

**AFP-L3
& DCP**



Increase Your Chances of Detecting Early HCC

The biomarkers lectin-reactive alpha-fetoprotein (AFP-L3) and des-gamma-carboxy prothrombin (DCP) have been shown to be specific to hepatocellular carcinoma (HCC) and their combined use aids in clinical assessment for early detection. Adding the two biomarkers, AFP-L3 and DCP, to your current HCC surveillance practice can increase your chances of detecting early HCC. These tests are available now through major US reference laboratories.

HCC SURVEILLANCE IMPROVES PATIENT OUTCOME

Early detection of HCC is crucial for the application of curative therapies and improving patient outcome. Since the underlying cause of HCC is usually identifiable, patients who are at-risk for development of liver cancer are highly encouraged to enroll in HCC surveillance programs for early detection of HCC. A 2008 HCC surveillance study conducted in the USA concluded that the application of even a modest surveillance program for patients with cirrhosis can identify patients with early-stage HCC. In turn, HCC surveillance improves long-term, tumor-free survival of HCC patients receiving early treatment [1].

HCC MANAGEMENT

HCC management guidelines from the American Association for the Study of Liver Diseases recommend that patients be screened at 6 month intervals using ultrasonography [2]. However, ultrasonography is not sensitive for detection of small HCC in patients with advanced cirrhosis [3]. Sensitivities of AFP-L3 and DCP remain high even with a tumor <2 cm [4]. HCC biomarker values can be used with standard cutoff values in conjunction with ultrasound for detecting early HCC.

HOW TO USE AFP-L3 AND DCP?

Both AFP-L3 and DCP testing are intended for in vitro diagnostic use as an aid 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. Patients with elevated AFP-L3% values ($\geq 10\%$) have been shown to have 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 the existing HCC practice guidelines in oncology. For details, contact Wako Diagnostics to request copies of the package insert of μ TASWako[®] AFP-L3 and DCP.

HOW TO ORDER AFP-L3 AND DCP?

AFP-L3 and DCP assays are available at major US reference laboratories. These tests can be ordered separately or in combination as a panel. Visit the website of your preferred reference laboratory for further details.

Both AFP-L3 and DCP tests have their own CPT does and are CMS reimbursed.

CPT Code	AFP-L3	82107
	DCP	83951

WHAT IS AFP-L3?

AFP is a glycoprotein normally produced by fetal liver. AFP-L3 is an isoform of AFP which has an additional fucose residue. AFP-L3 isoform interacts with the lectin *Lens culinaris* agglutinin (LCA). Many investigations revealed that the glycoform AFP-L3 appears to be more prevalent in patients with HCC [5]. AFP-L3% is the ratio of AFP-L3 to total AFP as a percentage. The AFP-L3% has been routinely used for many years as an HCC biomarker in countries where HCC detection and management have been a priority for decades [6].

WHAT IS DCP?

DCP is an immature form of the coagulation protein, prothrombin. In normal liver, the prothrombin precursor undergoes post-translational carboxylation before release into the peripheral blood. The vitamin K dependent carboxylase responsible for the modification is absent in many HCC cells, therefore the non-carboxylated form (DCP) is secreted instead and has been used as an HCC biomarker [7]. DCP is also known as Protein Induced by Vitamin K Absence or Antagonist-II (PIVKA-II).

COMBINED USE OF AFP-L3 AND DCP

Several studies have shown that AFP-L3 and DCP are independent markers and that the combined use of these biomarkers is shown to be effective for the early detection of HCC [8-11]. A study including 685 patients with HCC shows AFP-L3 and DCP appear to represent different features of tumor progression in patients with HCC [8].

Other studies cited in the guideline of the Japan Society of Hepatology show the sensitivity of AFP-L3 or DCP individually to detect small HCC of less than 3 cm in diameter ranged from 22.2 to 42.9% while that of the combined use of AFP-L3 and DCP was 41.7-66.7% [9-11]. The specificity of the combination assay reported in these studies ranged from 89.5 to 89.8%. The combined use of these assays is practical and convenient because serum levels of AFP-L3 and DCP can be measured with a single serum sample on a single analyzer, μ TASWako i30 [12].

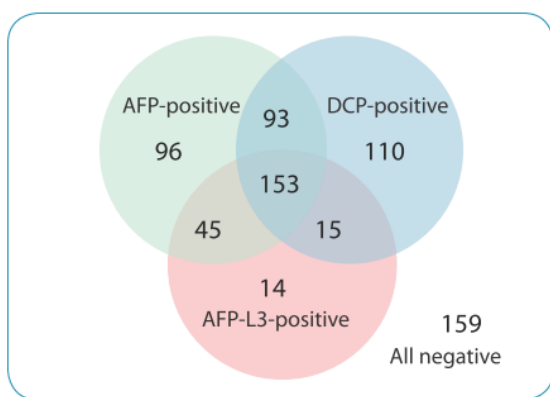


Figure 1 Distribution of HCC patients with various patterns of positivity for the HCC biomarkers [8]

CONTACT

For more product information, please contact customer service at 1-877-714-1924.

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