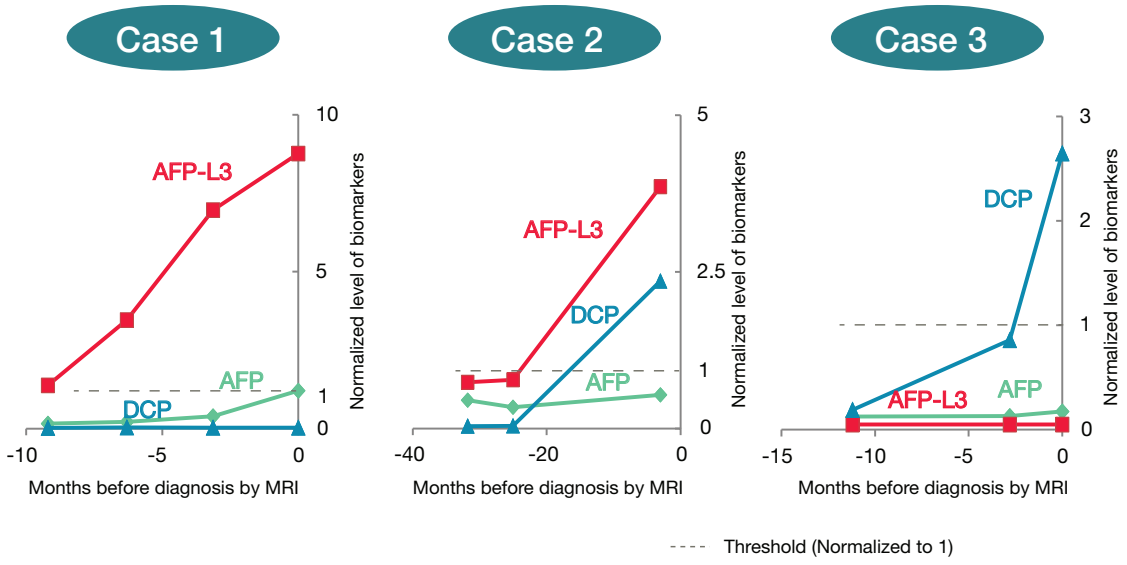
Independent

Combined results of AFP-L3 and DCP can:

- **Improve HCC risk assessment compared to the use of AFP results alone. AFP-L3%, DCP and AFP results are independent of each other.[1,2,3]**
- **Aid in the earlier identification of HCC.[1,2,3,4] Biomarker elevations can occur up to 21 months before HCC is identified by imaging.[4,5]**

Results from this study show independent biomarker elevation before detection by MRI.[1]



Case 1: AFP-L3% level was elevated before detection by MRI.
Case 2: Both AFP-L3% and DCP levels were elevated before detection by MRI.
Case 3: DCP level was elevated before detection by MRI.

This study compared AFP-L3% and DCP levels over time versus AFP and MRI results.* Elevated AFP-L3% levels were defined as ≥ 10% and elevated DCP was defined as ≥ 7.5 ng/mL. Analysis of AFP was performed using a threshold of 20ng/mL.

* FUJIFILM Wako Diagnostics does not have a claim for the use of the AFP Serum Biomarker in the risk assessment of patients with chronic liver disease for development of HCC and has not established a threshold for AFP.

References:
1. Hann HW, et al. J Med Microb Diagn 2014;3:130; 2. Ertle JM, et.al. Digestion 2013; 87:121-131; 3. Choi JY, et.al. World J. Gastroenterol 2013; 19: 339-346, 4. Data collected for μTASWako i30 Analyzer and AFP-L3 & DCP Test Systems; 5. Shimauchi Y, et al. Oncol Rep 2000;7:249-256

FUJIFILM
Value from Innovation

Wako

Enhance Your Hepatocellular Carcinoma (HCC) Risk Assessment

with AFP-L3 and DCP Biomarkers

AFP-L3 and DCP are *in vitro* diagnostic serum biomarkers

AFP-L3: Lectin-reactive alpha-fetoprotein
DCP: Des-gamma-carboxy prothrombin

AFP-L3% ≥ 10%:
Associated with 10.6-fold increased risk of developing HCC[1]

DCP ≥ 7.5 ng/mL:
Associated with 4.8-fold increased risk of developing HCC[1]

Both biomarkers are commercially available through major US Reference Labs and CMS reimbursed

Overview of Intended Uses (See package inserts):

The µTASWako AFP-L3 and DCP test systems are in vitro devices that consist of reagents used with the µTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, AFP-L3% and DCP in human serum. Both devices are intended for IVD use as aids in the risk assessment of patients with chronic liver disease for development of HCC in conjunction with other laboratory findings, imaging studies and clinical assessment.[1]

Ordering Test Codes of Major Reference Laboratories

Laboratory	HCC Risk Panel AFP-L3, AFP, and DCP	AFP-L3 AFP-L3 and AFP	DCP
Quest	16222	19529	19982
LabCorp	---------	141300	141325
ARUP	0081326	0081208	0081312
Mayo	HCCGS	L3AFP	DCP

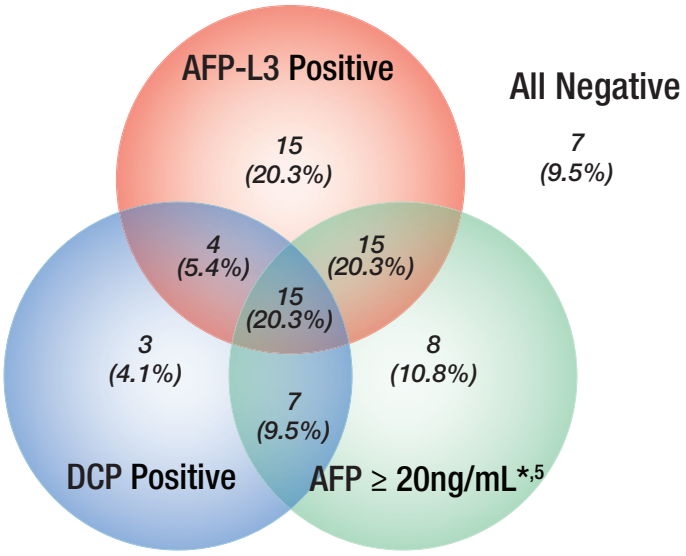
References:
1. µTASWako i30 Analyzer and AFP-L3 & DCP Test Systems Package Inserts

Complementary

Combined results of AFP-L3 and DCP can:

- **Identify patients with an increased risk of HCC development.[1,2,3]**
- **Identify more patients who may be at risk for developing HCC than the use of AFP alone. [2,3,4]**

Results from a study showing the complementary use of AFP-L3, DCP and AFP from 74 patients with HCC diagnosis.[1]



90.5% (67/74) of the patients with HCV-related cirrhosis and HCC diagnosis demonstrated at least one elevated biomarker at time of diagnosis. The use of AFP alone would not have identified 29.7% (22/74) of patients at risk of development of HCC.*

Biomarker	Patients with at least one elevated biomarker
AFP-L3, DCP and AFP	90.5% (67/74)
AFP (alone)*	60.8% (45/74)

This study compared the combined use of AFP-L3, DCP and AFP biomarkers to the use of AFP alone to identify patients at risk for development of HCC.

* FUJIFILM Wako Diagnostics does not have a claim for the use of the AFP Serum Biomarker in the risk assessment of patients with chronic liver disease for development of HCC and has not established a threshold for AFP.

References:
1. Same sample set to Sterling, RK et. al., Utility of Lens culinaris agglutinin-reactive fraction of alpha-fetoprotein and des-gamma-carboxy prothrombin, alone or in combination, as biomarkers for hepatocellular carcinoma. Clin Gastroenterol Hepatol. 2009 Jan;7(1):104-13. Samples retested using i30 and DCP and AFP-L3 μTASWako Test Systems, re-test results from K100464; 2. Ertle JM, et al. Digestion 2013;87:121-131; 3. Choi JY, et al. World J. Gastroenterol 2013;19:339-346; 4. Hann HW, et al. J Med Microb Diagn 2014;3:130; 5. Marrero, et al. Hepatology 2018: 68:723:735