Atellica IM Analyzer

Enhanced Liver Fibrosis (ELF) Test

siemens-healthineers.com/elf-test

Non-alcoholic fatty liver disease (NAFLD) impacts 25% of the global population and is projected to become the leading cause of liver-related mortality within 20 years.[1] About 20% of people with NAFLD are estimated to have non-alcoholic steatohepatitis (NASH), a form of NAFLD that includes liver cell damage.[2] As new therapies become available, non-invasive testing is an important tool to help identify patients at risk of developing cirrhosis and liver-related clinical events (LREs). The ELF™ Test measures three direct markers of liver fibrosis: Hyaluronic acid (HA), Procollagen III amino terminal peptide (PIINP), and Tissue inhibitor of metalloproteinase-1 (TIMP-1), and provides a numeric score correlating to the level of fibrosis. The ELF Test, in conjunction with other laboratory and clinical findings, can be used to assess the risk of progression to cirrhosis and LREs in patients with chronic liver disease.[3]

For use outside the U.S. only

Immunoassay

HA (Hyaluronic Acid)
PIIINP (Procollagen III amino terminal peptide)
TIMP-1 (Tissue inhibitor of metalloproteinase-1)

- Access non-invasive testing with a simple blood test available to all healthcare practitioners and patients, including those with type 2 diabetes mellitus and obesity.[4,5]
- Improve patient care by identifying NAFLD patients and stratifying those at risk of progressing to cirrhosis and LREs.[3]
- Enhance prognostic patient management with a test that has been shown to outperform biopsy for the risk assessment of progression to cirrhosis and LREs.[3]

The Atellica Solution provides a broad and expanding menu to help your lab drive better clinical and business outcomes. The Atellica® IM Analyzer utilizes proven advanced Acridinium Ester (AE) technology, with over 50 patents granted or pending.

The products/features (mentioned herein) are not commercially available in all countries. Their future availability cannot be guaranteed.

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Assay Characteristics

Assay Name	Specimen Type	Sample Volume (µL)	Time to First Result (min)	Expected Values	Reagent Onboard Stability (days)	Lot Calibration Interval (days)
HA	Serum	20 µL	39	Atellica IM HA, PIIINP, and TIMP-1 assay results are intended for use with the Atellica IM ELF Test to determine the ELF score using the Atellica IM Analyzer.	28	24
PIIINP	Serum	20 µL	14		30	63
TIMP-1	Serum	25 µL	14		60	64

Ordering Information

Assay Name	Kit	SMN No.	Tests per Kit	Contents
HA	Atellica IM HA	10995595	50	Atellica IM HA ReadyPack® primary reagent pack
PIIINP	Atellica IM PIIINP	10995653	50	1 Atellica IM PIIINP ReadyPack primary reagent pack
TIMP-1	Atellica IM TIMP-1	10995695	50	1 Atellica IM TIMP-1 ReadyPack primary reagent pack
ELF Test	Atellica IM ELF CAL	10995565	–	2 x 2.0 mL low calibrator 2 x 2.0 mL high calibrator
	Atellica IM ELF QC	10995566	–	3 x 2.0 mL quality control, level 1 3 x 2.0 mL quality control, level 2 3 x 2.0 mL quality control, level 3

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