



# **SOFIVA GENOMICS**



**Stock Code 6615**

**Investor Conference**

2023 / 12 / 13

**CEO**

**Yi-Ning Su, MD. Ph.D**

## Disclaimer

All statements for investors contain information that represent, other than historical facts, SOFIVA's plans and forward-looking statements are based upon management's current assumptions.

Environmental changes and other important factors could cause actual results to differ materially from those expressed in our statements.

Investors should carefully consider the investment objectives and risks before investing.

# SOFIVA - The Dual Operating Strategy

Maternal Fetal Medicine

Precision Cancer Medicine

Genetic Screening Category	Servicing Specialty	Target
<b>Reproductive</b>	IVF Center	IVF Embryo Screening
<b>Prenatal</b>	OB-GYN	Pre-pregnant couples Pregnant couples
<b>Newborn</b>	Pediatrics, Neonatology	Child Newborn
<b>Cancer</b>	Cancer-related Specialty	All Target Audience (Pre-Cancer & Patient)
<b>Rare Disease</b>	Genetics-related Specialty	All Target Audience
<b>Precision Medicine</b>	Treatment-related Specialty	All Target Audience

# Maternal Fetal Medicine and Precision Cancer Medicine One Stop Service

## Reproductive

- PGT-M
- PGT-A
- niPGT-A

## Rare Diseases

- Hearing Loss Genetic Test v1.0/v2.0/v3.0
- Achondroplasia
- Osteogenesis Imperfecta
- Duchenne Muscular Dystrophy
- Customized Genetic Test

## Prenatal

- NIPS
- Array
- Karyotyping
- Carrier Scan
- SMA Carrier Screening
- Fragile X Carrier Screening
- Thalassemia Carrier Screening
- Folate Metabolism Genetic Testing

## Cancer

- Cancer Monitor
- Cancer Scan v1.0/v2.0
- Cancer Risk v1.0/v2.0
- HPV test

## Newborn

- Baby Scan
- Hearing Loss Genetic Screening
- CCHS Genetic Screening
- Congenital CMV Infection Screening
- Atopic Dermatitis Genetic Screening

## Precision Medicine

- HRD Status
- CGP Genetic Test
- BRCA1/2 Genetic Testing
- Endometrial Cancer Genetic Subtypes
- Prostate Cancer Genetic Testing

# SOFIVA Genomics Medical Laboratory Certification qualifications

CAP

Food and Drug Administration,  
Ministry of Health and Welfare  
Listing and registration



衛生福利部食品藥物管理署

精準醫療分子檢測實驗室列冊登錄資料

機構名稱：慧智基因醫事檢驗所(地址：臺北市中正區寶慶路27號6樓、8樓)

機構負責人：連苡淨

實驗室名稱：慧智基因醫學實驗室(地址：臺北市中正區寶慶路27號)

實驗室負責人：洪加政 (實驗室品質主管：王志成)

列冊登錄編號：LDT0008

列冊有效期間：110年9月28日至113年9月27日止

列冊範圍：

項次	檢測名稱	分析標的	技術項目	服務範圍
1	非侵入性產前染色體篩檢	1. 檢體型態：血液。 2. 標的：胎兒第13、18、21對染色體及性染色體之基因體。	次世代定序	非侵入性胎兒染色體基因檢測
2	次世代定序胚胎著床前染色體篩檢	1. 檢體型態：胚胎細胞。 2. 標的：人類23對染色體之基因體。	次世代定序	生殖細胞突變
3	癌症基因突變檢測	1. 檢體型態：血液、組織(FFPE)。 2. 基因數：249 (附表1)	次世代定序	體細胞突變

# SOFIVA Genomics Medical Laboratory Certification qualifications

ISO  
15189



**賀! 慧智基因**

生殖 產前-孕前 新生兒  
癌症 精準用藥 基因檢測

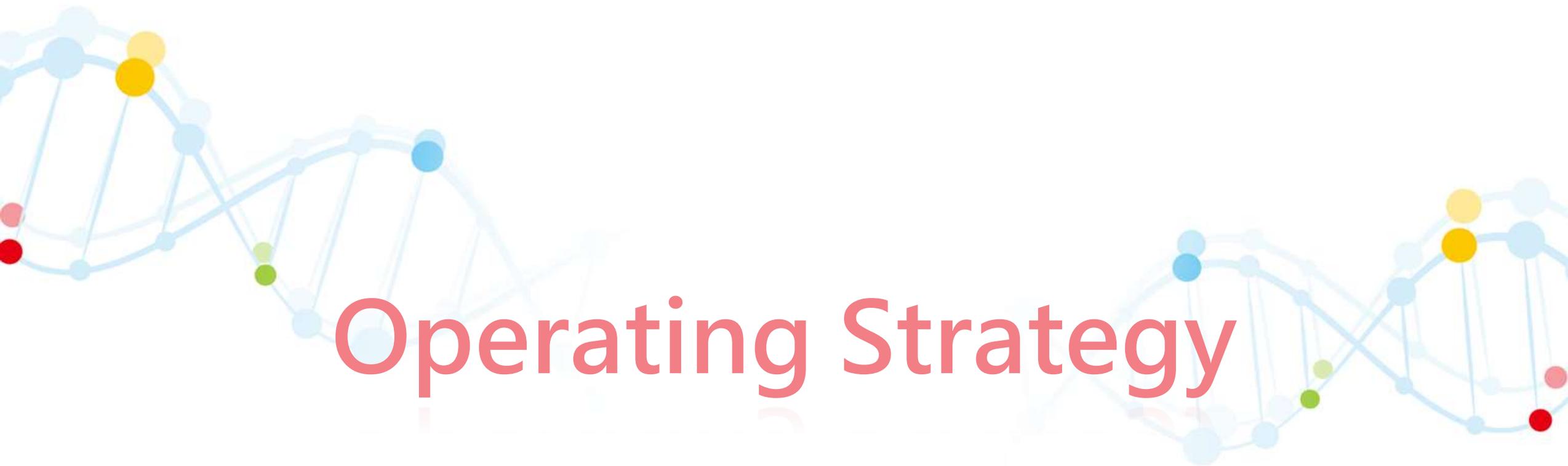
**全品項通過 ISO 15189 醫學實驗室認證!**

(非侵入性) 胚胎著床前染色體篩檢 (ni)PGT-A [(ni)PGS]  
 胚胎著床前單基因檢測 PGT-M [PGD]  
 非侵產前染色體篩檢 NIPS v1.0 / v2.0 / v3.0  
 全方位複合式晶片檢測 Array v1.0 / v2.0 / v3.0  
 帶因篩檢 Carrier Scan v1.0 / v2.0 / v3.0

脊髓性肌肉萎縮症基因檢測	X 染色體脆折症基因檢測
海洋性貧血基因檢測	葉酸代謝基因檢測
新生兒基因篩檢 Baby Scan v1.0 / v2.0 / v3.0	
感覺神經性聽損基因檢測	先天中樞性換氣不足症候群基因檢測
先天性巨細胞病毒感染檢測	異位性皮膚炎過敏基因檢測
聽損基因檢測 v1.0 / v2.0 / v3.0	全外顯子定序基因檢測
癌監控基因檢測 BRCA1/2 / 肺癌 / v1.0 / v2.1 / v2.2 / v3.0	
癌篩檢基因檢測 v1.0 / v2.0 男性 / v2.0 女性 / v3.0	
癌風險基因檢測 v1.0 / v2.0 / BRCA1/2 / 婦癌 / 大腸癌 / 兒癌	
CGP 癌症基因檢測	癌追蹤
HRD 檢測	子宮內膜癌基因分型
微衛星不穩定檢測 MSI	攝護腺癌基因檢測

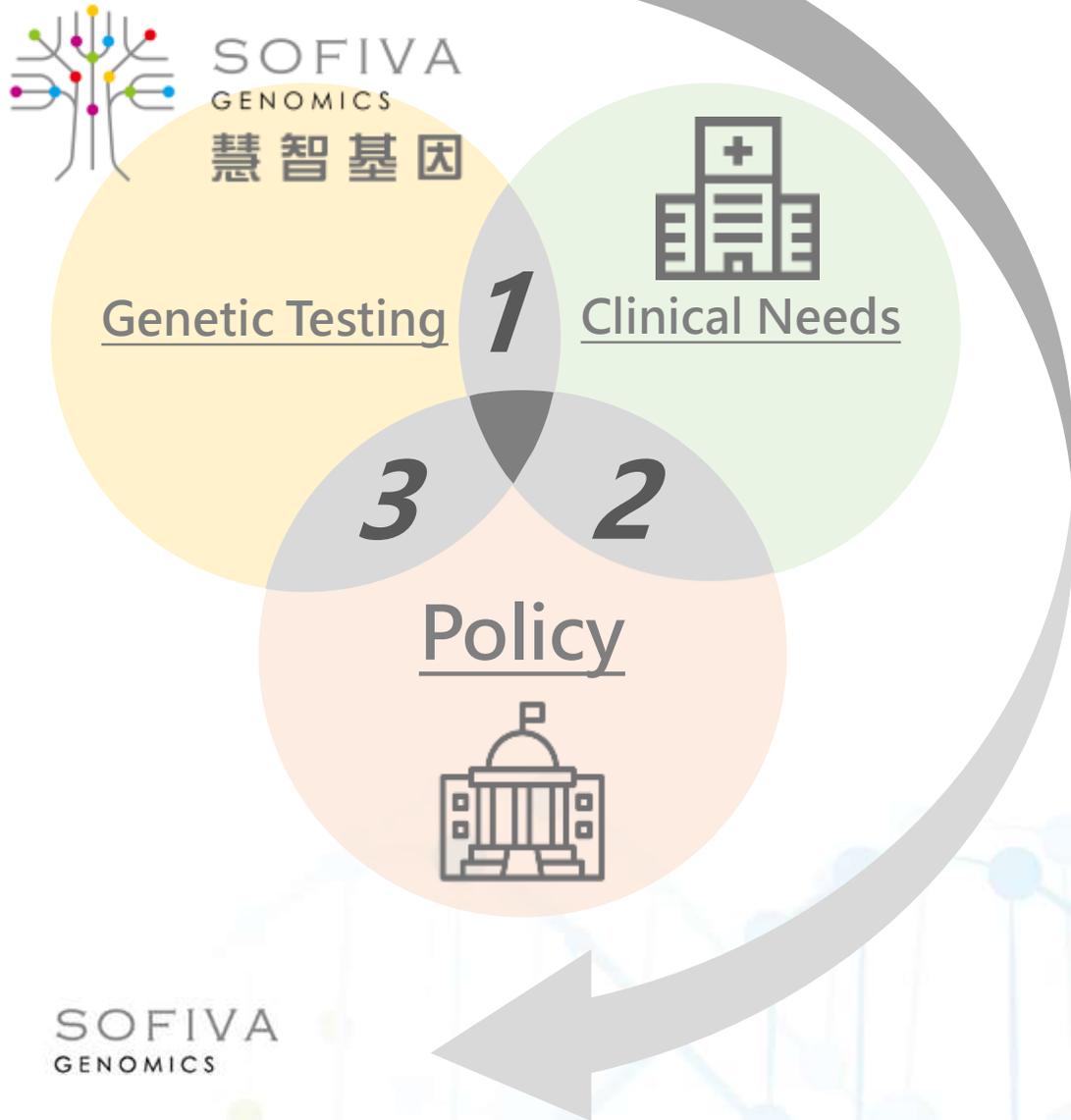
SOFIVA GENOMICS  
小細節 大不同  
Details Make Differences

SOFIVA  
GENOMICS



# Operating Strategy

# Operating Strategy-Integration of Needs



## 1. Integration of Clinical Needs

- Clinical Collaboration: Parallel Testing, Backup Laboratory.
- Compliance with Clinical Standards:
  - ✓ Pathological Sections, Bioinformatics Analysis, Report Information, Genetic Counseling, Report Discussion.
- Offering Genetic Testing: Therapeutic Drugs, Recurrence Monitoring.

## 2. National Policy –

### Health Insurance Benefits of Medicine

- Inclusion in National Health Insurance (NHI) Medication Reimbursement.
- ✓ Cross-Industry Alliances: Instrumentation, Pharmaceutical Companies, Foundations, Life Insurance.

## 3. National Policy –

### Health Insurance Benefits of Testing

- Incorporation into Special Handling Measures.
- SMA included in National Health Insurance coverage.
- NGS testing included in National Health Insurance coverage.





# Clinical Needs

# Integration of Clinical Needs

## 1. Integration of Clinical Needs

- Clinical Collaboration:

Parallel Testing, Backup Laboratory.

- Compliance with Clinical Standards:

Pathological Sections, Bioinformatics Analysis, Report Information, Genetic Counseling, Report Discussion.

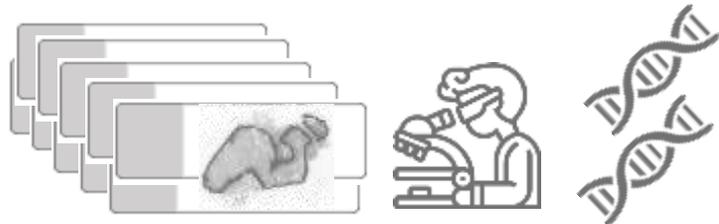
SOFIVA



Hospital



Parallel Testing, Backup Laboratory



Pathological Sections



Bioinformatics Analysis



Report Information, Genetic Counseling



Report Discussion

- Offering Genetic Testing: Therapeutic Drugs, Recurrence Monitoring.

Therapeutic Drugs

Monitoring: Therapy & Recurrence

Health

Cancer

Operation

Recurrence/Metastasis

Patient Journey



# National Policy – Health Insurance Benefits of Medicine

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# Health Insurance Benefits of Medicine

## 2. National Policy

### Last Year

Target Gene	Medicine	Condition
BRCA1/2 HRD	 Niraparib	Ovarian cancer, Fallopian tube cancer, Peritoneal cancer <b>Gene variant testing report must be attached</b>
	 Olaparib	Ovarian cancer, Fallopian tube cancer, Peritoneal cancer Prostate Cancer, Triple-Negative Breast Cancer <b>Gene variant testing report must be attached</b>

### This Year

目標基因	藥物	健保給付條件
NTRK1/2/3 fusion	 Larotrectinib	Children Cancer + 13 Adult Cancers <b>Gene variant testing report must be attached</b>
FGFR2 fusion	 Pemigatinib	Bile Duct Cancer <b>Gene variant testing report must be attached</b>
MET	 Tepotinib	NSCLC <b>Gene variant testing report must be attached</b>



# Strategic Alliance: Instrument, Pharmaceutical, Foundation, Insurance

INSTRUMENT, PHARMACEUTICAL, FOUNDATION, INSURANCE

# Strategic Alliance

## 2. Instrument, Pharmaceutical, Foundation, Insurance Medicine Use

Instrument

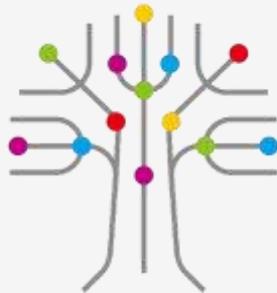


illumina



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Testing



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慧智基因

Hospital



Project of Foundation



國泰人壽  
Cathay Life Insurance



Insurance

Other  
Partner



# National Policy – Health Insurance Benefits of Testing

HEALTH INSURANCE BENEFITS OF TESTING

# Health Insurance Benefits of Testing

## 3. National Policy

- SMA Treatment Included in NHI Coverage



中文品名	諾健生靜脈懸液注射劑
Name	ZOLGENSMA Suspension for Intravenous Infusion
Indications	Treatment is applicable for patients diagnosed with Spinal Muscular Atrophy (SMA) through genetic testing, aged 2 years and below, with 2 or 3 sets of SMN2. However, it is not applicable to those who have used a ventilator for more than 12 hours per day continuously for over 30 days. °



**1** The most expensive dose in history, a sky-high priced rare drug for SMA gene therapy, will be covered by insurance starting in August! To avoid excluding other rare drugs, it will be available for the first time with installment payments.

A 4-month-old patient received a single injection costing 49 million! The first case in Taiwan where SMA gene therapy is covered by National Health Insurance. Doctors: Significant treatment effectiveness.

Spinal Muscular Atrophy Breakthrough: Medical experts at the hospital emphasize the importance of "SMA Newborn Screening," calling it indispensable.

**2** The Arrival of Sky-High Priced Rare Drug: Newborn SMA Screening to Be Included in Public Funding, Discussions Scheduled by the National Health Insurance Administration by the End of the Year.

Rare Disease Foundation: Emphasis Should Be Placed on Strengthening Prenatal Screening

**3** Can National Health Insurance Handle It? The First Instance of National Health Insurance Coverage for the 49 Million SMA Gene Therapy Benefits Infants; Industry Urges SMA Screening as the Solution.

**1**

**2**

**3**

Drug Treatment → Newborn Screening → Prenatal Screening

**Prenatal Screening  
Prevention is Better than Cure**



# Health Insurance Benefits of Testing

## 3. National Policy - NGS

### Taiwan LDTS

#### 7 Testing



Companion Diagnostics

Cancer Testing



Prenatal and Newborn



Virus and Infection



Genetics and Rare Diseases

Adverse Drug Reactions

Other Companion Diagnostics

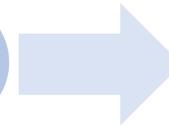


#### 8 Technique



Gene Amplification /  
Gene Sequencing

5



# 2024 NGS

## Health Insurance Benefits

## Cancer Testing



聯合報

### 石崇良：NGS健保給付下月有信心定案 擬納商業檢測套組

為讓癌症病人及早用藥，達到精準治療，衛福部健保署規畫，次世代基因檢測（NGS）於明年第二季納入健保給付，現已與專家舉行兩...

1 週前



今周刊

### NGS日韓納入給付專家會議討論資源分配次世代定序納健保治肺腺癌效益最高

癌症治療已走入精準醫療，依據不同基因變異給予合適藥物，讓病人得到最佳治療。次世代定序是否適用所有癌症，健保署又該如何合理分配資源？

1 個月前





# Corporate Sustainability – NGS Automation Solution

# Corporate Sustainability – NGS Automation Solution

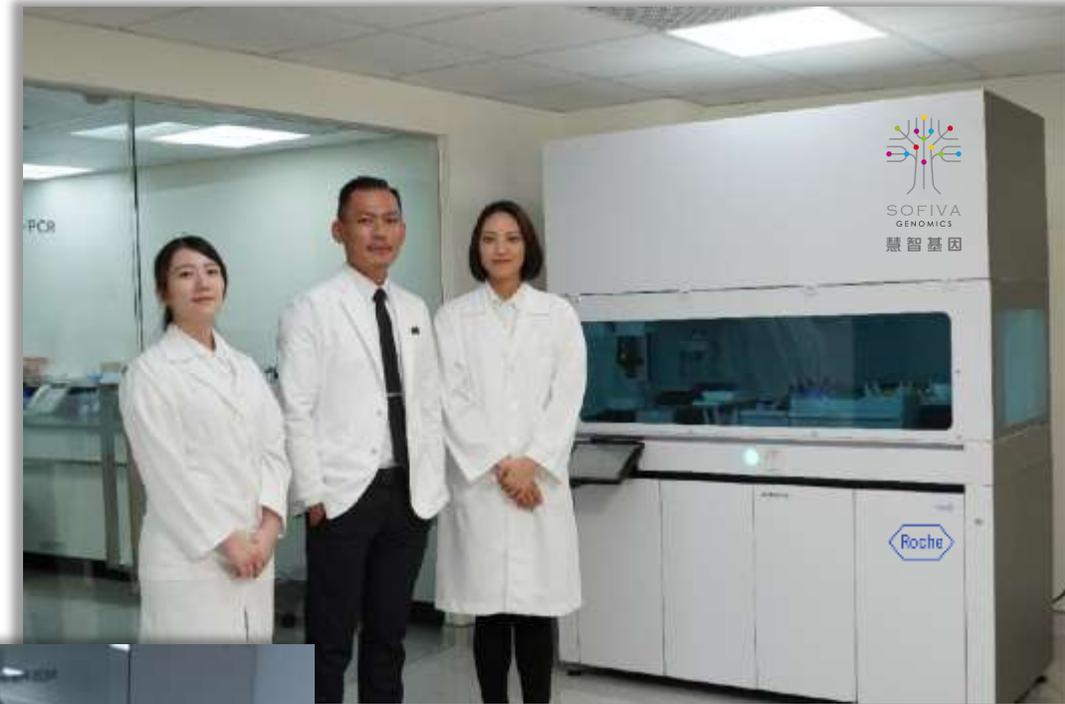
**SOFIVA** Clinical needs as a starting point, striving toward sustainable operation with the goal of achieving:

- Increase efficiency
- Reduce error rates
- Minimize process waste

***This year, the latest fully automated NGS library preparation instrument Edge from Roche has been introduced***

The first company to introduce this advanced technology

- Efficiently process a large number of samples
  - Simplifying over 100 operational steps
- ① Increase efficiency, enhance testing accuracy
  - ② Reduce human workload, minimize human errors
  - ③ Maintain consistently high-quality testing results



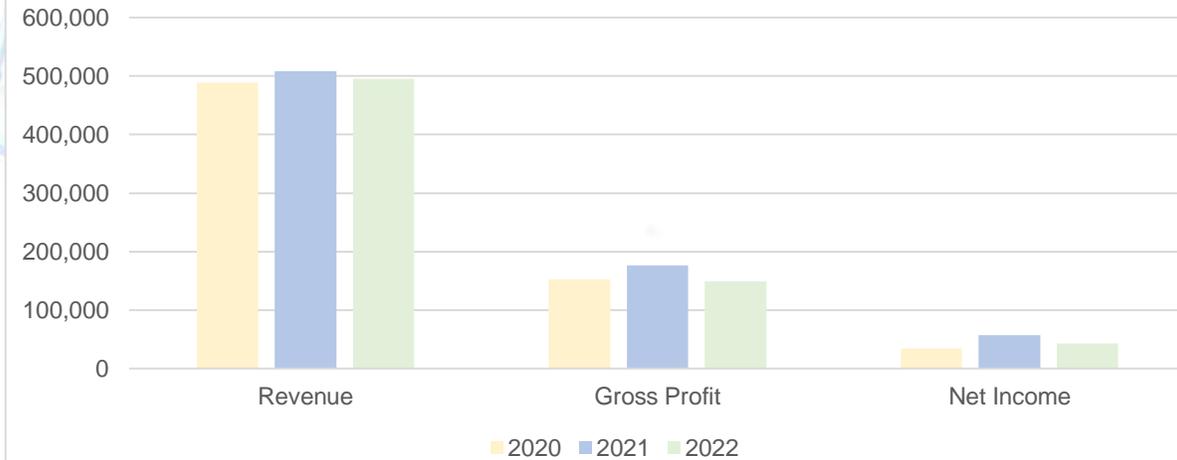


# Operating Performance

# Operational Performance

## Statements of Comprehensive Income of last 3 years

(In Thousands of New Taiwan Dollars)



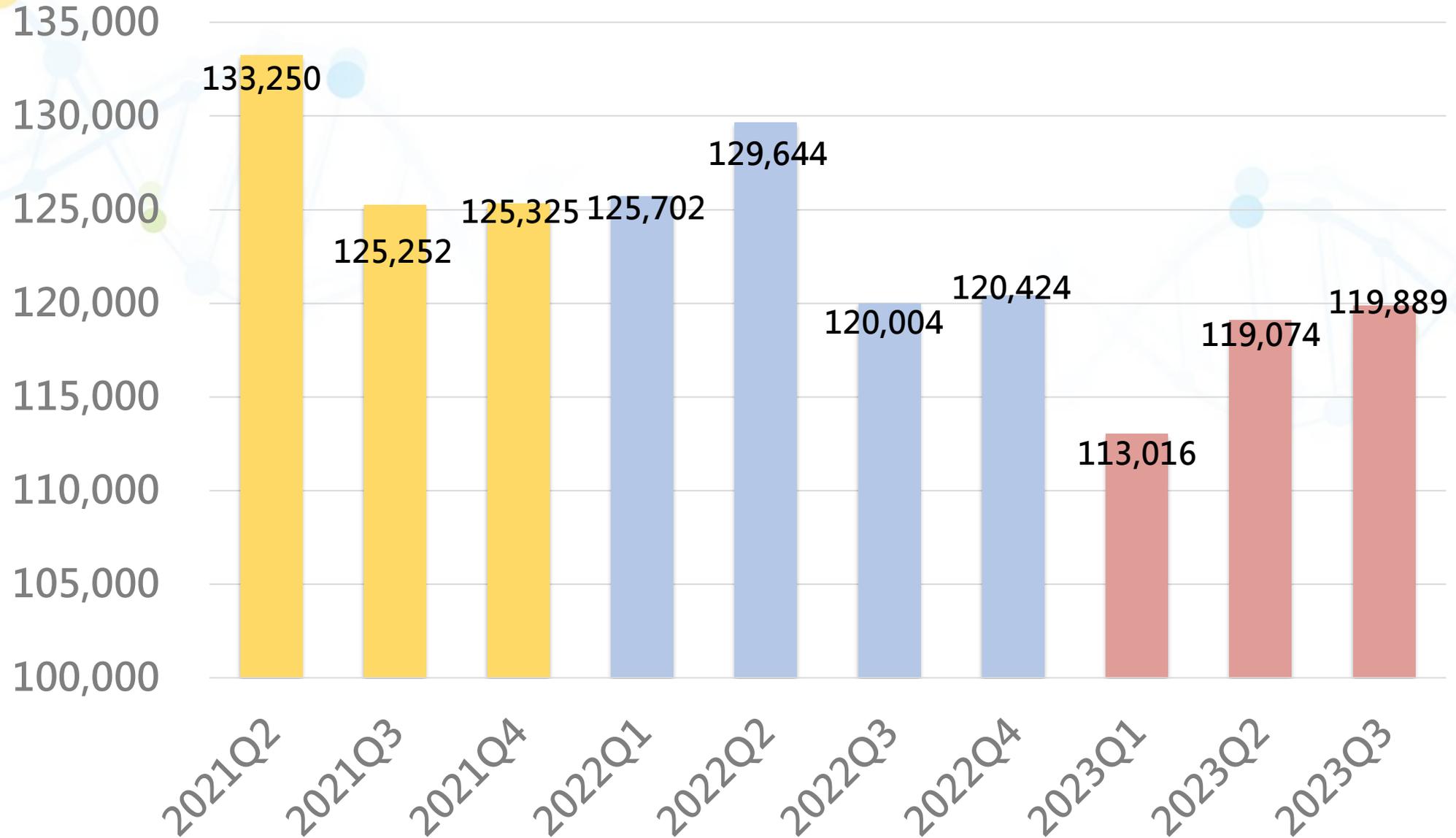
(In Thousands of New Taiwan Dollars)

	2020	2021	2022
Revenue	488,865	508,415	495,775
Gross Profit	152,741	176,813	148,988
Gross Profit (%)	31.24%	34.78%	30.05%
Operating Income	20,922	35,240	3,787
Total Non-Operating Income	16,356	28,453	43,562
Pre-Tax Income	37,278	63,693	47,349
Net Income	34,207	56,769	43,153
EPS	1.63	2.68	2.00

# Revenue Trend : The Last 10 Quarters

(In Thousands of New Taiwan Dollars)

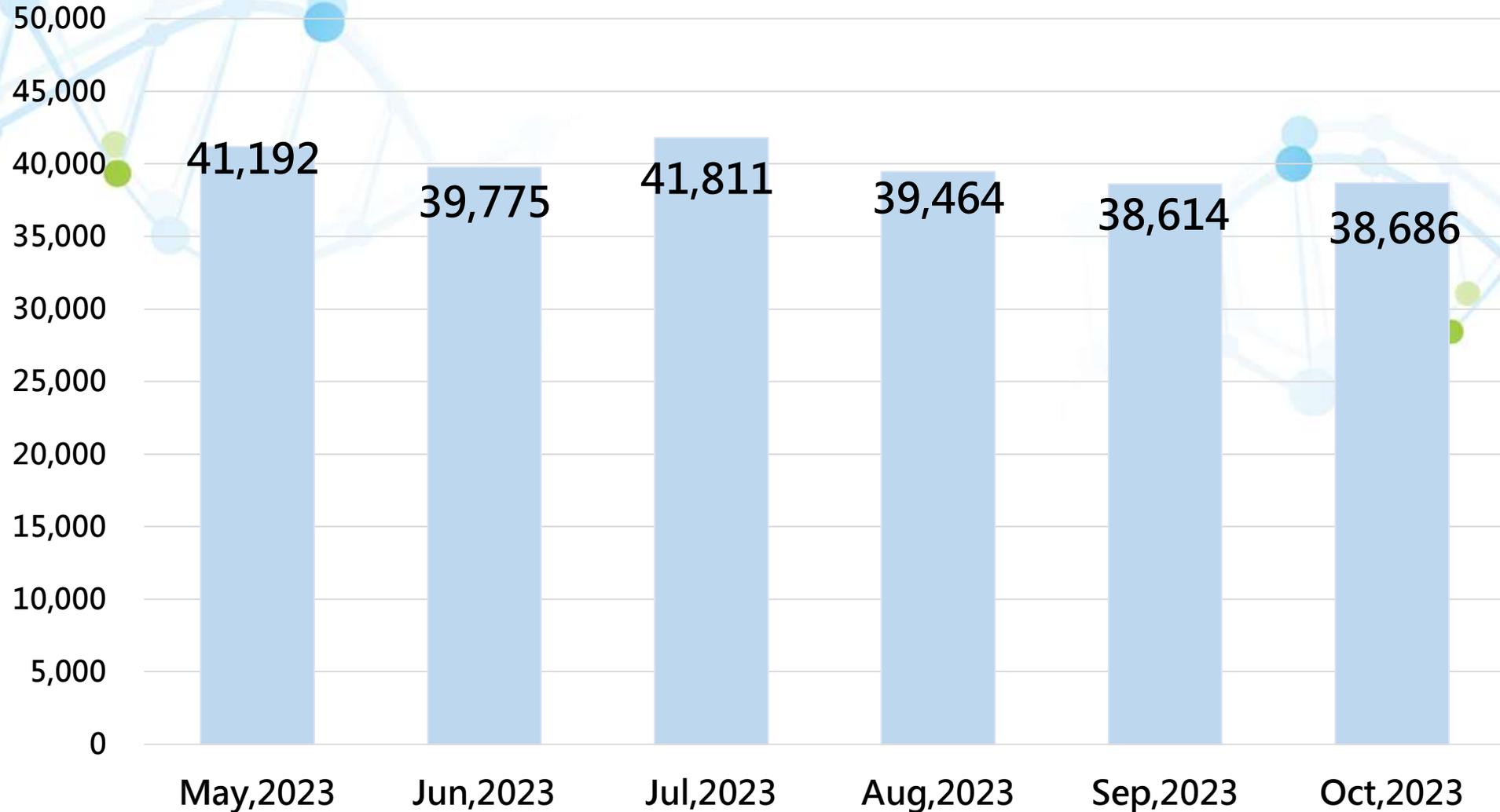
## Revenues of Last 10 Quarters



# Revenue Trend : The Last 6 Months

## Revenues of Last 6 Months

(In Thousands of New Taiwan Dollars)

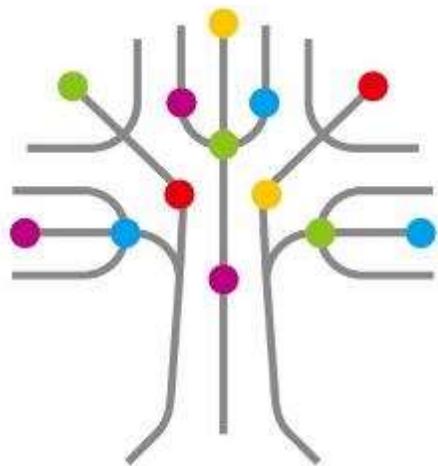


# Investment Performance

(In Thousands of New Taiwan Dollars)

DIANTHUS CO.,Ltd			
Statements of Comprehensive Income			
	2020	2021	2022
Sales Revenue	331,983	599,944	630,428
Comprehensive Income	81,955	171,767	253,022
Capital Stock	805,000	895,000	895,000
Investment from Sofiva	148,250	148,250	148,250
Shareholding Ratio of Sofiva	18.42%	16.56%	16.56%
Investment Income of Sofiva	17,498	31,047	41,902





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Thank you!



小細節 大不同

*Details Make Differences*