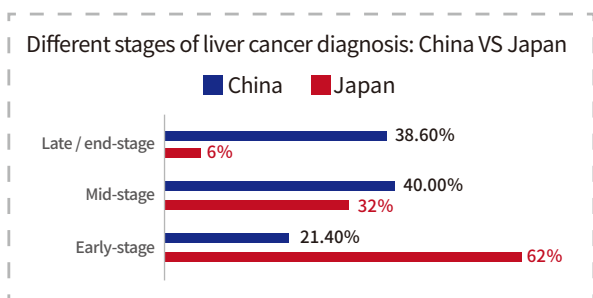


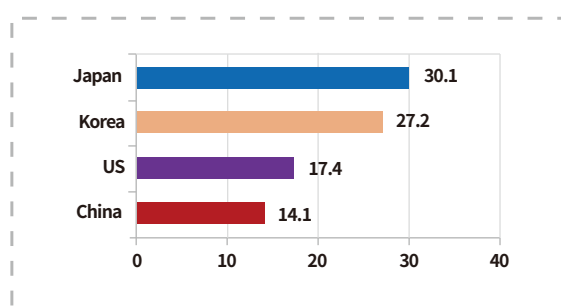


## **Three Liver Cancer Markers (AFP、AFP-L3%、DCP)**

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



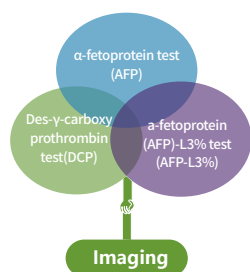
The proportion of early-stage HCC patients at initial diagnosis: Japan is nearly **3 times** that of China



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 + a-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/AFP-L3% and imaging examinations at 3-4 month intervals
- ◆ High-risk group: Monitor AFP/DCP/AFP-L3% 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.
- ◆ a-fetoprotein (AFP)-L3% test (AFP-L3%): AFP-L3 is a glycoprotein primarily derived from hepatocellular carcinoma cells, unaffected by AFP levels. An AFP-L3  $\geq 10\%$  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

**Past Medical History:** Occult hepatitis B

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

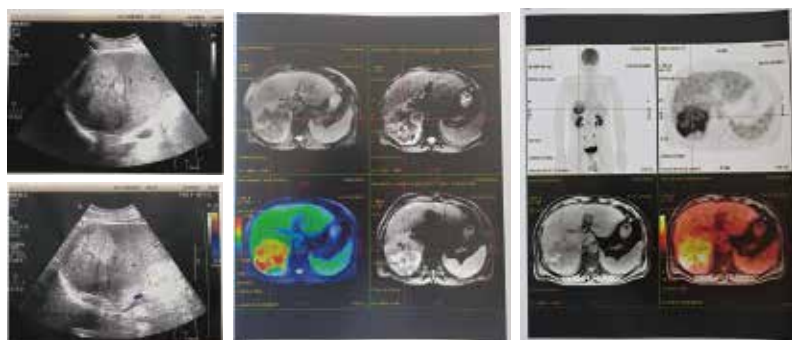
**Laboratory Tests:** AFP: 6.95 ng/ml (-) AFP-L3%: 23% (↑) DCP: 104 ng/ml (↑) GP73: 165.3 ng/ml (↑)

**Clinical Diagnosis:** liver cancer

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

**Family History:** Mother died of "liver disease," father died of "gastric 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
$\alpha$ -fetoprotein test (AFP)	NMPA, CE	Serum, plasma	0.6-1200 ng/mL	<7 ng/ml	C800、MQ60 series
$\alpha$ -fetoprotein (AFP)-L3% test (AFP-L3%)	NMPA, CE	Serum, plasma	5%-50%	<10%	MQ60 proB
Des- $\gamma$ -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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