# Instructions for Use

FIB Assay · REF 1061EU · UDI 59998629921061EU

## Intended Purpose

The FIB is a ready-to-use reagent for in-vitro diagnostic professional use, intended for qualitative examination of the fibrinogen level in citrated blood during viscoelastometry analysis.

CE IVD
Notified Body 2265

CAUTION: A use of the device outside of its intended purpose may lead to test results being incorrectly interpreted by the user.

## Indications for Use

Indicated when a diminished fibrinogen level in the patient's blood is suspected.

## Contra-indications for Use

None identified.

## Intended Users

- Trained healthcare professionals
- Trained laboratory professionals

## Intended Patient Population

Adult patients where an examination of coagulation activation, clot formation and/or clot stability is desired.

## Principle of the Assay

In the FIB assay, coagulation is activated by a combination of recombinant tissue factor, calcium chloride and polybrene (heparin antagonist). Platelet function is blocked using cytochalasin D (actin polymerisation inhibitor) and eptifibatide (fibrinogen receptor antagonist). The clot firmness measurement in the FIB assay represents a functional assessment of the fibrinogen level. Higher fibrinogen levels result in higher clot firmness.

Substances interfering with clot polymerisation (e.g. hydroxyethyl starch, HES) can impair clot firmness in the FIB assay.

## Materials Provided

10 sealed single-use pouches, each containing one pipet tip with dry chemistry reagent (recombinant tissue factor, cytochalasin D, eptifibatide, polybrene, calcium chloride, buffer and stabilizers). Each pouch contains one desiccant bag.

## Additional Materials and Devices Required

- Viscoelastometry analyzer and receptacles (Cups & Pins)
- Electronic pipette for 340 µL with 3-second aspiration/dispensing cycles
- Blood collection tube (3.2% sodium citrate) for coagulation testing

## Reagent Preparation

The reagent is ready to use.

## Storage and Stability

| Condition | Detail |
|---|---|
| Refrigerated (unopened) | Store at +2 to +8 °C. Stable until expiration date on pouch label. |
| Room temperature (unopened) | Unopened pouches may be stored at room temperature for up to 1 month. |
| After opening | For immediate use within 1 minute of opening the pouch. |

CAUTION: Incorrect storage conditions may affect reagent stability and lead to wrong test results.

## Warnings and Precautions

For professional use by trained personnel only.

CAUTION: Do not use tips from defective pouches or from pouches missing the desiccant pack.

CAUTION: Intended for single use — do not reuse.

CAUTION: Any serious incident that has occurred as a result of the use of the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: Failure to comply with these instructions for use may result in device handling errors leading to wrong test results.

CAUTION: Human blood samples should be handled with care, following general precautions recommended for bio-hazardous materials.

CAUTION: Wear gloves and minimise skin exposure to specimens and reagents.

NOTE: Dispose of waste according to local regulations.

NOTE: A material safety data sheet is available upon request.

## Residual Risks, Undesirable Side-Effects, and Information for the Patient

The following residual risks were identified during risk management activities for the device:

- In case of off-label use, test results may be incorrectly interpreted.
- In case of device handling errors, patient coagulation may be incorrectly reflected.
- In case of use of an expired product, patient coagulation may be incorrectly reflected.
- In case of unacceptable transport and storage conditions, patient coagulation may be incorrectly reflected.

Warnings related to residual risks are provided throughout this document. No undesirable side-effects were identified during post-market activities for the device. No information for the patient is required to be provided for the device.

## Sample Collection

CAUTION: Collect a venous blood sample according to recommended procedures using a blood collection tube with 3.2% sodium citrate. Samples should be analysed within 3 hours from blood collection. Store blood at room temperature. Always ensure blood collection tubes are filled to the indicated fill volume to avoid excessive citrate levels.

## Test Procedure

1. Check the expiry date of the device. The expiry date format is yyyy-mm-dd.

   CAUTION: Do not use the expired product. Use of an expired product may lead to wrong test results.

2. Allow the reagent tip pouch to reach room temperature.
3. If the sample is cold (<22 °C), allow the sample to warm up for 5 minutes on the heated position of the viscoelastometry analyzer.
4. Create the test in the software of the viscoelastometry analyzer according to the analyzer manual.
5. Place the Cup and Pin into the analyzer according to the analyzer manual.
6. Tear open the reagent tip pouch, attach the reagent tip to the electronic pipette, and aspirate 340 µL sample from the blood tube.
7. Dispense the blood sample into the Cup.
8. Aspirate and dispense the sample once again to facilitate thorough mixing of reagents with the blood sample. Ensure sample pipetting is performed without interruption.
9. Start the test as described in the analyzer manual.
10. The test will stop, or you can stop the test as described in the analyzer manual.
11. Remove the Cup & Pin and dispose according to local regulations.

## Quality Control

Plasma-based quality control materials can be used to confirm the stability of test results determined with the FIB assay over time.

## Result Interpretation and Expected Values

The clot formation is detected via A5, A10, A20 and MCF parameters. The reference range was determined in a clinical study including 121 healthy individuals (ages 19–79.3 years; 54.5% female, 45.5% male). Reference ranges were determined using the 95% central interval ($2.5^{th}$ – $97.5^{th}$ percentile):

| Parameter | Mean ± SD | 2.5th – 97.5th Percentile |
|---|---|---|
| A5 (mm) | 12.2 ± 3.6 | 6 – 20 |
| A10 (mm) | 13.4 ± 3.9 | 7 – 22 |
| A20 (mm) | 14.3 ± 4.1 | 8 – 24 |
| MCF (mm) | 15.6 ± 4.5 | 9 – 25 |
| CT (sec) | 41.6 ± 9.4 | 31 – 56 |

### Accuracy vs. FIB-test by enicor

Accuracy was evaluated against the FIB-test by enicor (n=103 samples, Deming regression per CLSI EP09):

| Comparison | N | Slope | Bias | Spearman r |
|---|---|---|---|---|
| FIBa-A5 vs FIBe-A5 | 102 | 1.06 | –1.08 | 0.90 |
| FIBa-A10 vs FIBe-A10 | 102 | 1.04 | –0.56 | 0.91 |
| FIBa-A20 vs FIBe-A20 | 102 | 1.04 | –1.04 | 0.91 |
| FIBa-MCF vs FIBe-MCF | 102 | 1.05 | –1.13 | 0.89 |

### High Fibrinogen Subgroup (>4 g/L, n=12)

| Parameter | Mean ± SD | 2.5th – 97.5th Percentile |
|---|---|---|
| A5 (mm) | — | 17.6 – 33.5 |
| A10 (mm) | — | 18.8 – 35.5 |
| A20 (mm) | 29.5 ± 6.3 | 19.8 – 37.5 |
| MCF (mm) | 31.4 ± 6.3 | 21.8 – 39.5 |

## Precision

In a precision study, citrated blood and 40% haemodiluted samples were tested in 3 runs, on 3 analyzers, by 3 operators, including 3 FIB assay lots (n=54 determinations per sample). Results for A20 amplitude (mm):

| Sample | A20 Mean (mm) | SD (mm) |
|---|---|---|
| Citrated blood | 15 | 1.7 |
| 40% hemodilution | 12 | 1.9 |

## Limitations and Interferences

Every in-vitro diagnostic method can deliver incorrect results under certain circumstances. Precautions should be taken to avoid misinterpretations.

Measurements with noisy or irregular curves should be discarded and repeated. The clinical context should be considered when interpreting FIB assay results.

Hydroxyethyl starch (HES) can impair clot firmness in the FIB assay.

### Interference Testing Results (A20 parameter, 6-fold determinations):

| Substance / Condition | Mean A20 (mm) | SD (mm) | Change vs. Control |
|---|---|---|---|
| Citrated blood (control) | 9 | 0.6 | n/a |
| + UFH 3 IU/mL | 8.2 | 1.5 | –0.8 mm |
| + UFH 5 IU/mL | 8 | 0.6 | –1 mm |
| + LMWH 1 IU/mL | 9 | 0.9 | 0 |
| + Apixaban 100 ng/mL | 8 | 0 | –1 mm |
| + Apixaban 300 ng/mL | 9.3 | 0.5 | +0.3 mm |
| 20% hemodilution | 8 | 0 | –1 mm |
| 40% hemodilution | 7.2 | 0.8 | –1.8 mm |

NOTE: Only minor variations in A20 were observed in the presence of UFH, LMWH or apixaban. 40% haemodilution decreased clot firmness by 1.8 mm.

## Summary of Safety and Performance

Summary of safety and performance is provided in electronic format and is available for download at www.apiro.eu/eIFU.

## Manufacturer


| | |
|---|---|
| APIRO Diagnostics Kft. | Liget utca 3/2, HU-2040 Budaörs, Hungary |
| +36 30 203 3334 | info@apiro.eu \| www.apiro.eu |
| Distributed in Australia by: | Haemoview Diagnostics |


## Symbols

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| Manufacturer icon | Manufacturer | Hourglass icon | Use-by date |
| LOT | Batch code | REF | Catalogue number |
| Country of manufacture (HU) | Country of manufacture | Crossed box icon | Do not use if package is damaged |
| 2°C – 8°C | Temperature limit | No-reuse icon | Do not re-use |
| IFU book icon | Consult instructions for use or eIFU | Σ n | Contains sufficient for <n> tests |
| Not for near-patient testing | Not intended for near-patient testing | ■ Caution/Warning | Caution / Warning |
| UDI | Unique device identifier | CE 2265 | CE marking of conformity (NB 2265) |
| IVD | In vitro diagnostic medical device | Biohazard icon | Biological risks |

## Version History

| Date | Version | Change Description |
|---|---|---|
| 2025-10-29 | 1 | Initial version |

Disclaimer for Australian Healthcare Professionals
This document is the Instructions for Use for the FIB Assay (REF 1061EU), distributed in Australia by Haemoview Diagnostics. This document has been reformatted for readability; all technical content is derived from the official IFU_1061EU_EN Rev.1 as issued by APIRO Diagnostics Kft. (Hungary). Clinical decisions must be made in accordance with local protocols, institutional governance, and the full clinical context of the individual patient. For regulatory queries, contact Haemoview Diagnostics at violeta.jardin@haemoview.com.au.

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