

## Overview

### Useful For

Risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC)

Aiding in the monitoring of HCC patients post therapy if des-gamma-carboxy prothrombin (DCP) level was elevated prior to therapy

### Method Name

Isotachopheresis with Laser-Induced Fluorescence

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

For diagnostic use, this test is most cost-effective for at-risk patients with normal levels of total and L3 alpha fetoprotein in serum. For more information see L3AFP / Alpha-Fetoprotein (AFP) L3% and Total, Hepatocellular Carcinoma Tumor Marker, Serum.

### Specimen Required

#### Collection Container/Tube:

**Preferred:** Red top

**Acceptable:** Serum gel

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.5 mL

### Forms

[If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:](#)

[-Oncology Test Request \(T729\)](#)

[-Gastroenterology and Hepatology Client Test Request \(T728\)](#)

### Reject Due To

Gross hemolysis    Reject  
Gross lipemia      OK

### Specimen Minimum Volume

0.2 mL

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	90 days	
	Refrigerated	7 days	

### Clinical & Interpretive

#### Clinical Information

Des-gamma-carboxy prothrombin (DCP), also known as the protein induced by vitamin K absence or antagonist II (PIVKA-II), is an abnormal form of the coagulation protein, prothrombin. DCP is a nonfunctional prothrombin resulting from a lack of carboxylation of 10 glutamic acid residues in the N-terminal portion of the molecule. In normal liver, prothrombin undergoes post-translational carboxylation before release into the peripheral blood. The carboxylation converts specific amino-terminal glutamic acid residues to gamma-carboxyglutamic acid. The vitamin K dependent carboxylase responsible for the carboxylation is absent in many hepatocellular carcinoma (HCC) cells, and an abnormal prothrombin with all or some of unconverted glutamic acid is secreted. Therefore, this noncarboxylated form (DCP) has been used as an HCC biomarker.

DCP is considered a complementary biomarker to alpha fetoprotein (AFP) and third electrophoretic form of lentil lectin-reactive AFP% (AFP-L3%) for assessing the risk of developing HCC. The elevation of both AFP-L3 and DCP indicate progression of HCC, albeit they reflect different features of the progression. In a prospective study of patients in the United States with an established diagnosis of HCC, the sensitivities for AFP, AFP-L3%, and DCP were 68%, 62%, and 73%, respectively. When the 3 markers were combined, the sensitivity was 86%. In another study, DCP levels were shown to correlate with tumor size and metastatic HCC. In this study, compared to AFP and AFP-L3%, DCP had the highest sensitivity (87%) and the highest positive predictive value (87%) in patients with HCC due to chronic hepatitis B and C infections. A number of studies have shown that elevated serum DCP is significantly related to portal vein invasion and/or intrahepatic metastasis, which significantly affect prognosis for patients with HCC.

DCP can be elevated in other conditions besides HCC. Conditions such as obstructive jaundice, intrahepatic cholestasis causing chronic decrease in vitamin K, and ingestion of drugs such as warfarin or wide-spectrum antibiotics can result in high concentrations of DCP. In addition, 25% to 50% of patients with HCC will have a DCP value within the reference range. Because of this, a normal DCP value does not rule out HCC.

**Reference Values**

<7.5 ng/mL

**Interpretation**

In patients with an elevated des-gamma-carboxy prothrombin (DCP) result ( $>$  or  $=$ 7.5 ng/mL), the risk of developing hepatocellular carcinoma (HCC) is 36.5% (95% CI 23.5%-49.6%). The risk of developing HCC with a negative DCP result ( $<$ 7.5 ng/mL) is 7.6% (95% CI 4.4%-10.8%).

For patients with HCC and an elevated DCP level prior to therapy, an elevated DCP level posttherapy is associated with an increased risk of HCC recurring.

**Cautions**

Some patients who have been exposed to animal antigens, either in the environment or as part of treatment or imaging procedures, may have circulating anti-animal antibodies present. These antibodies may interfere with the assay reagents to produce unreliable results.

Serum markers are not specific for malignancy, and values may vary by method. Do not interpret des-gamma-carboxy prothrombin (DCP) levels as absolute evidence of the presence or absence of malignant disease. Results should be used in conjunction with information from the clinical evaluation of the patient, cytology, and imaging procedures.

DCP producing tumors other than hepatocellular carcinoma can show elevated DCP values.

Liver disease caused by other etiologies such as alcohol liver disease, hemochromatosis, Wilson disease, autoimmune hepatitis, and steatohepatitis have not been studied with this assay.

Medication containing vitamin K preparations may cause a negative bias with DCP values.

Medication containing vitamin K antagonist or antibiotic may cause a positive bias with DCP values.

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**Clinical Reference**

1. Lai Q, Iesari S, Levi Sandri GB, Lerut J: Des-gamma-carboxy prothrombin in hepatocellular cancer patients waiting for liver transplant: a systematic review and meta-analysis. *Int J Biol Markers*. 2017 Oct 31;32(4):e370-e374. doi: 10.5301/ijbm.5000276
2. Zhu R, Yang J, Xu L, et al: Diagnostic Performance of Des-gamma-carboxy Prothrombin for Hepatocellular Carcinoma: A Meta-Analysis. *Gastroenterol Res Pract*. 2014;2014:529314. doi: 10.1155/2014/529314
3. De J, Shen Y, Qin J, et al: A Systematic Review of Des-gamma-Carboxy Prothrombin for the Diagnosis of Primary Hepatocellular Carcinoma. *Medicine (Baltimore)*. 2016 Apr;95(17):e3448. doi: 10.1097/MD.0000000000003448

**Performance****Method Description**

Testing is performed using the uTASWako i30 instrument and the uTASWako DCP Immunological Test System and reagents. Sample is added to the reagent well with the fluorescent dye labeled anti-human prothrombin antibody (mouse monoclonal) to form the primary immunocomplex. The second labeled antibody solution, anion-conjugated anti-human des-gamma-carboxy prothrombin (DCP) antibody (mouse monoclonal), is concentrated by isotachopheresis when voltage is applied. The concentrated anion-conjugated antibody then reacts with the primary immunocomplex to form the secondary immunocomplex. This secondary complex is further concentrated during isotachopheresis and is separated from unbound fluorescent dye-labeled antibody by capillary gel electrophoresis. The remaining dye labeled DCP is measured by laser-induced fluorescence. The concentration of DCP in the specimen is directly proportional to the amount of fluorescence. (Package insert: uTASWako i30 DCP, version 18.07.18K11. Wako Diagnostics 07/2018)

**PDF Report**

No

**Specimen Retention Time**

12 months

**Performing Laboratory Location**

Rochester

**Fees & Codes****Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per

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manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

83951

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
DCP	Des-Gamma-Carboxy Prothrombin, S	34444-0

Result ID	Reporting Name	LOINC®
DCP	Des-Gamma-Carboxy Prothrombin, S	34444-0