

五鼎生技

APEXBIO

T a i w a n

Jul 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 670 people (upto 3/31/2024)

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 notify
2023 MDSAP (USA/Canada/
Brazil notified)

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 (21CFR Part 820) 510K's FDA on-site audit w/o 483 citations
China	NMPA	Medical Device Class II
Brazil	ANVISA	2017 passed on-site audit
Canada	Health Canada	MDSAP (USA/Canada/Brazil)

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

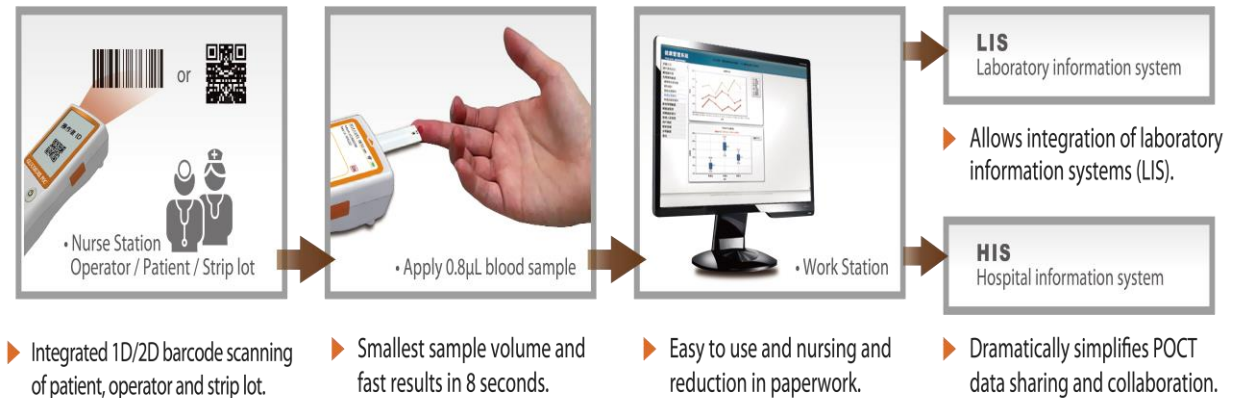


GLUCOSURE POC

Glucose/Ketone POC barcode scanner
+ Wi-Fi



+ Hospital



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



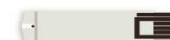
GlucoseSure POC III

8-in-1 Point of Care Monitoring System



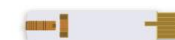
- Strip Ejection
- Battery: 3.7V Rechargeable Lithium-Ion Battery / 2200mAh
- Camera: 8 MP / Automatic Focus / Flash LED
- Wireless Function: 1. WiFi 2.4GHz + 5Ghz with IEEE 802.11 a/b/g/n/ac
2. HF RFID Reader
3. 4G Cat-M1 or NB-IoT (Optional)
- Battery Charge Method: 1. With USB Type-C Connector
2. 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

8 IN 1 MULTI-TESTING



Blood Glucose

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



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%~60%
- Operating Temperature: 10~40°C



Ketone

- Blood Sample: Capillary, Venous
- Autocode
- Measurement Range: 0.1~8.0mmol/L
- Test Time: 8 Seconds
- Sample Volume: ≥0.8 µL
- Hematocrit Range: 20%~60%
- Operating Temperature: 10~40°C



Hemoglobin

- Blood Sample: Capillary, Venous
- Autocode
- 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
- Autocode
- 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
- Autocode
- Measurement Range: 0.5~27mg/dL
- Test Time: 30 Seconds
- Sample Volume: ≥1.2 µL
- Hematocrit Range: 20%~60%
- 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%~60%
- 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

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 in EU.
- Cooperated with customers for Rapid tests had passed TFDA/QMS in Feb/2024

Global sales distribution

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

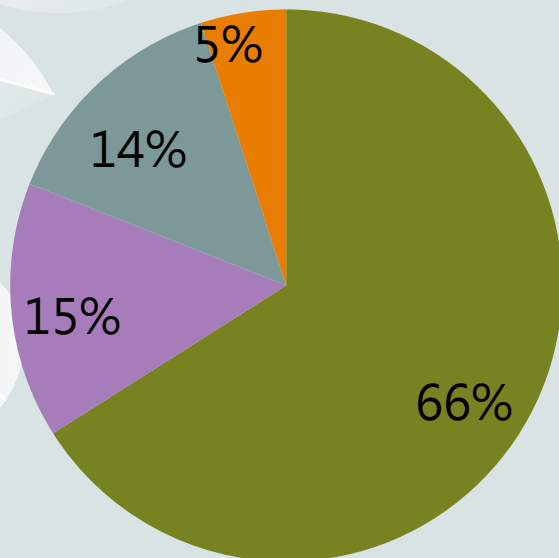
Finance Performance

Year	2022	2023	2024/1Q
Revenue	2,244,176	1,676,537	450,658
Gross margin	576,839	531,116	109,532
Operation profit	176,560	141,716	16,374
Profit after tax	181,451	115,714	29,124
EPS	1.82	1.16	0.29
G/M ratio	26%	31%	24%
Shipped Meter Qty (kit)	1,821K	1,189K	315K
Shipped Strip Qty(pcs)	1,118M	900M	221M

Product ratio

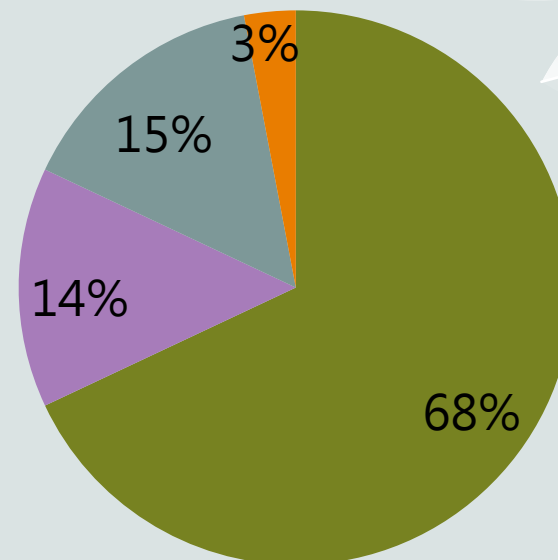
2023

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



2024/1Q

■ BGM & A1C
■ Non-BGM
■ Electrode
■ 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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