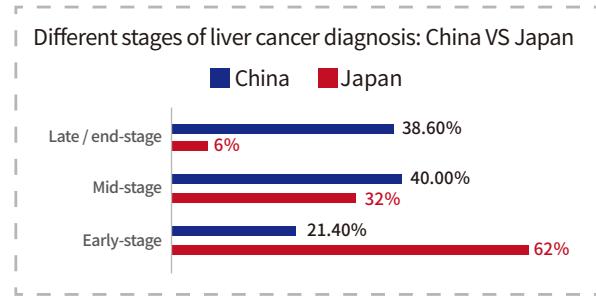


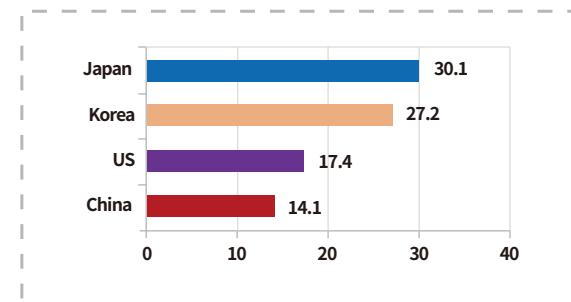
A background image of a human liver, rendered in a soft, glowing purple hue. The liver is shown from a slightly elevated angle, with a bright, star-like glow emanating from its surface, suggesting a healthy or active organ.

## **Three Liver Cancer Markers (AFP, AFP-L3%, DCP)**

## The early diagnosis rate of liver cancer in China is low, while the mortality rate is high.



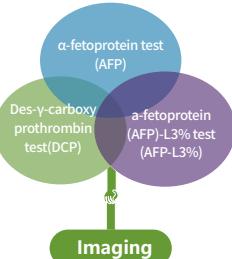
The proportion of early-stage HCC patients at initial diagnosis:  
Japan is nearly **3 times** that of China



The five-year survival rate for liver cancer in China is low,  
less than **50%** of that in Japan

## Successful Model for Liver Cancer Screening: $\alpha$ -fetoprotein test + $\alpha$ -fetoprotein (AFP)-L3% test+ Des- $\gamma$ -carboxy prothrombin test + Liver Ultrasound

Japan's recommended early screening methods for liver cancer: AFP + AFP-L3% + DCP + ultrasound



### 2021 Japan Society of Hepatology (JSH) Consensus Recommendations: Management of Hepatocellular Carcinoma (Updated Version)

- ◆ Extremely high-risk group: Monitor AFP/DCP/AFPL3% and imaging examinations at 3-4 month intervals
- ◆ High-risk group: Monitor AFP/DCP/AFPL3% and ultrasound examinations at 6-month intervals

## What are the Three Liver Cancer Markers?

- ◆  $\alpha$ -fetoprotein test (AFP): Routinely used for HCC screening and clinical diagnosis.
- ◆  $\alpha$ -fetoprotein (AFP)-L3% test (AFPL3%): AFPL3 is a glycoprotein primarily derived from hepatocellular carcinoma cells, unaffected by AFP levels. An AFPL3  $\geq 10\%$  serves as the diagnostic threshold for HCC.
- ◆ Des- $\gamma$ -carboxy prothrombin test (DCP): A protein elevated in the liver during HCC and vitamin K deficiency.

## The advantages of the Three Liver Cancer Markers

### Mature

- ◆ Japan began clinical application in 1998, and the U.S. FDA approved it in 2005 for early warning, diagnosis, and prognostic evaluation of liver cancer.

### Effective

- ◆ Detects early-stage liver cancer 3-28 months earlier than imaging methods, capable of identifying very early-stage liver cancer.

### Precise

- ◆ Early-stage liver cancer detection rate reaches 81.6%-87.8%; mid-to-late-stage detection rate reaches 96%.

### Convenient

- ◆ Only requires 1-4 ml of serum to complete the test.

### Authoritative

- ◆ Recommended by multiple liver cancer guidelines/consensus documents in the U.S., Europe, Japan, and China.

## Intended use of the Three Liver Cancer Markers

- ◆ For auxiliary diagnosis of early-stage liver cancer in high-risk populations.
- ◆ Combined testing of AFP, AFP-L3%, and DCP improves the detection rate of early-stage liver cancer.

### Target population:

(1) Hepatitis B virus and/or hepatitis C virus infection	(2) Long-term alcohol abuse (alcoholic liver disease)
(3) Non-alcoholic steatohepatitis	(4) Consumption of food contaminated with aflatoxin
(5) Individuals with a family history of liver cancer	(6) People with diabetes, obesity, or severe obesity
(7) Males over 35 years old and females over 45 years old	
(8) Liver cirrhosis caused by various factors such as schistosomiasis	

## Guideline Consensus

Three Liver Cancer Markers has been incorporated into numerous domestic and international guidelines and consensus documents. It is recommended that AFP, AFP-L3%, and DCP be used for liver cancer diagnosis as complementary markers to AFP. Combined detection can improve the early detection rate of liver cancer.

- ◆ "Guidelines for Liver Cancer Screening in the Chinese Population (2022, Beijing)"
- ◆ "Guidelines for the Diagnosis and Treatment of Primary Liver Cancer (2022 Edition)"
- ◆ "Guidelines for Stratified Screening and Surveillance of Primary Liver Cancer (2020 Edition)"
- ◆ "Expert Consensus on Basic Health Examination Items (2022)"
- ◆ "Expert Consensus on Blood Biomarkers for Early Clinical Screening of Hepatocellular Carcinoma"
- ◆ "NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers (2020.V1)"

## Typical case

### Case 1

AFP, AFP-L3%, and DCP serve as effective indicators for liver cancer diagnosis, and combined testing is recommended. Particularly for high-risk populations with low AFP levels and liver cancer patients, the three-marker panel for liver cancer can effectively compensate for the limitations of AFP single-item testing. This approach not only aids in the differential diagnosis of benign and malignant liver diseases among high-risk groups, improving early diagnosis rates, but also serves as a basis for clinical stratification and prognosis (recurrence, survival) management of liver cancer.

**Patient:** Male, 69 years old

**Chief Complaint:** Discovery of a right hepatic space-occupying lesion for 1 week

**Past Medical History:** Occult hepatitis B

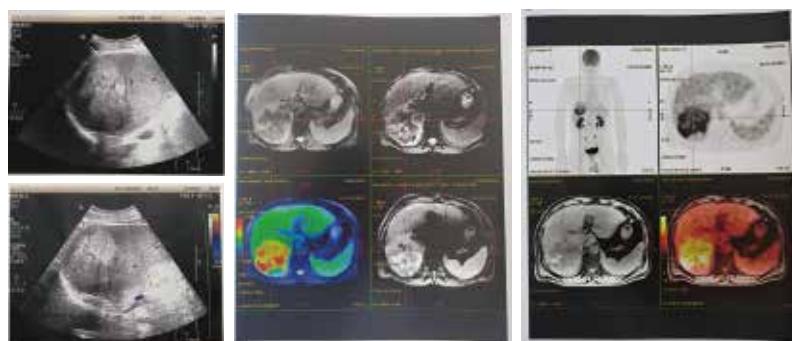
**Family History:** Mother died of "liver disease," father died of "gastric cancer"

**Imaging Findings:** Both liver ultrasound and PET-MR imaging suggested liver cancer

**Laboratory Tests:** AFP: 6.95 ng/ml (-) AFP-L3%: 23% (↑) DCP: 104 ng/ml (↑) GP73: 165.3 ng/ml (↑)

**Clinical Diagnosis:** liver cancer

**Treatment:** Liver biopsy + TACE procedure



## Case 2

Three Liver Cancer Markers serve as crucial tools in the follow-up monitoring of hepatocellular carcinoma patients. A higher number of positive results among AFP, AFP-L3%, and DCP correlates with poorer prognosis, increased recurrence rates, and thus warrants enhanced imaging examinations and follow-up frequency.

**Laboratory tests:** AFP: 11.18 ng/ml (↑); AFP-L3%: 11.84 (↑); DCP: 81065 ng/ml (↑)

**Imaging findings:** Liver cirrhosis, recurrence of liver cancer after treatment



## Detection method: Chemiluminescence Immunoassay



C800



MQ60 smart



MQ60 proB

Test Item	Qualification	Sample	Detection Range	reference value	Detection Equipment
α-fetoprotein test (AFP)	NMPA, CE	Serum, plasma	0.6-1200 ng/mL	<7 ng/ml	C800、MQ60 series
α-fetoprotein (AFP)-L3% test (AFP-L3%)	NMPA, CE	Serum, plasma	5%-50%	<10%	MQ60 proB
Des-γ-carboxy prothrombin test (DCP / PIVKA-II)	NMPA, CE	Serum	5-20000 ng/mL	< 40 ng/ml	C800、MQ60 series

## Result interpretation

AFP  $\geq 20$  ng/mL indicates a high risk of liver cancer or chronic liver disease in patients.

AFP-L3%  $\geq 10\%$  suggests a high risk of liver cancer in patients.

DCP  $\geq 40.0$  ng/mL implies an elevated risk of primary liver cancer, chronic liver disease, and benign liver space-occupying lesions in patients.

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