Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 35 Y

Referral Testing

Collected: 07/16/2024 12:01 Received: 07/16/2024 12:01

Test Name	Result	Flag	Ref-Ranges	Units	Site
Alpha-Fetoprotein (AFP) and AFP-L3					
AFP	3.4		1.6-4.5	ng/mL	QCRL
AFP-L3	4.5		0.5-9.9	%	QCRL

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 (>=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, hemachromatosis, Wilson's disease, autoimmune hepatitis and steatohepatisis 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.
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

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Reported Date: 07/16/2024 12:01 AFPL3

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

G316000286
WX0000003826
Printed D&T: 07/16/24 12:02

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1