Introducing FUJIFILM µTAS Wako® AFP-L3 and DCP HEPATOCELLULAR CARCINOMA BIOMARKERS

NEVER STOP

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For In Vitro Diagnostic Use to Aid in Hepatocellular Carcinoma (HCC) Risk Assessment

Intended Use:

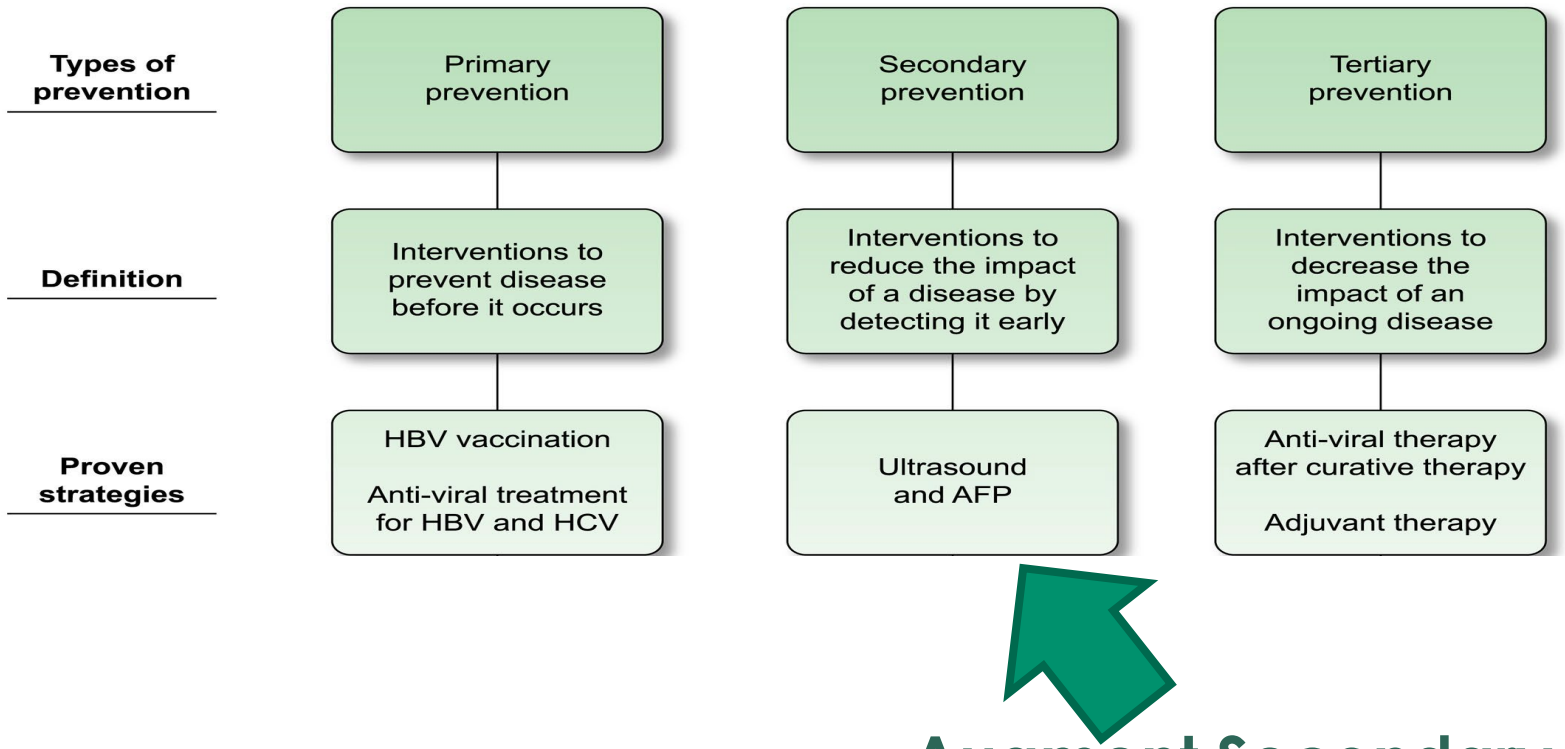
AFP-L3

The uTASWako AFP-L3 Immunological Test System is an in vitro device that consists of reagents used with the uTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, AFP-L3% in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment. Patients with elevated AFP-L3% values (10%) have been shown to be associated with an increase in the risk of developing HCC within the next 21 months and should be more intensely evaluated for evidence of HCC according to existing HCC practice guidelines in oncology.

DCP

The uTASWako DCP Immunological Test System is an in vitro device that consists of reagents used with the uTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, des-gamma-carboxy-prothrombin (DCP) in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment.

AASLD Surveillance Algorithm Can Be Augmented with AFP-L3 and DCP Biomarkers



Augment Secondary Prevention with AFP-L3%* and DCP

*AFP-L3% = (AFP-L3/Total AFP) * 100

Figure adapted from:
Singal, Amit G.; Llovet, Josep M.; Yarchoan, Mark; Mehta, Neil; Heimbach, Julie K.; Dawson, Laura A.; Jou, Janice H.; Kulik, Laura M.; Agopian, Vatche G.; Marrero, Jorge A.; Mendiratta-Lala, Mishal; Brown, Daniel B.; Rilling, William S.; Goyal, Lipika; Wei, Alice C.; Taddei, Tamar H. AASLD Practice Guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma. Hepatology : May 22, 2023. doi: 10.1097/HEP.0000000000000466

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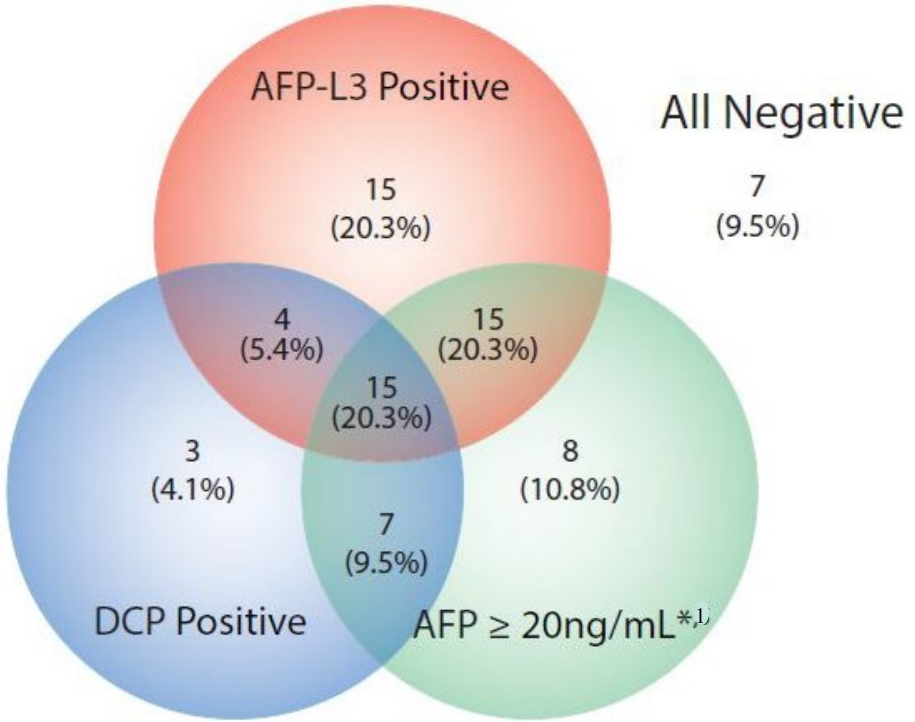
Complementary Use of AFP-L3 and DCP Tests Increases Sensitivity

Combined use of AFP-L3 and DCP biomarkers aids in HCC surveillance

- 90.5% of HCV-related cirrhosis patients exhibited at least one elevated biomarker at the time of HCC diagnosis
- AFP* alone was not elevated in 29 patients at the time of HCC diagnosis



*AFP is not cleared for use as a biomarker in patients at risk for liver disease.

1. Oka H, et al. Multicenter prospective analysis of newly diagnosed hepatocellular carcinoma with respect to the percentage of Lens culinaris agglutinin-reactive alpha-fetoprotein. J Gastroenterol Hepatol. 2001;16:1378-83.

Diagnostic Value of AFP, AFP-L3% and DCP in HCC Screening in Liver Cirrhosis Patients HBV- or HCV-related[1]

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Clinical features of groups: HCC Vs Liver Cirrhosis (LC)

- Serum biomarker levels determined by uTASWako system in HCC or LC groups (HBV- or HCV-related)

- Mean age:
  - HCC = 59.8 ±11.3 yrs
  - LC = 46.5 ±13.8 yrs

- Male/Female ratios:
  - HCC = 4.0
  - LC = 1.12

- BCLC stage (# patients):
  - 0 & A = 92 (HCC) and 170 (LC)
  - B,C,D = 78 (HCC) and 0 (LC)

- Tumor size (# patients HCC group):
  - <2 cm = 44
  - 2 – 5 cm = 70
  - >5 cm = 5

- Number of Tumors (# patients HCC group):
  - 1 = 100
  - >2 = 70

Table 1. Clinical features of patients in 2 groups.

	HCC (N=170)	LC (N=170)	*P* VALUE
AFP (ng/mL)	33 (5.60-347.95)	1.95 (1.30-2.90)	<.001*
AFP-L3 (%)	7.5 (0.5-39.8)	0.5 (0.5-05)	<.001*
DCP (mAU/mL)	206.94 (42-3790)	16 (12.75-20)	<.001*

Data were expressed as mean ± std or median (interquartile range, lower quartile – upper quartile) and numbers (n) with percentage (%). The age variable was measured by *T*-test. The binary variable (gender) was identified by Chi-squared test. The continuous variables (levels of AFP, AFP-L3, DCP, hTERT) with abnormal distribution were analyzed by Mann-Whitney *U* test.
**P*-value < .05.

Table 2. Correlation between concentration of AFP, AFP-L3%, DCP with tumor size.

	TUMOR SIZE			p_A	p_B	p_C	p_D
	<2CM	2-5CM	>5CM				
AFP, ng/mL	8.7 (3.8; 58.5)	183.6 (8.4; 9647.5)	34.8 (8.8; 290.6)	.05	.005*	.027*	.101
AFP-L3, %	2.4 (0.5; 7.7)	16.7 (0.7; 76.1)	9.2 (0.9; 50.3)	.001*	.001*	.221	<.001*
DCP, mAU/mL	31.5 (20.9; 70.7)	3747.7 (750.4; 35 422.5)	178.0 (60.5; 1866.0)	.291	<.001*	<.001*	.003*

Data were showed as median (lower quartile; upper quartile).
[a]Tumor size group <2 cm with 2 to 5 cm.
[b]Tumor size group <2 cm with >5 cm.
[c]Tumor size group 2 to 5 cm with >5 cm.
[d]Tumor size with each biomarker.
**P*-value < .05, using Kruskal-Wallis test to calculate difference of each biomarker.

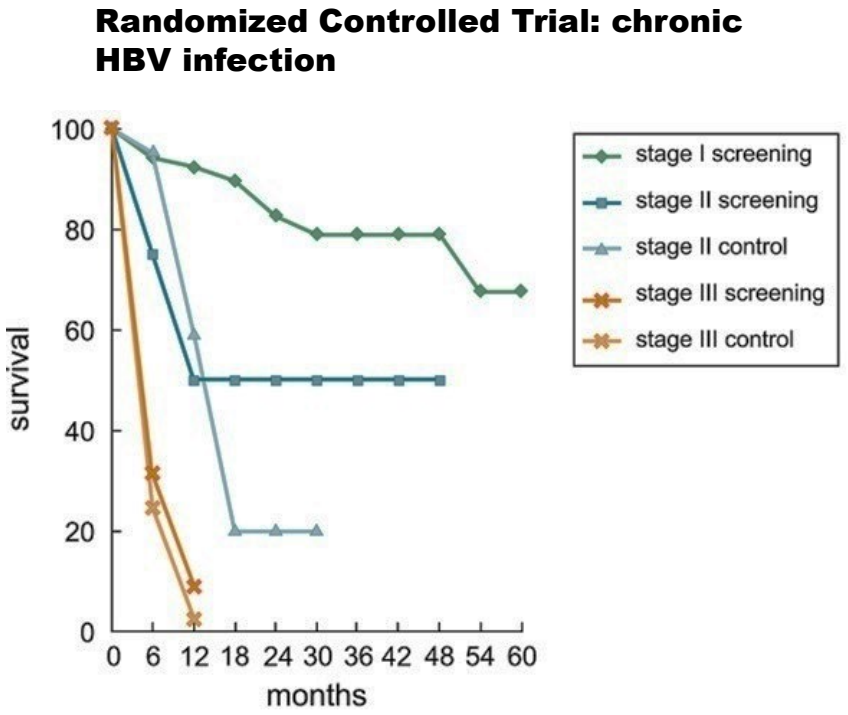
Table 4. Diagnostic values of AFP, AFP-L3, DCP, and hTERT mRNA in combination.

	AUC	SENSITIVITY (%)	SPECIFIC (%)
AFP+AFP-L3	0.853	81.2	89.4
AFP+DCP	0.900	92.4	87.6
AFP-L3+DCP	0.891	91.2	87.0
AFP+AFP-L3+DCP	0.897	93.5	85.8

Data from Receiver Operating Characteristic (ROC) curves for AFP, AFP-L3 and DCP in detection HCC for liver cirrhosis patients HBV or HCV-related.

1. Figures adapted from: Nguyen, et al. Cancer Informatics. 2022; Volume 21: 1-8.

“HCC surveillance has been shown to significantly reduce HCC-related mortality”[1]



Adapted from (1) Singal, et al., AASLD Practice Guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma Hepatology: May 22, 2023.

The FUJIFILM Solution: Robust HCC Risk Assessment Aids in Early Cancer Detection, Curative Treatments and Greater Patient Survival.

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