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 fibrosis¹, and subsequently has been shown to be at least as good as biopsy at predicting liver disease-related outcomes²⁻³.

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:**

EF score = 2.278 + 0.851 ln(CH₄A) + 0.751 ln(CP3NP) + 0.394 ln(CTIMP1)

**ADVIA Centaur CP:**

EF score = 2.494 + 0.846 ln(CH₄A) + 0.735 ln(CP3NP) + 0.391 ln(CTIMP1)

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Sample Volume</th>
<th>Sample Volume</th>
<th>Assay Range</th>
<th>Onboard Stability</th>
<th>Calibration Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIMP-1 Serum</td>
<td>25 µL</td>
<td>3.5 - 1,300 ng/mL</td>
<td>60 days</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td>PIIINP Serum</td>
<td>20 µL</td>
<td>0.5 - 150 ng/mL</td>
<td>60 days</td>
<td>28 days</td>
<td></td>
</tr>
<tr>
<td>HA Serum</td>
<td>20 µL</td>
<td>1.6 - 1,000 ng/mL</td>
<td>60 days</td>
<td>14 days</td>
<td></td>
</tr>
</tbody>
</table>

### Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Contents</th>
<th>No. of Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>10631070</td>
<td>TIMP-1 ReadyPack®</td>
<td>50</td>
</tr>
<tr>
<td>10493157</td>
<td>HA ReadyPack</td>
<td>50</td>
</tr>
<tr>
<td>10492440</td>
<td>PIIINP ReadyPack</td>
<td>50</td>
</tr>
</tbody>
</table>

Materials Required but Not Provided:
- ADVIA Centaur ELF Calibrator: 2 x 2.0 mL low calibrator, 2 x 2.0 mL high calibrator
- 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
- 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:**

Centaur, ELF, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

---

**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](http://www.siemens.com/liverdisease).