

Patient Information	Specimen Information	Client Information

COMMENTS:

Test Name	In Range	Out Of Range	Reference Range	Lab
ALPHA-FETOPROTEIN (AFP)				
AND AFP-L3				
AFP	2.8		1.6-4.5 ng/mL	
AFP-L3	SEE NOTE		0.5-9.9 %	

NO VALUE DETERMINED

The micro-total analysis system (uTASWako) employs microchip capillary electrophoresis to quantitatively measure AFP and AFP-L3% by immunochemical techniques. The assay principle involves DNA-coupled antibodies and dye labeled antibodies, which react with proteins in liquid phase within the microchannels. Both analytes are quantified using laser-induced fluorescence. Instrument and associated reagents are supplied by Wako Diagnostics Richmond, VA, USA.

Patients with elevated AFP-L3% values ($\geq 10\%$) have been shown to have an increased risk of developing hepatocellular carcinoma (HCC). In a selected group of patients, the risk of developing HCC was 48.8% with an elevated AFP-L3% and was 7.0% with a negative AFP-L3% result.

Limitations of Procedure:

1. The AFP-L3% value is not calculated when the AFP-L3 concentration is below 0.3 ng/mL. In such cases the AFP-L3% result field will indicate "NO VALUE DETERMINED"
2. Heterophilic antibodies in human serum can react with the immunoglobulins included in the assay components causing interference with in vitro immunoassays. Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference and can potentially cause an anomalous result. The Wako uTAS System has been formulated to minimize the risk of the interference; however, potential interactions between rare sera and ingredients can occur.
3. For diagnostic purposes, the results obtained from this assay should always be used and interpreted in conjunction with clinical examination, patient medical history, and other findings.
4. Pregnancy can cause high values of AFP-L3% and AFP is not interpretable in pregnant females.
5. AFP producing tumors other than HCC can show high values of AFP-L3% and AFP.
6. Samples from patients having acute hepatitis and fulminant hepatitis can show high values of AFP-L3% and AFP.
7. It is recommended that this assay be used in conjunction with imaging studies for clinical diagnosis.
8. Liver diseases caused by other etiologies such as alcoholic liver disease, hemochromatosis, Wilson's disease, autoimmune hepatitis and steatohepatitis have not been studied with the assay.
9. The assay is linear for AFP concentration of 0.3 to 1000 ng/mL.
10. Values obtained with different assay methods or kits cannot be used interchangeably.

SPECIMEN: