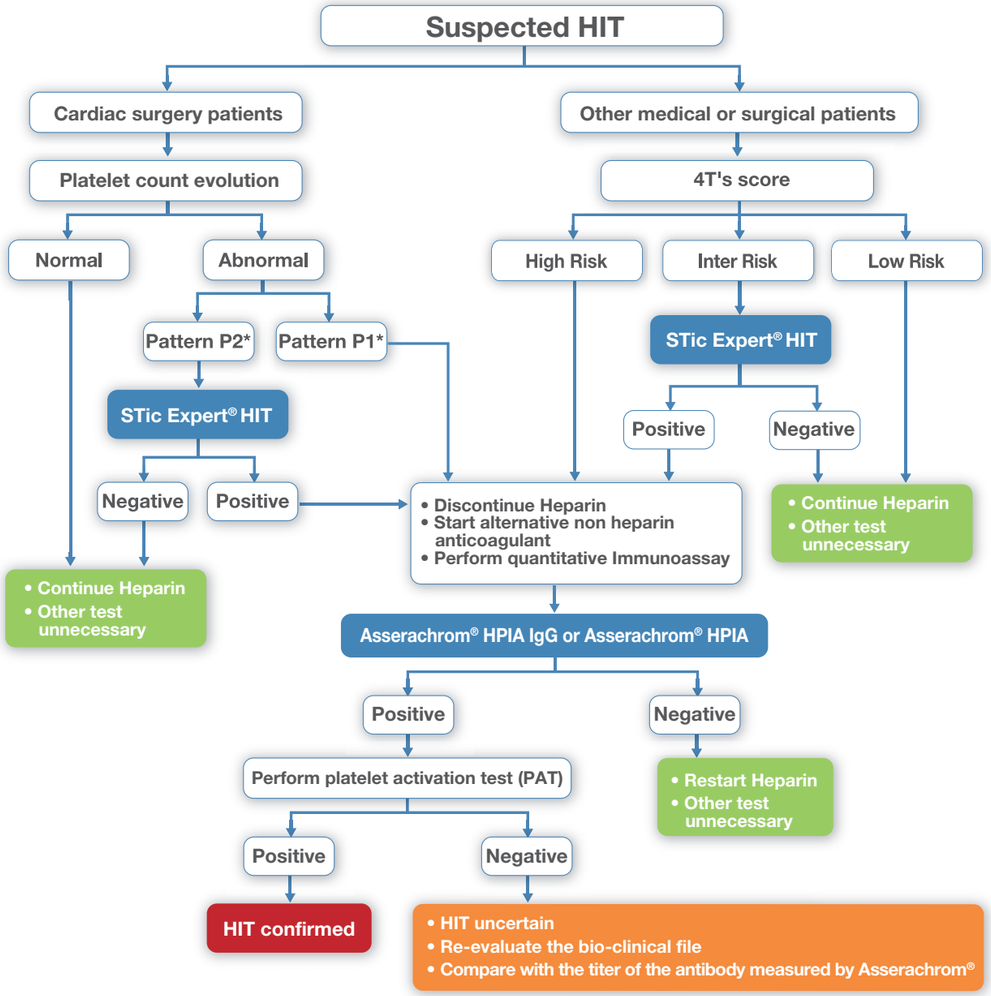
Diagnosis algorithm



In all cases, it is essential to consider both the **clinical assessment** and the **results of biological tests** (4T's, ELISA, PAT, evolution during treatment) before reaching any conclusion. If HIT is confirmed, it should be reported as a serious undesirable event.

**Pattern P1: decrease in platelet count by at least 40% compared to the maximum post-operative level, after correction of any thrombocytopenia which may occur during cardio-pulmonary bypass (specific for pathogenic antibodies to PF4/H complexes with a high PPV for HIT).*

**Pattern P2: defined by persistent thrombocytopenia in days 5-10 postoperatively without any previous correction of PC after CPB (less frequently associated with HIT).*

Realised in collaboration with: Dr Claire Pouplard & Pr Yves Gruel - CHRU Tours - France

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HIT Range

A range of highly reliable tests in the event of HIT suspicion

- ▲ STic Expert® HIT
- ▲ Asserachrom® HPIA-IgG
- ▲ Asserachrom® HPIA

Stago

A range of highly reliable tests in the event of HIT suspicion

HIT is a rare but serious prothrombotic complication associated with UFH and LMWH treatments. Diagnosis of HIT is based on clinical (4T's score) and laboratory criteria.

Nevertheless, over-diagnosis and over-treatment are currently the major problem [1]

▲ *a clinical HIT is confirmed in only [±10%] of patients with a suspicion of HIT [2].*

In 90% of patients investigated for HIT, it is important to rule-out HIT early and :

▲ *continue the heparin therapy*

▲ *reduce bleeding risks and costs associated with alternative anticoagulants[3]*

This is why it is important to have available a test which can be used to detect HIT antibodies.

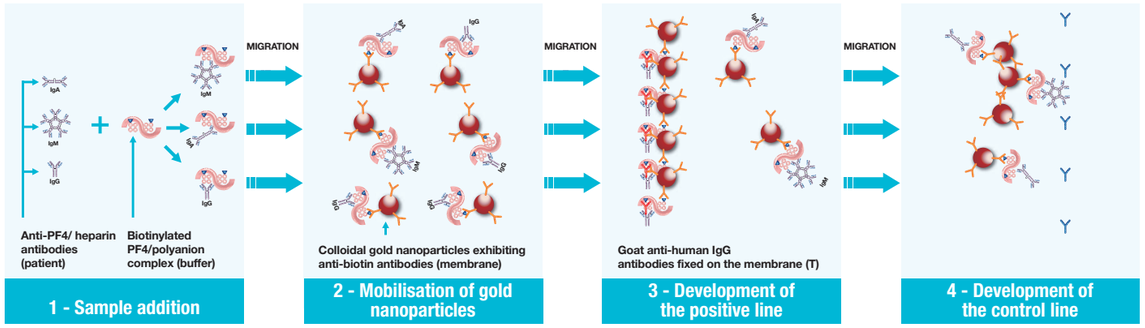
A negative result generally rules out HIT [4]

STic Expert® HIT

Rapid lateral flow immunoassay that detects anti-heparin-PF4 IgG antibodies:

- ▲ works with **plasma or serum**
- ▲ no need for **extra equipment**
- ▲ results in **10 minutes**
- ▲ internal control included

Test principle: positive example



1 - Sample addition

Patient's IgG, IgA, IgM antibodies bind biotinylated **PF4/polyanion complexes.**

2 - Mobilisation of gold nanoparticles

Anti-biotin antibodies from **gold nanoparticles** bind to the **biotin** of the immune complexes.

3 - Development of the positive line

Goat **anti-human IgG** antibodies fixed on the membrane
1. Specifically retain the **IgG isotype** immune complexes. Other immune complexes (IgA, IgM isotypes) and free gold nanoparticles migrate as far as the **control line (C)** where specific antibodies bind them.

4 - Development of the control line

The development of the control line **validates the test.**

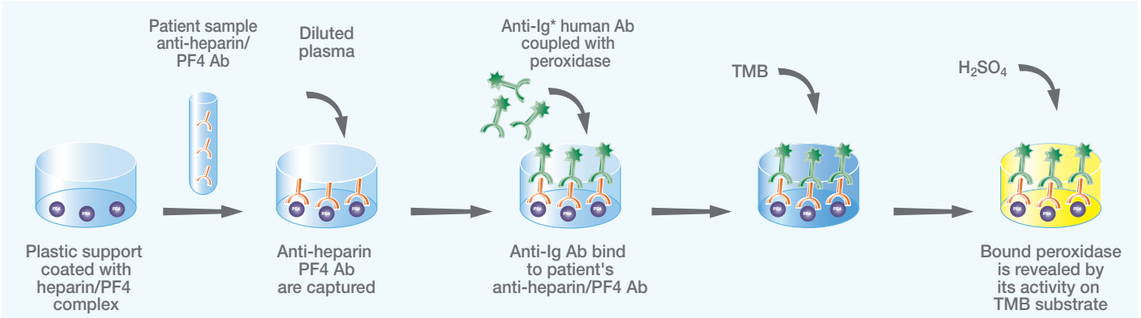
Asserachrom® HPIA

Two ELISA kits are available:

- ▲ 00624 Asserachrom® HPIA-IgG for detection of anti-heparin/PF4 IgG antibodies
- ▲ 00615 Asserachrom® HPIA for detection of anti-heparin/PF4 IgA, G and M antibodies

Convenient test format

- ▲ microplate format with **breakable strips** to better suit test series of different sizes
- ▲ quality controls and standards included in the kits



** Anti-IgG, IgA, IgM Ab for Asserachrom® HPIA - Anti-IgG Ab for Asserachrom® HPIA IgG*

Results of multicentric studies

STic Expert® HIT [5]	
NPV (%)	*99.6 / 100*
Specificity (%)	*83.4 / 82.2*
Principle	*Lateral Flow*
Format	*Unitary*
Isotype	*IgG*
Sample Type	*Plasma / Serum*
Packaging	*5 or 20 tests*
Cat. Nr.	*01058 (5) / 01059 (20)*

- ▲ **Very good concordance** between plasma and serum
- ▲ **Excellent Negative Predictive Value** (NPV) to exclude the presence of functionally relevant HIT antibodies [5]
- ▲ **High specificity** to reduce the risk of over-diagnosis

	Asserachrom® HPIA-IgG [6]	Asserachrom® HPIA [6]
NPV (%)	*100*	*100*
Specificity (%)	*92.7*	*90.9*
Principle	*ELISA*	*ELISA*
Format	*Series / Unitary*	*Series / Unitary*
Isotype	*IgG*	*IgA, G, M*
Sample Type	*Plasma / Serum*	*Plasma / Serum*
Packaging	*6 strips x 8 tests*	*6 strips x 8 tests*
Cat. Nr.	*00624*	*00615*

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1 - Cuker A; Heparin-induced thrombocytopenia (HIT) in 2011: An epidemic of overdiagnosis. Thromb Haemost. 2011; 106: 993-994

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3 - Gardiner E. et al. DiagnoSTic assays for heparin-induced thrombocytopenia. Br. J. Haematol. 2014, May 12.

4 - Warkentin TE. et al. Laboratory testing for heparin-induced thrombocytopenia : a conceptual framework and implications for diagnosis. J. Thromb. Haemost. 2011; 9 : 2498-500

5 - Leroux D. et al. Prospective evaluation of a rapid nanoparticle-based lateral flow immunoassay (STic Expert® HIT) for the diagnosis of heparin-induced thrombocytopenia. Br. J. Haematol. 2014, May 12

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