ADVIA Centaur Enhanced Liver Fibrosis (ELF) Test Specifications

The ADVIA Centaur systems' Enhanced Liver Fibrosis (ELF™) test is an in vitro diagnostic multivariate index assay intended to provide a single ELF score by combining in an algorithm the quantitative measurements of hyaluronic acid (HA), amino-terminal propeptide of type III procollagen (PIIINP) and tissue inhibitor of metalloproteinase 1 (TIMP-1) in human serum using the ADVIA Centaur, ADVIA Centaur® XP and ADVIA Centaur® CP systems.

The ELF test is indicated, in conjunction with other laboratory findings and clinical assessments, as an aid in the diagnosis and assessment of the severity of liver fibrosis in patients with signs and symptoms of chronic liver disease.

- First direct marker panel of liver fibrosis
- Standardized component assays (HA, PIIINP, TIMP1)
- Uses a routine blood serum sample
- Clinically validated for liver fibrosis assessment in mixed, HCV, and NAFLD patient groups

The ELF test was clinically validated on the Immuno 1 system in an international multi-centre study with a mix of patient groups and was found to be accurate to differentiate mild, moderate and severe fibrosis[1], and subsequently has been shown to be at least as good as biopsy at predicting liver disease-related outcomes[2-3].

Calculating the ELF Score

To calculate the ELF score for the ADVIA Centaur systems, first obtain results for the ADVIA Centaur HA, PIIINP, and TIMP-1 assays and then use the following equation/algorithm to calculate the ELF score:

ADVIA Centaur and Centaur XP:

$$\text{ELF score} = 2.278 + 0.851 \ln(C_{HA}) + 0.751 \ln(C_{P3NP}) + 0.394 \ln(C_{TIMP1})$$

ADVIA Centaur CP:

$$\text{ELF score} = 2.494 + 0.846 \ln(C_{HA}) + 0.735 \ln(C_{P3NP}) + 0.391 \ln(C_{TIMP1})$$

Concentrations (C) of each assay are in ng/mL

Interpretation of Results

Interpretation of the ELF score is as follows:

< 7.7	None to mild
≥ 7.7 to < 9.8	Moderate
≥ 9.8	Severe

Siemens ELF Test

Assay Summary					
Test	**Sample Type**	**Sample Volume**	**Assay Range**	**Onboard Stability**	**Calibration Interval**
TIMP-1	Serum	25 µL	3.5 - 1,300 ng/mL	60 days	28 days
PIIINP	Serum	20 µL	0.5 - 150 ng/mL	60 days	28 days
HA	Serum	20 µL	1.6 - 1,000 ng/mL	60 days	14 days

Ordering Information

Catalog No.	Contents	No. of Tests
10631070	TIMP-1 ReadyPack®	50
10493157	HA ReadyPack	50
10492440	PIIINP ReadyPack	50
Materials Required but Not Provided:		
10492344	ADVIA Centaur ELF Calibrator	2 x 2.0 mL low calibrator 2 x 2.0 mL high calibrator
10492342	ADVIA Centaur ELF QC	3 x 2.0 mL Control 1 3 x 2.0 mL Control 2 3 x 2.0 mL Control 3
10492364	ADVIA Centaur Multi-Diluent 13	2 x 5.0 mL ReadyPack ancillary reagent packs

The ELF tests are CE- marked. Not available for sale in the U.S.

References:

1. Rosenberg et al. "Serum Markers Detect the Presence of Liver Fibrosis: A Cohort Study" Gastroenterology 2004;127:1704-1703.
2. Parkes et al. "Enhanced Liver Fibrosis Test Can Predict Clinical Outcome in Patients with Chronic Liver Disease" Gut 2010;59:1245-1251
3. Pinzani. "The ELF panel: a new crystal ball in hepatology?" Gut 2010;59:1165-1167

The ELF test is available on the ADVIA Centaur Immunoassay systems:

ADVIA Centaur XP System—proven technology with enhanced productivity to meet the peak workload demands of the busiest labs, and the flexibility to easily connect to Siemens Healthcare Diagnostics automation systems.

ADVIA Centaur CP System—powerful system providing optimal productivity, speed, and efficiency in a compact design.

For additional information on the Siemens ELF test, go to www.siemens.com/liverdisease.

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