGM launch
2009 Taoyuan factory set-up
2010 Tele-health tech build-up
2011 AEO certified by Customs Admin

2012-2016

2012 ApexBio Suzhou Corp set-up
2013 1st Taiwan MITTELSTAND
Award from MOEA
2015 .HbA1C/MultiSure GK
products launch
.ISO14001/OHSAS18001
notified

2017-2021

2017 .Acquired Omnis Health LLC
.Brazil ANVISA notified
2018 .ivCGM production set-up
.Getone KET-1 FDA 510K
approval
2019 ISO45001:2018 notified
2020 GCTU CE approval

2022-2023

2022 Setup Molecular Bio Div and
production line at TaoYuan
factory and passed TFDA QMS
passed
2023 MDSAP (USA/Canada/Brazil)
passed
2024 .MDSAP(Japan/Australia) passed
.ivCGM TFDA/CE QMS passed
.Influ rapit test TFDA QMS passed
.MCS Eclipse PLUS 2025 Taiwan
Excellence Award

Quality System

Region	The Authority	Regulatory compliance
Taiwan	TFDA	QMS
EU	CE	ISO 13485:2016 CE mark number:CE0197 EN ISO 15197:2015
USA	FDA	Quality System Regulation (21 CFR Part 820) 510K's on-site audit w/o 483 citations 2023 MDSAP (USA/Canada/Brazil)
China	NMPA	Medical Device Class II
Brazil	ANVISA	2017 passed on-site audit 2023 MDSAP (USA/Canada/Brazil)
Canada	Health Canada	2023 MDSAP (USA/Canada/Brazil)
Japan	PMDA	2024 MDSAP (Japan/Australia)
Australia	TGA	2024 MDSAP (Japan/Australia)

Product profile



Blood glucose monitoring systems



Professional Monitoring systems

- Uric Acid
- Hemoglobin
- Lactate
- Ketone



Multi-functional systems

- Glucose + Ketone
- Glucose + Cholesterol + TG + Uric Acid

Eclipse PLUS

For Clinic and Hospital

Pre-screening Diabetic Kidney Disease

- HbA1c
- Microalbumin
- Creatinine
- ACR



KETOSURE™ POC

BLOOD KETONE MONITORING SYSTEM

Ketone POC barcode scanner + Wi-Fi

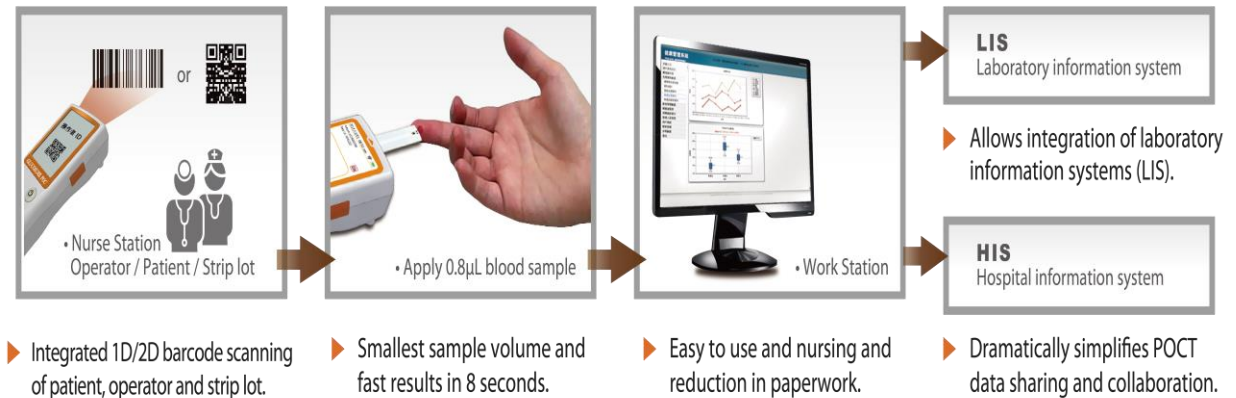


GLUCOSURE POC

Glucose/Ketone POC barcode scanner + Wi-Fi



+ Hospital



- ▶ Integrated 1D/2D barcode scanning of patient, operator and strip lot.
- ▶ Smallest sample volume and fast results in 8 seconds.
- ▶ Easy to use and nursing and reduction in paperwork.
- ▶ Dramatically simplifies POCT data sharing and collaboration.

HemoSmart™ PRO

Hemoglobin Monitoring System



THE EDGE^{Pro}

Blood Lactate Monitoring System

NEW PRODUCTS

Neue Produkte
Nye Produkter
Nuevos Productos
Nouveaux Produits
Nuovi Prodotti
Nieuwe Producten



HemoSmart™ PRO

Hemoglobin Monitoring System



- Blood Sample: Capillary, Venous
- Autocode
- Measurement Range: 0~24g/dL
- Test Time: 5 Seconds
- Sample Volume: ≥1 µL
- Hematocrit Range: 0%~70%
- Memory: 500 Test Results
- Insufficient Blood Prompt
- Strip Ejection
- Battery: 2 Alkaline AAA Battery
- Battery Life: > 1,000 Times
- Dimension: 109L x 64W x 24H (mm)
- Weight: 75g without Batteries
- Operating Temperature: Temp: 5~45°C, RH: 20%~90%
- Data Transfer: Micro-USB port, Bluetooth (Optional)



THE EDGE^{Pro}

Blood Lactate Monitoring System



- Blood Sample: Capillary, Venous
- Autocode
- Lactate oxidase
- Measurement Range: 6~200mg/dL
- Test Time: 15 Seconds
- Sample Volume: ≥1 µL
- Hematocrit Range: 20%~70%
- Memory: 500 Test Results
- Insufficient Blood Prompt
- Strip Ejection
- Battery: 2 Alkaline AAA Battery
- Battery Life: > 1,000 Times
- Dimension: 109L x 64W x 24H (mm)
- Weight: 78.5g without Batteries
- Operating Temperature: Temp: 10~40°C, RH: 20%~90%
- LCD Backlight
- Data Transfer: Micro-USB port, Bluetooth

GlucoSure POC III

8-in-1 Point of Care Monitoring System

■ Blood Glucose

■ Uric Acid

■ Cholesterol & LDL

■ Hemoglobin

■ Lactate

■ Ketone

■ Creatinine

■ Triglycerides



GlucoSure POC III 8-in-1 Point of Care Monitoring System

Specifications

- **Strip Ejection**
- **Battery:** 3.7V Rechargeable Lithium-Ion Battery / 3000mAh
- **Camera:** 8 MP / Automatic Focus / Flash LED
- **Wireless Function:**
 1. WiFi 2.4GHz + 5GHz with IEEE 802.11 a/b/g/n/ac
 2. HF RFID Reader
 3. 4G Cat-M1 or NB-IoT (Optional)
- **Battery Charge Method:**
 1. With USB Type-C Connector
 2. Wireless Power Transfer (WPT) _RX Mode (Optional)
- **Dimension:** 160L x 90W x 23H (mm)
- **Weight:** < 500g with Batteries
- **LCD Backlight:** 5.5 inch Color TFT LCD with Touch Panel
- **Data Transfer:**
Type-C Connector for Battery Charging and Converting to Ethernet with DOCK
- **Communication Protocol:**
 1. APEXBio Middleware Protocol
 2. POCT1-A Protocol (Optional)
- **Memory:**
 - up to 100 Proficiency Test Results
 - up to 2,000 Patient Result Records
 - up to 3 Comments for each Test Record
 - up to 500 QC Result Records
 - up to 50 Linearity Test Results
 - up to 300 Test Strip Lot Code Containers
 - up to 15,000 User ID Records
 - up to 15,000 Patient Records
 - up to 200 OTE Reagents Records
 - up to 50 QC Lot Records
 - up to 10 Linearity Lot Records
 - up to 5,000 Entries Audit Trail Records



Selectable Measurement Options

Blood Glucose

- Blood Sample: Capillary, Venous, Arterial and Neonatal
- Autoocode
- Measurement Range: 10~600mg/dL
- Test Time: 5 Seconds
- Sample Volume: ≥0.6 μL
- Hematocrit Range: 0%~70%
- Operating Temperature: 5~45°C

CHOL

Chol (Cholesterol)

LDL

(Low-Density Lipoprotein Cholesterol)

CHOL & LDL

Cholesterol & LDL

Cholesterol & LDL

- Blood Sample: Capillary
- Measurement Range:
Cholesterol: 100~400mg/dL
LDL: 50~200mg/dL
- Test Time: 60 Seconds
- Sample Volume: ≥3.6 μL
- Hematocrit Range: 30%~80%
- Operating Temperature: 10~40°C

Ketone

- Blood Sample: Capillary, Venous
- Autoocode
- Measurement Range: 0.1~8.0mmol/L
- Test Time: 8 Seconds
- Sample Volume: ≥0.8 μL
- Hematocrit Range: 20%~80%
- Operating Temperature: 10~40°C

Hemoglobin

- Blood Sample: Capillary, Venous
- Autoocode
- Measurement Range: 0~24g/dL
- Test Time: 5 Seconds
- Sample Volume: ≥1 μL
- Hematocrit Range: 0%~70%
- Operating Temperature: 5~45°C

Lactate

- Blood Sample: Capillary, Venous
- Autoocode
- Measurement Range: 6~200mg/dL
- Test Time: 15 Seconds
- Sample Volume: ≥1 μL
- Hematocrit Range: 20%~70%
- Operating Temperature: 10~40°C

Creatinine

- Blood Sample: Capillary, Venous
- Autoocode
- Measurement Range: 0.5~27mg/dL
- Test Time: 30 Seconds
- Sample Volume: ≥1.2 μL
- Hematocrit Range: 20%~80%
- Operating Temperature: 10~40°C

Uric Acid

- Blood Sample: Capillary
- Measurement Range: 3~20mg/dL
- Test Time: 10 Seconds
- Sample Volume: ≥1.5 μL
- Hematocrit Range: 20%~80%
- Operating Temperature: 10~38°C

Triglycerides

- Blood Sample: Capillary
- Measurement Range: 50~650mg/dL
- Test Time: 60 Seconds
- Sample Volume: ≥1.2 μL
- Hematocrit Range: 30%~55%
- Operating Temperature: 18~38°C

New pipeline products

■ Rapid test

TFDA QMS passed

- COVID-19 Antigen Rapid Test Kit
- KP Rapid Test Kit
- Influenza Rapid Test Kit

Developing items:

- Vector-borne Disease Detection for Mosquito-borne Illnesses
- Economic Animal and Animal Epidemic Prevention Detection
- DOA

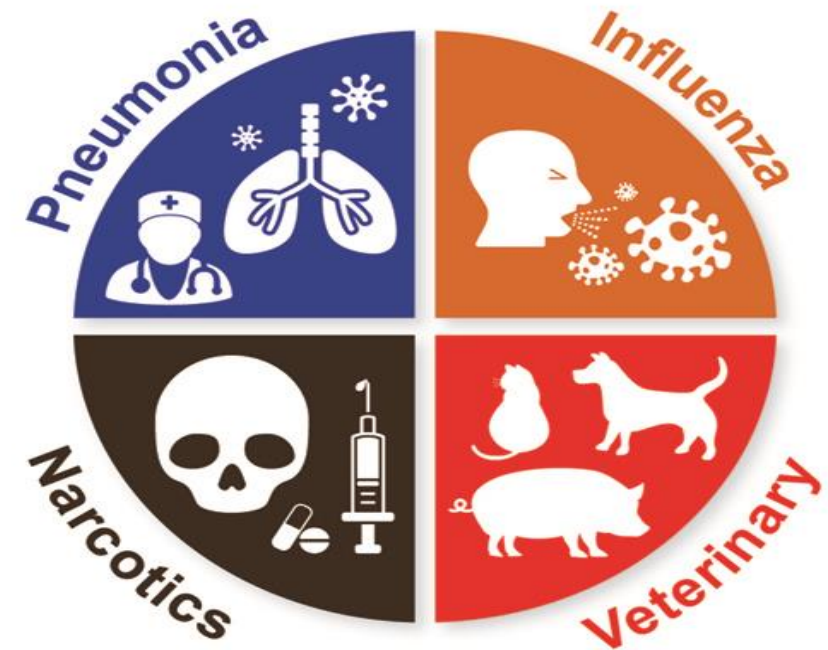
■ Home use CGM



Technology Innovation in Lateral Flow Rapid Tests

Public health, epidemic prevention & surveillance,
and professional diagnosis by medical institutions

Development Initiatives



Customized projects

- Product platform focus on electrochemistry/photometry/ Lateral flow assay , to derive new parameter tests and optimize our core platform.
- Sharing our advantage of regulation/quality control/sales channels/clinical trails/manufacturing to alliance with partners and customers.
- Integrate to IOT with hospitals and healthcare service centers
- Cooperated with Italy customer for ivCGM (ICU use), TFDA/QMS had passed in Feb/2024. CE/MDR notification is under certified by Customer.
- Cooperated with customers for Rapid tests had passed TFDA/QMS in Feb/2024

Global sales distribution

Territory	2022	2023	2024/1-3Q
America	40%	41%	40%
EU	49%	44%	48%
Asia	10%	13.5%	11%
Africa	1%	1.5%	1%

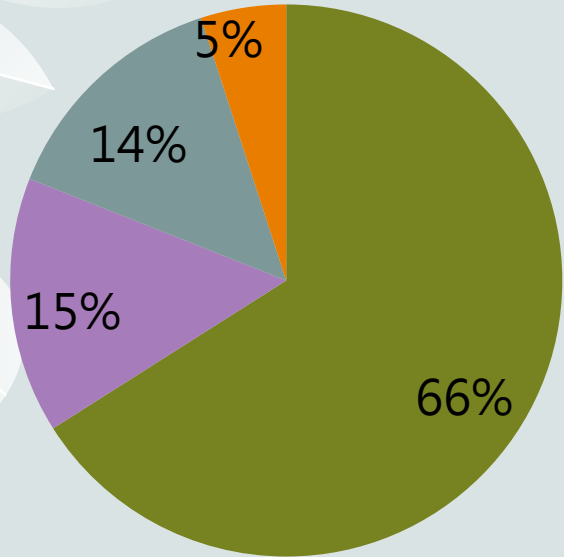
Finance Performance

Year	2022	2023	2024/1-3Q
Revenue	2,244,176	1,676,537	1,398,215
Gross margin	576,839	531,116	370,336
Operation profit	176,560	141,716	80,691
Profit after tax	181,451	115,714	89,602
EPS	1.82	1.16	0.9
G/M ratio	26%	31%	27%
Shipped Meter Qty (kit)	1,821K	1,189K	1,045K
Shipped Strip Qty(pcs)	1,118M	900M	659M

Product ratio

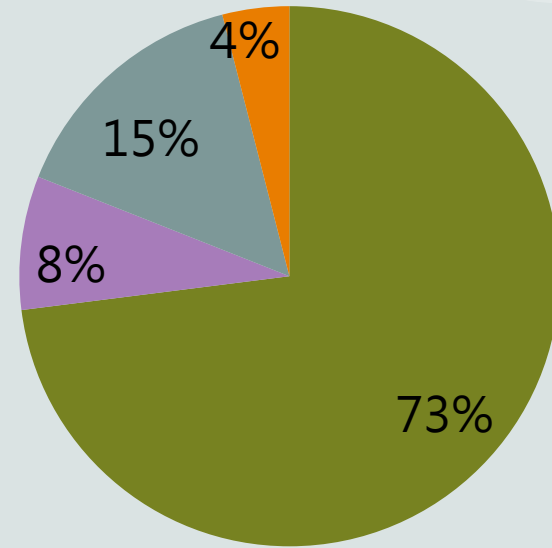
2023

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



2024/1-3Q

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



Non-BGM
Hemoglobin/Ketone/Uric Acid/Lactate/Cholesterol/
Pesticide quick check etc.

the 10th Corporate Governance Evaluation (2023)

Category	Total number of indicators		Points for satisfied indicators		Number of inapplicable indicators		Extra Credit Indicators:	
	2022	2023	2022	2023	2022	2023	2022	2023
Protecting Shareholder Rights and Interests and Treating Shareholders Equitably	16	18	13	15	0	0	1	1
Enhancing Board Composition and Operation	26	25	21	19	0	0	3	3
Increasing Information Transparency	18	15	11	10	0	0	0	1
Putting Corporate Social Responsibility into Practice	18	22	13	14	0	0	1	1
others	2	2	-	-	-	-	-	-

Total score : 78.38

Ranking (SEC): 36%~50%



Thank you

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