Emosis
CELL-BASED HEMOSTASIS TESTING

HIT-Confirm®

confirming HIT in minutes
not days!

- 30 minutes to result
  On demand, 24/7
- As specific as SRA
- Only needs healthy platelet donors
  Works on any flow cytometer
- HEPLA Index for better standardization
  Objective readouts, easy to compute
- Empower your decision making on
  alternative anticoagulants and hospital stay

CE

Heparin Induced Thrombocytopenia - Flow-Cytometry-based functional assay

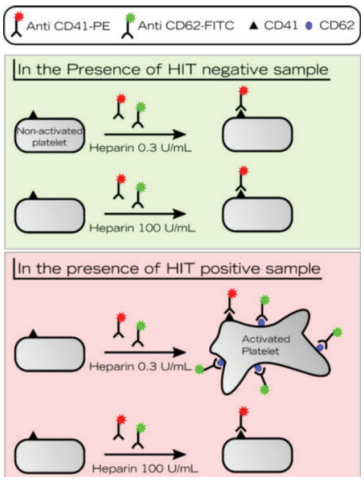
5-Diagnostics
Research and Diagnostic Solutions. Delivered.

Emosis HIT Confirm®

CELL-BASED HEMOSTASIS TESTING

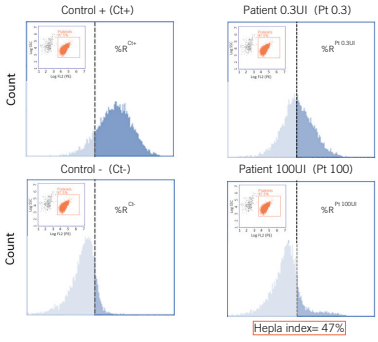
Heparin Induced Thrombocytopenia
When time matters most

HIT is a very serious medical complication for some patients on Heparin, especially in cardio-surgery or ECMO, where its prevalence can reach up to 8%. Clinicians must rely on laboratory results, based on two types of tests. Immunological tests (screening) are very sensitive but have poor specificity and often must be batched. Functional tests (confirmatory) are more specific, yet poorly available on-site and technically challenging. Most hospitals therefore need to send out their samples, causing delays (days to weeks) in confirmation of a potential HIT. Extra costs are incurred, with patients being switched to an expensive alternative anticoagulant (with additional bleeding risk) and having an extended stay in the ICU/hospital. HIT Confirm® provides a clear functional result in 30 min!



HIT Confirm®
Test principle and the HEPLA index

HIT Confirm is a rapid, one-step,functional cytometric test. Detection relies on the platelet surface marker, CD41, and the platelet activation marker, CD62. Heparin-induced platelet activation is quantified by incubating the patient sample and the platelets in presence of two heparin concentrations (0.3 and 100 IU/mL). The test can be read on any standard flow cytometer. Adding to the convenience of an on demand (therefore easily repeatable) test, platelets from healthy donors,e.g., from a Transfusion Center, can be used for the PRP – no need for selectively reactive donors or washed platelets. Results are then easily computed into a HEPLA index, allowing both normalization and standardization of the test.



HEPLA INDEX

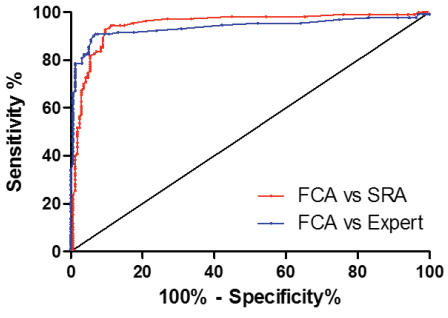
For a given plasma or serum sample, the platelet activation index in the presence of heparin (HEPLA) is calculated using the following formula

$$\%HEPLA = \frac{\%R\ H0{,}3 - \%R\ H100}{\%R\ Pos - \%R\ Neg} \times 100$$

Results you can rely on
as specific as gold standard test, SRA

Evaluation of the test in suspected HIT patients : 290 plasmas were tested, of which 131 were considered positive and 159 negative by adjudication of an expert panel. In parallel, all the plasmas were evaluated using the Serotonin Release Assay (SRA).*

	Sensitivity (CI 95%)	Specificity (CI 95%)
SRA vs Experts	80% (73-87%)	94% (90-97%)
HIT Confirm™ vs Experts	90% (85-95%)	94% (90-97%)



% HEPLA	RESULT	SPECIFICITY
< 9.6%	Negative	N/A
From 9.6% to 13.0%	Ambiguous	≥ 94.7%
> 13.0%	Positive	≥ 96.5%

A standardized functional assay for routine reliable HIT diagnosis : a potential alternative to the Serotonin Release Assay. Oral communication, ISTH 2017 : Dr Brigitte Tardy, Laboratoire Sainbiose DVH-hemostase, St Etienne France.

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