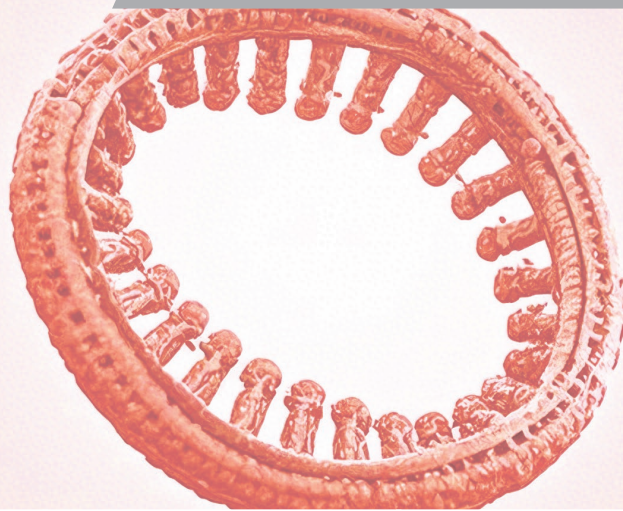




NANJING HEALED GENE BIOTECHNOLOGY CO.,LTD.

## circRNA RT-PCR DETECTION KIT



# MAJOR DEPRESSIVE DISORDER

## OBJECTIVE DIAGNOSTIC BIOMARKERS

 HIGH STABILITY  HIGH SENSITIVITY  HIGH SPECIFICITY



# WHAT IS MDD

Major depressive disorder (MDD), also known as depressive disorder, is characterized by significant and persistent depressed mood as the main clinical feature, and is the main type of mood disorder.

## 1. Emotional Disorder

- Persistent low or depressed mood
- Loss of interest or pleasure
- Feelings of worthlessness or excessive guilt
- Irritability

## 2. Physical Disorder

- Changes in appetite or weight
- Sleep disturbances
- Fatigue or loss of energy
- Psychomotor retardation or agitation
- Physical aches and pains

## 3. Cognitive Disorder

- Difficulty concentrating or making decisions
- Increased forgetfulness
- Slowed speech or movement
- Thoughts of death or suicide



# EPIDEMIOLOGY

The average lifetime prevalence of MDD in Europe is approximately 11%, significantly higher than the global average of 3.8%.



# KEY GROUPS



Adolescents



Pregnant and Postpartum women



Elderly



High-Stress Occupational Groups

- IT professional
- Pilots
- Military
- Police
- Teacher



# CLINICAL DATA

Figure 1: Gene1, Gene2, Gene3, Gene4 show significantly increased expression in plasma or saliva samples from depression patients.

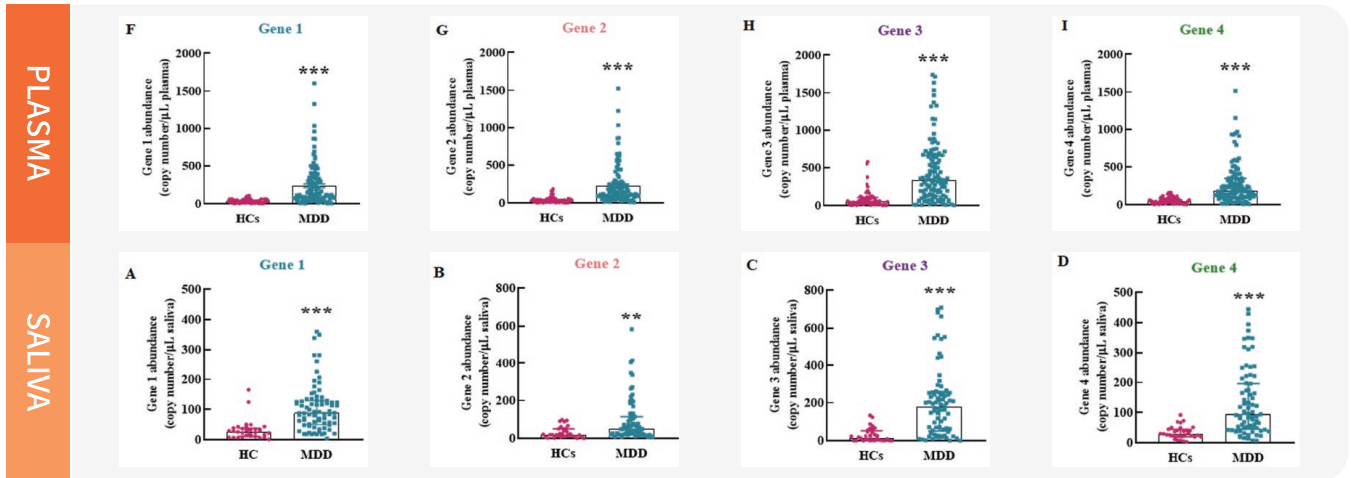


Figure 2: The four-indicator combined test correlates with clinical scale evaluations at 99.5% in plasma or saliva samples.

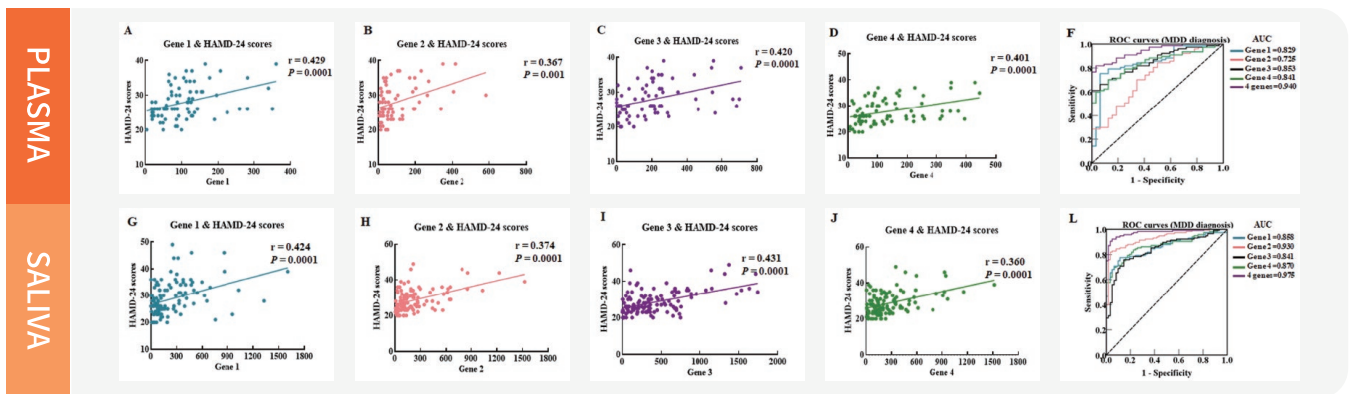


Figure 3: Gene1, Gene2, Gene3, Gene4 show good therapeutic effects in plasma or saliva samples from depression patients.

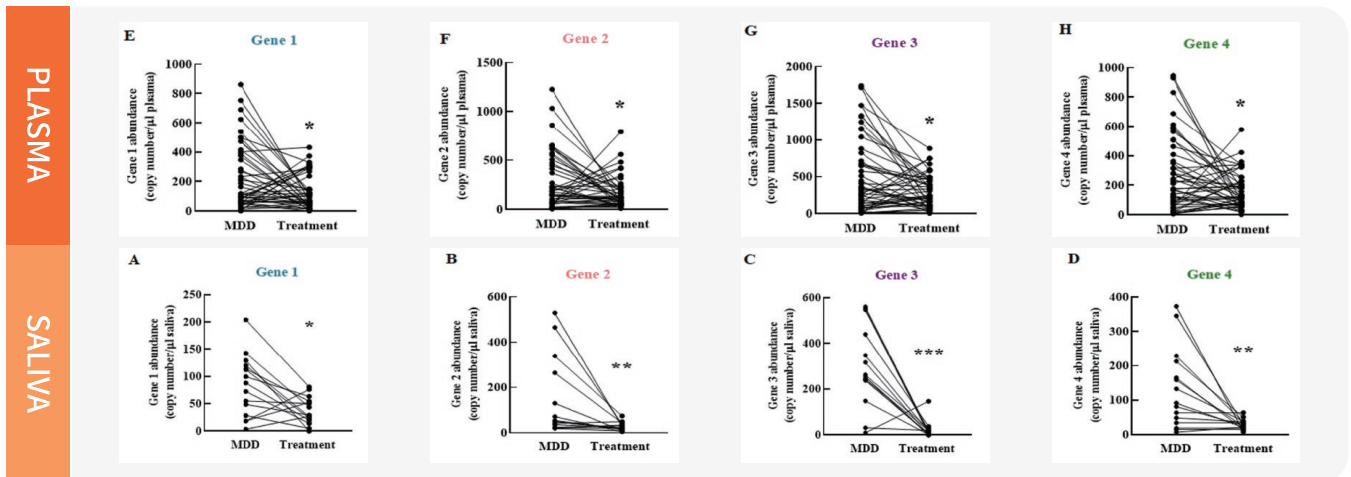
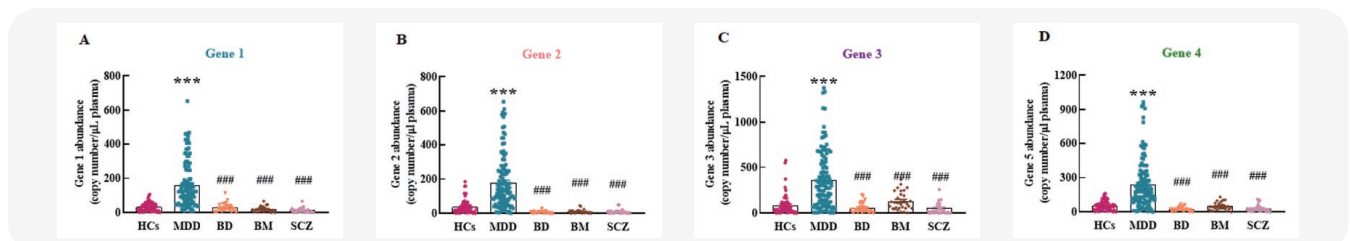









Figure 4: Gene1, Gene2, Gene3, Gene4 exhibit excellent specificity, showing 100% specificity only in depression clinical samples.



Assessment Tools: Depression severity: 24-item Hamilton Depression Rating Scale (HAMD-24)/Montgomery-Asberg Depression Rating Scale (MADRS)/Patient Health Questionnaire-9 (PHQ-9).









# DIAGNOSTIC METHODOLOGY COMPARISON

	 PATHOLOGICAL EXAMINATION	 MEDICAL IMAGING	 BIOELECTRICAL SIGNAL	 PROTEIN	 RATING SCALE	 NIACIN	 circRNA (PLASMA/SALIVA)
<b>PATHOLOGICAL FEATURES</b>	✓	✓	✓	✓	✗	✓	✓
<b>NON-INVASIVE</b>	✗	✓	✓	✓	✓	✓	✓
<b>REPEATABILITY</b>	✗	✓	✓	✓	✓	✓	✓
<b>HIGH SENSITIVITY AND SPECIFICITY</b>	✗	✗	✗	✗	✗	✗	✓
<b>EARLY SCREENING AND DIAGNOSIS</b>	✗	✗	✗	✗	✗	✗	✓
<b>MASS SCREENING</b>	✗	✗	✗	✗	✓	✓	✓
<b>MEDICATION GUIDANCE</b>	✗	✗	✗	✓	✗	✓	✓



## PRODUCT ADVANTAGES

-  **1.Objective Assessment**  
Innovative diagnostic method
-  **2.High Accuracy and Specificity**  
4 biomarkers, specificity  $\geq 95\%$ , accuracy  $\geq 90\%$
-  **3.Circular RNA Detection Technology**  
Ground-breaking technology
-  **4.Saliva or Plasma sample**  
Easy to collect, non-invasive, well-accepted, and widely applicable
-  **5.Quantitative Detection**  
Differentiation of mild, moderate, and severe depression in patients
-  **6.Therapeutic Effects Evaluation**  
Evaluation of therapeutic effects, provide treatment reference



# OPERATING PROCEDURE

## 01 SAMPLE COLLECTION (SALIVA, PLASMA)



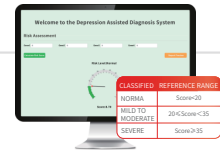
## 02 circRNA EXTRACTION



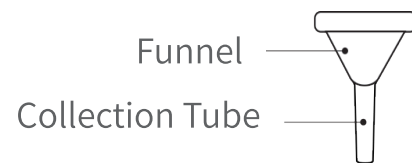
## 03 RT-PCR PROCEDURE



## 04 DATA ANALYSIS (CALCULATE THE SCORE AND PROVIDE THE TEST RESULTS)



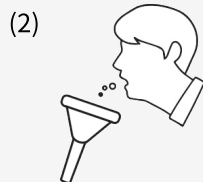
### Saliva Collection Kit



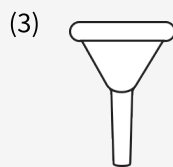
#### Collection Instructions:



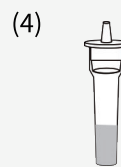
(1) Before collecting saliva, rinse your mouth with water for 30 minutes to clean out any debris.



(2) Relax the cheek muscles and gently massage for 30 seconds, or use the tip of your tongue against the roof of your mouth or lower teeth to stimulate saliva production. Gently spit into the collection funnel until the liquid saliva reaches the scale (around 2mL).



(3) Unscrew the collection funnel from the tube and dispose of it (handle as hazardous waste to avoid contact or contamination).



(4) Secure the cap on the saliva collection tube to complete the sample collection.



(5) Place the collection tube and test request form into the foam box for shipping. If the temperature is above 25°C, ice packs (provided) should be used (follow ice pack packaging instructions).

#### Notes:

1. Do not eat, drink, smoke, or chew gum for 30 minutes before sampling.
2. Before collecting saliva, relax the cheek and gently massage for 15–30 seconds to stimulate saliva flow.
3. Ensure the collection tube's outer packaging is intact and confirm that the saliva tube is not leaking.
4. This product is for single use only. Do not share the collection tube between individuals.





## circRNA Four-Indicator Test Report

Total Score:

Score value

■ **Normal (Total Score < 20):**

Indicates the sample is within the normal range, with a low risk of depression

■ **Mild and Moderate (20 ≤ Total Score < 35):**

Indicates a higher risk of mild to moderate depression. Clinical and psychological evaluation is recommended

■ **Severe (Total Score ≥ 35):**

Indicates a higher risk of severe depression. Clinical and psychological evaluation is recommended

**STATEMENT :**

The test results are for auxiliary purposes only, such as for clinical or research purposes and cannot be used as a definitive diagnosis of depression. The final interpretation of the test results is to be made by a clinical doctor or psychological assessment expert.

**NANJING HEALED GENE BIOTECHNOLOGY CO.,LTD.**

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