

五鼎生技

**APEXBIO**

Taiwan

May 2025



# Company profile

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**TSEC 1733**

**Industry** IVD Medical Device

## **Operation Locations**

**.Head quarter:** No. 7, Li-Hsin 5<sup>th</sup> 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** 661 people (upto 4/30/2025)

# 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

## 2022-2024

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

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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

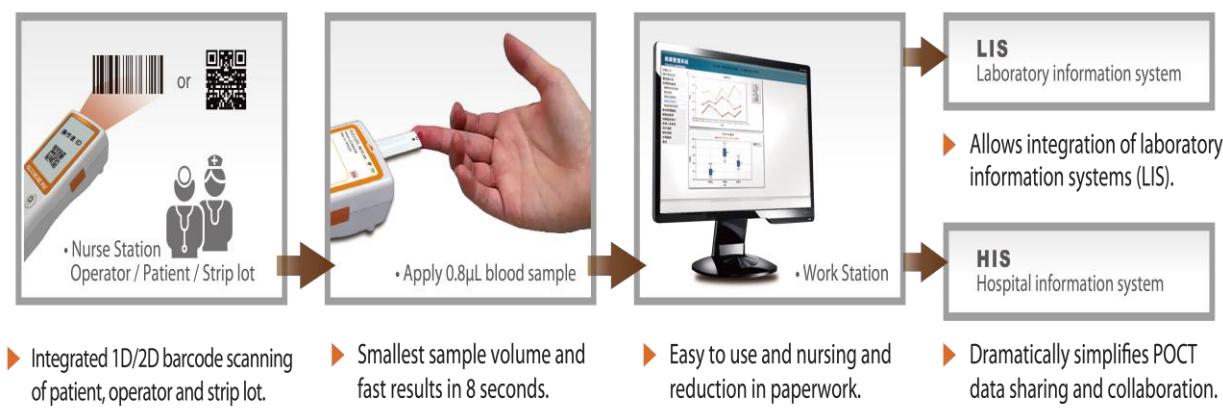
Ketone POC barcode scanner + Wi-Fi

# GLUCOSURE POC

Glucose/Ketone POC barcode scanner + Wi-Fi



**Hospital**



# HemoSmart™ PRO

Hemoglobin Monitoring System

# THE EDGE<sup>Pro</sup>

Blood Lactate Monitoring System

# NEW PRODUCTS



## HemoSmart™ PRO

Hemoglobin Monitoring System

- Blood Sample: Capillary, Venous
- Autocode
- Measurement Range: 0~24g/dL
- Test Time: 5 Seconds
- Sample Volume:  $\geq 1 \mu\text{L}$
- 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<sup>Pro</sup>

Blood Lactate Monitoring System

- Blood Sample: Capillary, Venous
- Autocode
- Lactate oxidase
- Measurement Range: 6~200mg/dL
- Test Time: 15 Seconds
- Sample Volume:  $\geq 1 \mu\text{L}$
- 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 Blacklight
- Data Transfer: Micro-USB port, Bluetooth

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

# 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 Blacklight: 5.5 inch Color TFT LCD with Touch Panel
- Data Transfer:  
Type-C Connector for Battery Charging and Converting to Ethernet with DOCK

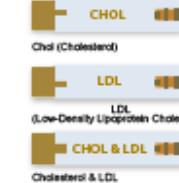
- Communication Protocol:
  - 1. APEXBIO Middleware Protocol
  - 2. POCT1-A Protocol (Optional)
- Memory:
  - up to 100 Proficiency Test Results
  - up to 2,000 Patient Result Records
  - up to 3 Comments for each Test Record
  - up to 500 QC Result Records
  - up to 50 Linearity Test Results
  - up 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
- Autocode
- Measurement Range: 10~600mg/dL
- Test Time: 5 Seconds
- Sample Volume:  $\geq 0.8 \mu\text{L}$
- Hematocrit Range: 0%~70%
- Operating Temperature: 5~45°C



- Blood Sample: Capillary
- Measurement Range: Cholesterol: 100~400mg/dL
- LDL: 50~200mg/dL
- Test Time: 60 Seconds
- Sample Volume:  $\geq 3.8 \mu\text{L}$
- Hematocrit Range: 30%~80%
- Operating Temperature: 10~40°C

#### Ketone

- Blood Sample: Capillary, Venous
- Autocode
- Measurement Range: 0.1~8.0mmol/L
- Test Time: 8 Seconds
- Sample Volume:  $\geq 0.8 \mu\text{L}$
- Hematocrit Range: 20%~80%
- Operating Temperature: 10~40°C

#### Hemoglobin

- Blood Sample: Capillary, Venous
- Autocode
- Measurement Range: 0~24g/dL
- Test Time: 5 Seconds
- Sample Volume:  $\geq 1 \mu\text{L}$
- 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:  $\geq 1 \mu\text{L}$
- 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:  $\geq 1.2 \mu\text{L}$
- 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:  $\geq 1.2 \mu\text{L}$
- Hematocrit Range: 20%~80%
- Operating Temperature: 10~38°C

#### Triglycerides

- Blood Sample: Capillary
- Measurement Range: 50~650mg/dL
- Test Time: 60 Seconds
- Sample Volume:  $\geq 1.2 \mu\text{L}$
- Hematocrit Range: 30%~55%
- Operating Temperature: 18~38°C

# New pipeline products

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## ■ 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

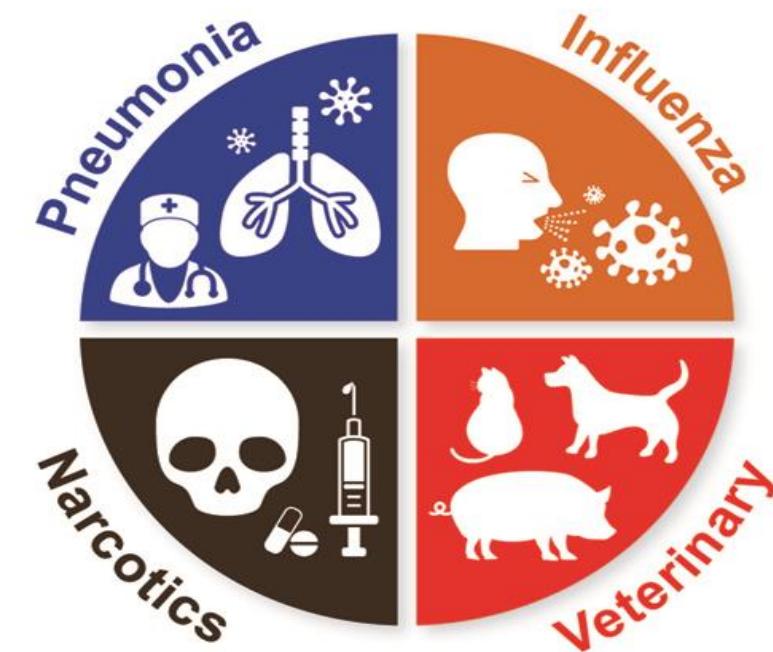
## ■ Home use CGM



## 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 trials/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. CE/MDR notification is under certified by Customer.
- Cooperated with customers for Rapid tests had passed TFDA/QMS .

## Global sales distribution

Territory	2023	2024	2025/1Q
<b>America</b>	41%	39%	52%
<b>EU</b>	44%	48%	41%
<b>Asia</b>	13.5%	12%	6%
<b>Africa</b>	1.5%	1%	1%

# Finance Performance

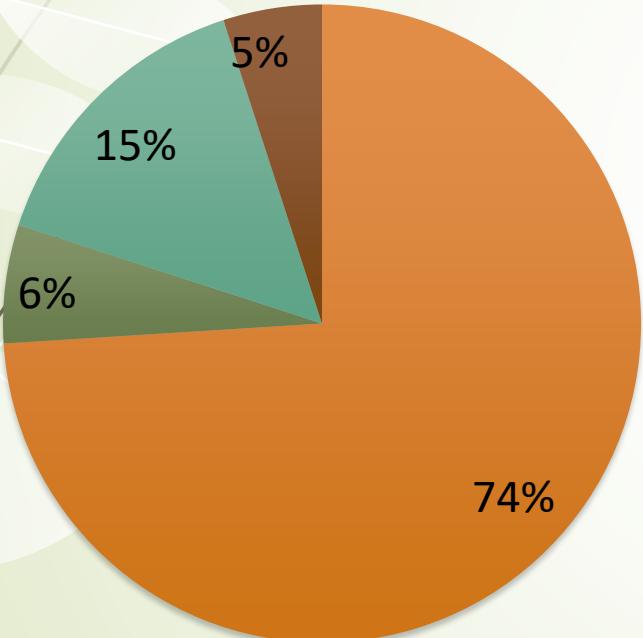
Year	2023	2024	2025/1Q
<b>Revenue</b>	1,676,537	1,852,211	558,753
<b>Gross margin</b>	531,116	521,342	162,659
<b>Operation profit</b>	141,716	128,464	56,200
<b>Profit after tax</b>	115,714	128,104	61,988
<b>EPS</b>	1.16	1.28	0.62
<b>G/M ratio</b>	31%	28%	29%
<b>Shipped Meter Qty (kit)</b>	1,189K	1,368K	331K
<b>Shipped Strip Qty(pcs)</b>	900M	859M	256M

# Product ratio

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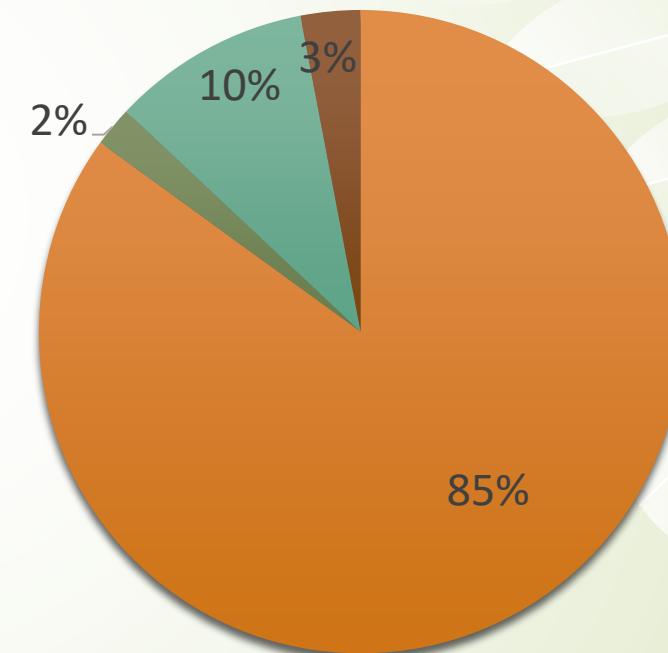
2024

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



2025/1Q

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



## Non-BGM

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

# the 11<sup>th</sup> Corporate Governance Evaluation (2024)

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Category	Total number of indicators		Distribution weight		Points for satisfied indicators		Number of inapplicable indicators		AA/A+ Extra Credit Indicators	
Year	2023	2024	2023	2024	2023	2024	2023	2024	2023	2024
Protecting Shareholder Rights and Interests and Treating Shareholders Equitably	18	<b>14</b>	0.22	0.19	15	<b>13</b>	0	<b>0</b>	1	<b>1</b>
Enhancing Board Composition and Operation	25	<b>22</b>	0.31	0.29	19	<b>17</b>	0	<b>0</b>	3	<b>3</b>
Increasing Information Transparency	15	<b>13</b>	0.19	0.17	10	<b>10</b>	0	<b>0</b>	1	<b>1</b>
Putting Corporate Social Responsibility into Practice	22	<b>26</b>	0.28	0.35	14	<b>21</b>	0	<b>0</b>	1	<b>2</b>
Others	2	<b>0</b>	-	-	-	-	-	-	-	-

Total score: **88.4**

Ranking (SEC): **21%~35%**

Industry Category: Market Capitalization Under NT\$5 Billion, ranking : **2% %~10%**



Thank you

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