



2022 3Q

2022 Nov

**APEXBIO**

# 五鼎生技公司簡介

股票代號            上市公司 1733

產業別              醫療器材業

營運據點

- 總公司：新竹科學園區力行五路7號
- 桃園廠：桃園縣大園鄉五權村五青路70巷180號
- 蘇州五鼎生技醫療器械進出口貿易有限公司：  
          江蘇省蘇州工業園區科成路2號2樓106室
- 美國公司Omnis Health LLC：  
          1736 River Hills Dr Suite 6, Nashville, TN 37210,USA

成立日期            12/02/1997

上市日期            06/13/2000(4101上櫃)    09/17/2001(1733上市)

實收資本額         10億元

董事長/總經理     沈燕士 博士

員工人數            737人 (至 9/30/2022)

# 公司沿革

1997 五鼎設立  
1998 血糖套組取得FDA 510K  
1999 尿酸專利取得  
2000 上櫃掛牌  
2001 轉上市掛牌

2007 乳酸產品上市  
2008 語音血糖產品上市  
2009 桃園試片廠設立  
2010 遠距雲端技術建置  
2011 優質企業通過海關認證 (AEO)

2017 取得美國Omnis 股權  
取得巴西認證  
2018 ivCGM生產線建置完成  
Ket-1 取得FDA 510K  
2019 取得ISO45001:2018認證  
2020 GCTU取得CE認證

1997-2001

2002-2005

2006-2011

2012-2015

2016-2020

2021-2022

2002 取得歐盟認證  
ISO 9001/13485  
2003 取得CE mark 認證  
2005 農藥殘餘快速檢測產品上市

2012 蘇州五鼎設立  
2013 獲得經濟部第一屆中堅企業獎  
2015 糖化血色素產品上市  
血糖/血酮雙功能套組產品上市  
獲亞太企業家精神獎  
取得ISO14001/OHSAS18001認證

2022 研發成立免疫分生課並於桃園廠建置生產線, 年底完成醫療器材QMS製造許可審查

# 品質系統

區域	主管機關	符合法規
台灣	<b>TFDA</b>	GMP
歐盟	<b>CE</b>	ISO 13485:2016 CE mark number:CE0197 EN ISO 15197:2015
美國	<b>FDA</b>	510K's FDA四次查廠無缺失通過
中國	<b>CFDA</b>	Medical Device Class II
日本	<b>PMDA</b>	
巴西	<b>ANVISA</b>	2017 查廠通過並取得認證

# 環安衛系統

因應環境保護及職業安全與衛生政策，已逐年建立各項管理程序來持續符合GRI準則，以達企業永續發展之目標。

Certificate TW15/11085

The management system of

**Apex Biotechnology Corp.**

No.7, Li-Hsin 5th Rd., Hsinchu Science Park,  
Hsinchu 30078, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

**ISO 14001:2015**

For the following activities

For the design and development, Manufacture and Distribution of In-vitro Diagnostic Devices used in the Monitoring of Blood Glucose and Uric Acid/Lactate/Hemoglobin/Cholesterol/Ketone/HbA1c etc, and Pesticide Residual system including Meters, Test Strips and control Solution including the Point of Care and Home use.

This certificate is valid from 25 October 2021 until 23 October 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 4. Certified since 23 October 2015

The audit leading to this certificate commenced on 22 September 2021  
Previous issue certificate validity date was until 23 October 2021

Authorised by




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Certificate TW16/00926

The management system of

**Apex Biotechnology Corp.**

No.7, Li-Hsin 5th Rd., Hsinchu Science Park,  
Hsinchu 30078, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

**ISO 45001:2018**

For the following activities

For the design and development, Manufacture and Distribution of In-vitro Diagnostic Devices used in the Monitoring of Blood Glucose and Uric Acid/Lactate/Hemoglobin/Cholesterol/Ketone/HbA1c etc, and Pesticide Residual system including Meters, Test Strips and control Solution including the Point of Care and Home use.

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Authorised by




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# 全方位健康產品檢測



## 血糖免校正檢測儀套組



## 專業快速檢測系列

- 尿酸
- 血紅素
- 乳酸
- 血酮
- 糖化血色素



## 多功能檢測儀MultiSure系列

- 血糖+尿酸
- 血糖+血酮
- 血糖+膽固醇
- 血糖+膽固醇+三酸甘油酯+尿酸



# GLUCOSURE POC

## 欣舒測專業型血糖/血酮連線測試儀

# KETOSURE™ POC

BLOOD KETONE MONITORING SYSTEM

## 專業型血酮連線測試儀

(羅氏為歐洲總代理)



**+** 醫院專用



行動推車  
操作者ID/患者ID



試片批號  
支援1維/2維條碼



POC平台  
血糖管理系統



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# Eclipse PLUS

MULTI-PURPOSE ANALYZER

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



## Specifications

- 5" LCD Touch Panel
- HbA1c: %, mmol/mol, eAG
- Microalbumin: mg/dL
- Creatinine: mg/dL, mmol/L
- ACR: mg/g, mg/mmol
- Type-A USB Interface
- Universal Power Supply 1W~240V, 50/60Hz
- Dimension: 290L x 206W x 137H (mm)
- Weight: 1.7kg
- Operating Condition: 18~35°C/Humidity: <80%
- Analyzer Storage Condition: 4~50°C/Humidity: <80%
- Cartridge Storage Temperature:
  - HbA1c: 2~8°C
  - Microalbumin: 4~30°C
  - Creatinine: 4~30°C
  - ACR: 4~30°C
- Memory: 250 Test Results

Rev.10022

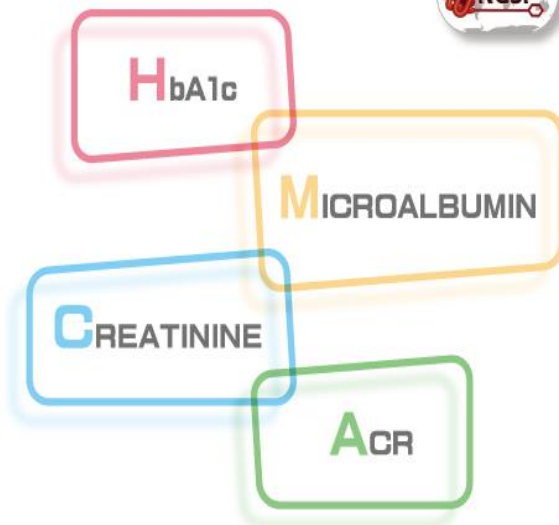


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# Eclipse PLUS

MULTI-PURPOSE ANALYZER



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## 診所、醫院專用

### 糖尿病腎病變早期 診斷指標

- 糖化血色素(HbA1c)
- 微量白蛋白(Microalbumin)
- 肌酸酐(Creatinine)
- 微量白蛋白/肌酸酐比值(ACR)



# 客製化開發產品專案

## 與國內外客戶共同開發產品

- 創新技術領域產品開發(電化學、光學、側流免疫分析)  
協助客戶開發肝功能檢測為全球第一款能夠實際檢測肝功能的工具，已獲衛福部醫材許可並刊登於國際生醫分析期刊Analytical and Bioanalytical Chemistry.
- 結合五鼎成熟技術平台衍生新產品，並持續優化產品
- 運用五鼎法規、品質、通路、臨床、製造優勢之結盟
- 透過4G/5G/Barcode/BLE/WIFI/APP等傳輸載具，結合醫療物聯網與醫院及醫療服務機構進行雲端整合；目前與美國客戶正進行5G血糖儀開發。
- 與義大利客戶合作的醫用(ICU)連續血糖監測系統已進入臨床階段預計於2023年進行各國主管機關認證



# 新創產品

- 居家型連續血糖監測系統(CGM)
- 血脂檢測套組
- 快篩檢測試劑 –  
    流感檢測、病媒蚊傳染性疾病檢測及  
    經濟動物及動物防疫檢測

# 全球市場銷售佈局



洲別	2020	2021	2022/1-3Q
美洲	42%	43.5%	41%
歐洲	46%	45%	49%
亞洲	11%	11%	9%
非洲	1%	0.5%	1%

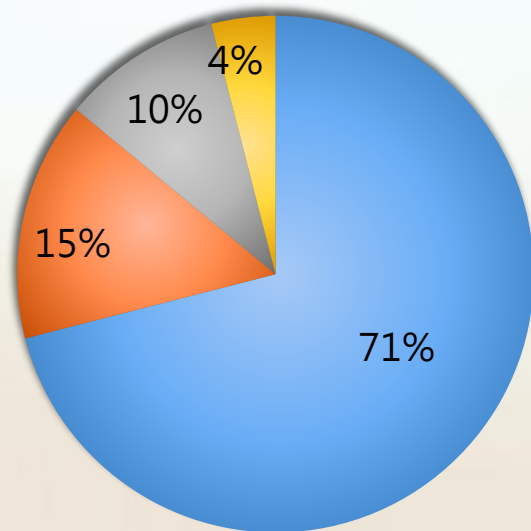
# 財務分析

	2020	2021	2022/1-3Q
營收	2,005,337	2,131,656	1,735,537
毛利	452,224	571,512	418,971
營業利益	103,328	204,949	125,879
稅後淨利	94,629	202,289	138,582
每股盈餘	0.95	2.03	1.39
毛利率	22%	27%	24%
儀器出貨量	1,731K	1,677K	1,471K
試片出貨量	1,061M	1,167M	846M

# 產品占比

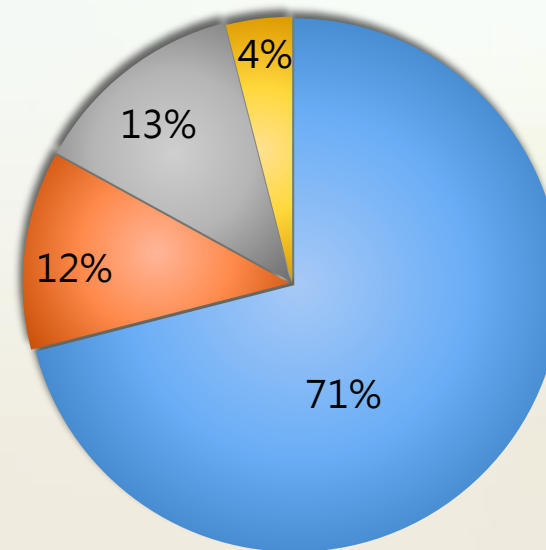
2021

- 血糖類及糖化血色素
- 電極測試片
- 非血糖類測試套組
- 其他(附件)



2022/ 1-3Q

- 血糖類及糖化血色素
- 電極測試片
- 非血糖類測試套組
- 其他(附件)



非血糖類測試套組

血紅素/血酮/尿酸/乳酸/膽固醇/農藥檢測 等

# 第8屆公司治理評鑑（110年）

構面	總指標數		配分比重		符合指標數		不適用指標數		AA/A+題型加總分題數	
	109	110	109	110	109	110	109	110	109	110
年度	109	110	109	110	109	110	109	110	109	110
維護股東權益及平等對待股東	16	16	0.19	0.2	14	15	0	0	0	0
強化董事會結構與運作	28	26	0.34	0.33	20	22	0	0	3	3
提升資訊透明度	21	21	0.26	0.26	12	13	0	0	0	0
落實企業社會責任	17	16	0.21	0.21	15	14	0	0	3	1
其他	2	2	-	-	-	-	-	-	-	-

總分: 85.14

上市公司排平級距: 21%~35%

謝謝聆聽