SPECIALTIES

Complete standardized high quality kit

for the diagnosis of

Heparin-Induced Thrombocytopenia

HITAlert™ Kit

Key benefits

- Complete kit with ready-to-use components
- Functional assay
- Non-radioactive method
- No-wash method

Applications

- Detection of heparin complexes specific antibodies
- Reactivity *independent* of PF4
- Kit also detects IL-8/heparin and NAP-2/heparin complex antibodies

Features

- Standard equipment and methodology
- Rapid results (<2 hours)
- Patented method
- IVD CE

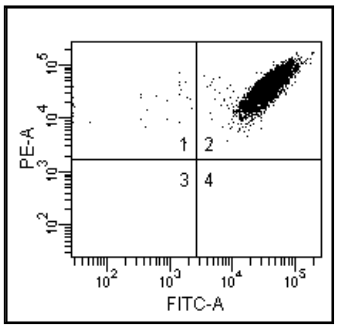
Rozenburglaan 13a • 9727 DL Groningen • The Netherlands
Tel. +31 (0)50 57 57 000 • *Fax* +31 (0)50 57 57 002 • *Email* marketing@iqproducts.nl • *Web* www.iqproducts.nl

Background information

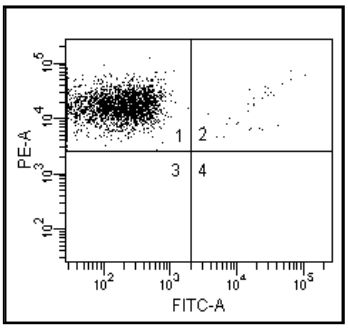
Heparin-induced thrombocytopenia (HIT) is an immune-mediated distinct syndrome in which laboratory detection of the pathogenic antibodies is diagnostically useful. The present functional flow cytometric assay determines the capacity of the patient's serum to activate platelets in presence of heparin (similar in concept to the gold-standard, the radioactive serotonin-release assay).

This functional assay reproduces the in vivo pathophysiology, and highly correlates with the clinical presentation of HIT. This is in contrast to the immune-detection antigen assays, which measure antibodies reactive to heparin platelet-factor 4 (PF4) complexes. However, only fraction of patients positive in these tests develop clinical HIT. On the other hand, pathogenic antibodies may react with other heparin complexes such as heparin-interleukin-8, or heparin- neutrophil activating peptide 2, thus, not being detected by those assays.

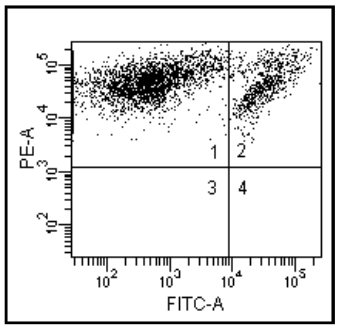
HIT antibodies are initially detected in circulation after 5 to 10 days of heparin therapy. However, subsequent to previous exposure, they may be formed in shorter time, i.e. 24 to 48 hours after re-exposure. Indications for testing in patients exposed to heparin include the appearance of thrombocytopenia, or of thrombosis irrespective to platelet count.



Artificial positive



Negative patient sample



Positive patient sample

For the HIT*Alert*™ kit donor platelets (PRP) are used, which are incubated in the presence of patient serum and in the presence or absence of heparin. When pathogenic antibodies are present the activation of the donor platelets is shown using a platelet activation marker. By incubating the samples with an antibody against platelets and the activation marker this reaction can be visualized using flow cytometry. The diagnosis of HIT is difficult because its signs are non-specific. Although both antigen and activation assays are very sensitive, activation assays have greater diagnostic specificity for clinical HIT. Results should always be used in conjunction with clinical findings or other serological tests.

Lab tests for HIT vary in their correlation to clinical HIT. Each test provides unique information. In 2012, the American College of Chest Physicians (ACCP) posted updates on recommendations for testing of HIT. Here they state that not all of the antibodies detected by immune assays are capable of causing clinical HIT; hence, the specificity of these tests is only moderate. The guideline describes various cases in which a functional assay must be conducted to confirm the diagnosis of HIT. The HIT*Alert*™ Kit is such a functional assay.

Item	Description	Package size	Product code
HIT*Alert*™ Kit IVD CE	A complete kit for the Reliable Diagnosis of Heparin-Induced Thrombocytopenia (HIT)	30 tests	IQP-396

IVD CE In vitro diagnostic medical device. The products are registered as IVD in the countries belonging to the European Union.

Rozenburglaan 13a • 9727 DL Groningen • The Netherlands
Tel. +31 (0)50 57 57 000 • *Fax* +31 (0)50 57 57 002 • *Email* marketing@iqproducts.nl • *Web* **www.iqproducts.nl**