One Step Dementia Risk Test Kit

(Colloidal Gold Lateral Immunochromatography)

Hunan Qankorey Biotechnology Co., Ltd.

Features

✓ **Accurate**

Non-Invasive

Easy
1 step

Fast 10 Minutes

Clinically Approved

Globally First

Urine-based amyloid-β(Aβ) biomarker testing for risk of Alzheimer's Disease

Specifications

Product Name	One Step Dementia Risk Test Kit (Colloidal Gold Lateral Immunochromatography)
Certificate	CE, NMPA, MDA
Packing	1pcs/box, 25pcs/box, 50pcs/box
Usage	This product is an *in vitro* auxiliary screening device for risk alert of dementia (including but not limited to Alzheimer's disease). It may be used to evaluate brain health status and assist doctors to decide whether further tests are required.

Clinical Performance

75.7%	**91.03%**	**0.67**
Sensitivity	**Specificity**	**Kappa Value**

Diagnostic group	Qty	Aβ-PET Scan positive	Urine Aβ detection positive	Aβ-PET Scan positive coincidence rate	Urine Aβ detection positive coincidence rate
AD group	80	75	64	93.75%	80.00%
Other dementia	6	1	4	16.7%	66.7%
MCI	21	10	13	47.62%	61.90%
CN	301	/	27	/	8.97%

		Reference Principle		In total
		Case Group(+)	Comparison Group(-)	
Urine Aβ Detection	Positive (+)	81	27	108
Urine Aβ Detection	Negative (-)	26	274	300
	In total	107	301	408

Sensitivity=A/(A+C)=81/107x100%=75.7%

Specificity =D/(B+D) =274/301x100%=91.03%

Actual Coincidence Rate $P_o = \dfrac{(A+D)}{(A+B+C+D)}$ x100%= $\dfrac{(81+274)}{408}$ x100%= 87%

Theoretical Coincidence Rate $P_e = \dfrac{(A+B)*(A+C)+(C+D)*(B+D)}{(A+B+C+D)^2}$ x100%= $\dfrac{108*107+300*301}{408^2}$ x100%≈61.2%

Kappa Value $K = \dfrac{P_o - P_e}{1 - P_e} = \dfrac{0.87 - 0.612}{1 - 0.612}$ =0.67

This clinical verification was completed independently by Sichuan Provincial People's Hospital in 2023. Total 408 participants were enrolled and classified as the cognitively normal (CN) group, the mild cognitive impairment (MCI) group, the AD group and the other dementia group. Meanwhile, Aβ-PET Scan was performed for comparison in clinically defined patients. The results support our One Step Dementia Risk Test Kit as an early screening device for MCI and dementia, and warrant the further longitudinal studies.

Instructions

1 Drinking

Please drink 200-300mL water 30-60 min before test.

2 Sampling

Collect midstrem urine sample with the disposable cup supplied.

3 Testing

Draw some urine with the supplied straw, and slowly dispense 4 drops, one by one, to the sample hole of the test strip.

4 Result

Place the strip on a table, wait for 10 min, then take a picture.
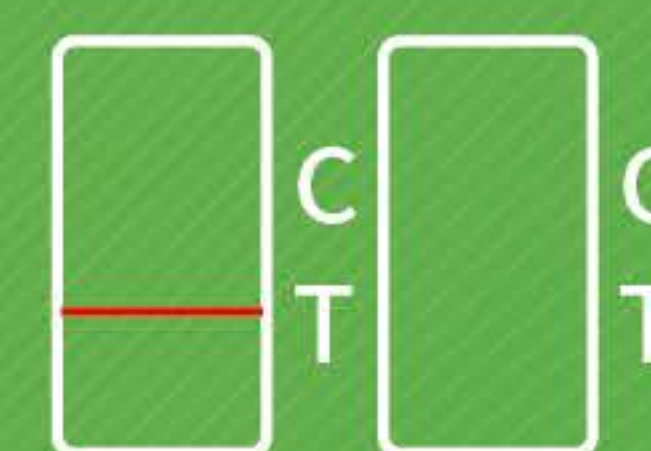
5 Positive

If positive, repeat 1 or 2 times in weeks. If the positivity continues, it is recommended to see a doctor for further check.

6 Negative & Invalid
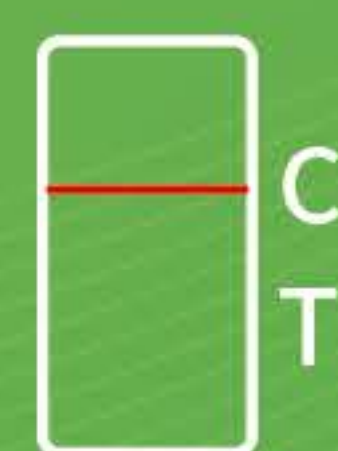
If negative, monitor again in every 6-12 months.

Please contact customer service.

Interpretation of test results

Positive: The concentration of amyloid-β protein(Aβ) is above the normal range, indicating the high risk of AD progression. It is recommended to check the potential risk factors accordingly and adjust life style, e.g.(Reducing alcohol and smoke intake, getting quality sleep etc.)

Negative: The concentration of amyloid-β protein(Aβ) is in the normal range. It is recommended to maintain the existing lifestyle and test regularly every year.