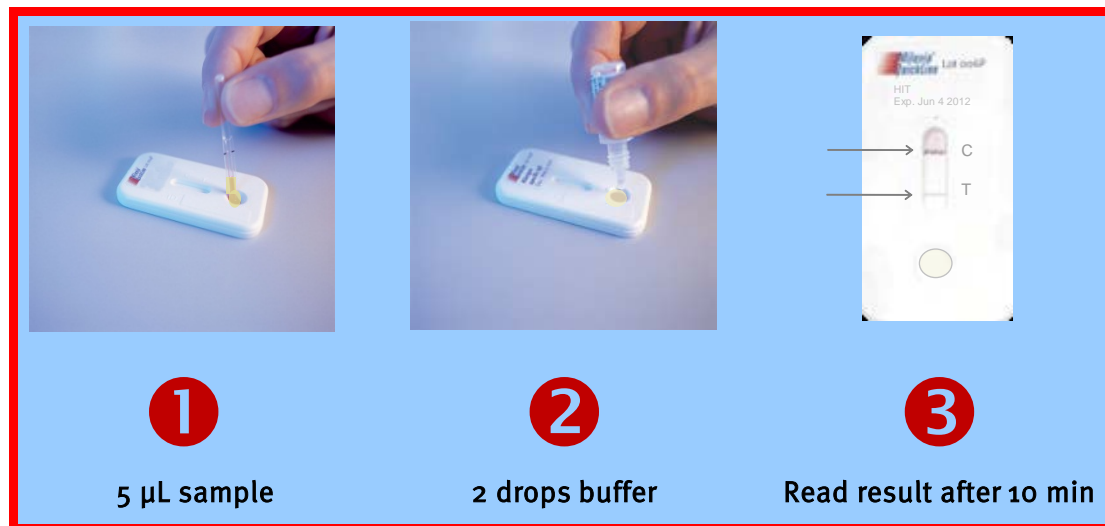


## Heparin Induced Thrombocytopenia (HIT)

Milenia<sup>®</sup> QuickLine HIT –  
Simple and rapid procedure to detect IgG antibodies against  
PF<sub>4</sub>/ Polyanion-Complexes

### Easy Handling



### Benefits

- **Easy handling**
- **Results within 10 minutes**
- **Qualitative results with ELISA-like quality**
- **IgG specific: Detection of the pathogenic antibodies only**
- **Enables real-time therapy decisions**
- **Excellent sensitivity and specificity**
- **Ready-to-Use reagents**

Allergy ▼ Milenia Biotec GmbH · Versailler Str. 1 · 35394 Gießen · Germany

Autoimmunity ▼ Phone: +49 (641) 948883-0 · Fax: +49 (641) 948883-80

Immunology ▼ Web: [www.milenia-biotec.de](http://www.milenia-biotec.de) · Email: [info@milenia-biotec.de](mailto:info@milenia-biotec.de)

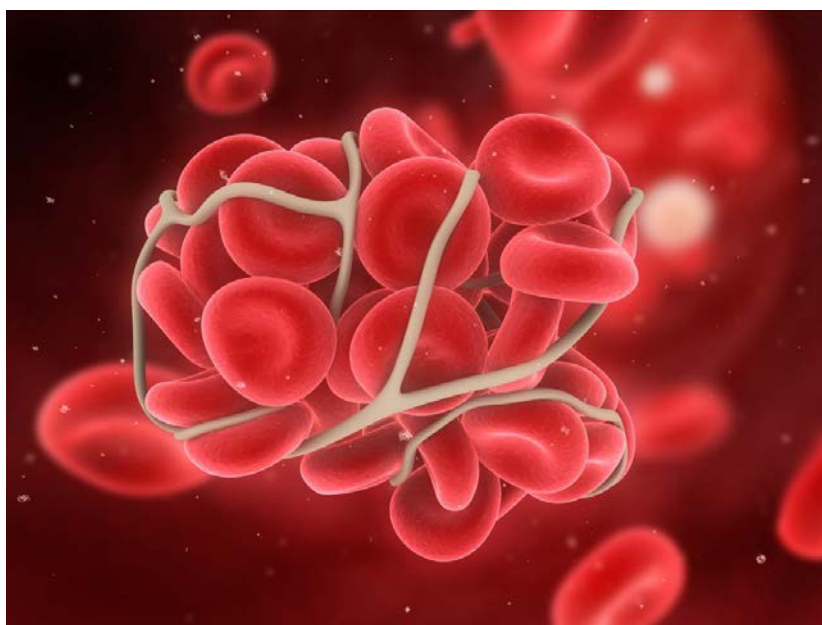
Infection ▼ Managing Director: Dr. Ralf Dostatni · HRB 6805 Gießen · USt-IdNr.: DE813002127

## Clinical Background

Heparin induced thrombocytopenia (HIT) is a life-threatening syndrome associated with exposure to unfractionated or (less commonly) low-molecular-weight heparin, drugs which are used very frequently for various indications. HIT occurs in up to 5 % of patients on heparin. The prevalence varies with the type of patients or procedures. Heart and major orthopedic surgery expose a higher risk than other clinical situations when heparin is used.

HIT is caused by antibodies directed against a complex of platelet factor 4 (PF<sub>4</sub>) and polyanions such as heparin. The pathogenic species is IgG. There is evidence for a correlation between antibody concentration and clinical severity. Platelet activation and massively enhanced thrombin generation promote venous and/ or arterial thromboembolism. The rate of severe patient injury (e.g. amputations) and mortality is very high.

Patients with HIT require alternative anticoagulation, but the drugs used in this setting have a high rate of hemorrhagic complications. There is no antidote available. Monitoring with standard methods is either not reliable or impossible. On top of this the drug costs are significantly higher than for heparins. Alternative anticoagulants should be reserved for patients with high clinical probability for HIT and with confirmed antibodies. Excluding HIT-antibodies is an important step towards selecting the most appropriate anticoagulation strategy.



## Test Principle

This assay is based on lateral flow immunoassay, a reliable technology which does not require washing steps.

Immobilized anti-human IgG on the nitrocellulose membrane binds patient's IgG-antibodies which are previously captured by the complex of PF<sub>4</sub> and a polyanion which is detected by intensely colored gold nanoparticles.

## Result Interpretation

The results could only be interpreted with an evaluation card.

- **Milenia® QuickLine HIT- Test Line- positive:** The result will be evaluated **positive**, if the **Test Line-T** shows the **same or a darker shade of color** than the given line on the Evaluation Card.
- **Milenia® QuickLine HIT- Test Line- negative:** The result will be evaluated **negative**, if the **Test Line-T** shows a **lighter-colored or weaker shade of color** than the given line on the Evaluation Card.
- **Control Line:** An integrated control line assures proper function of the test unit.

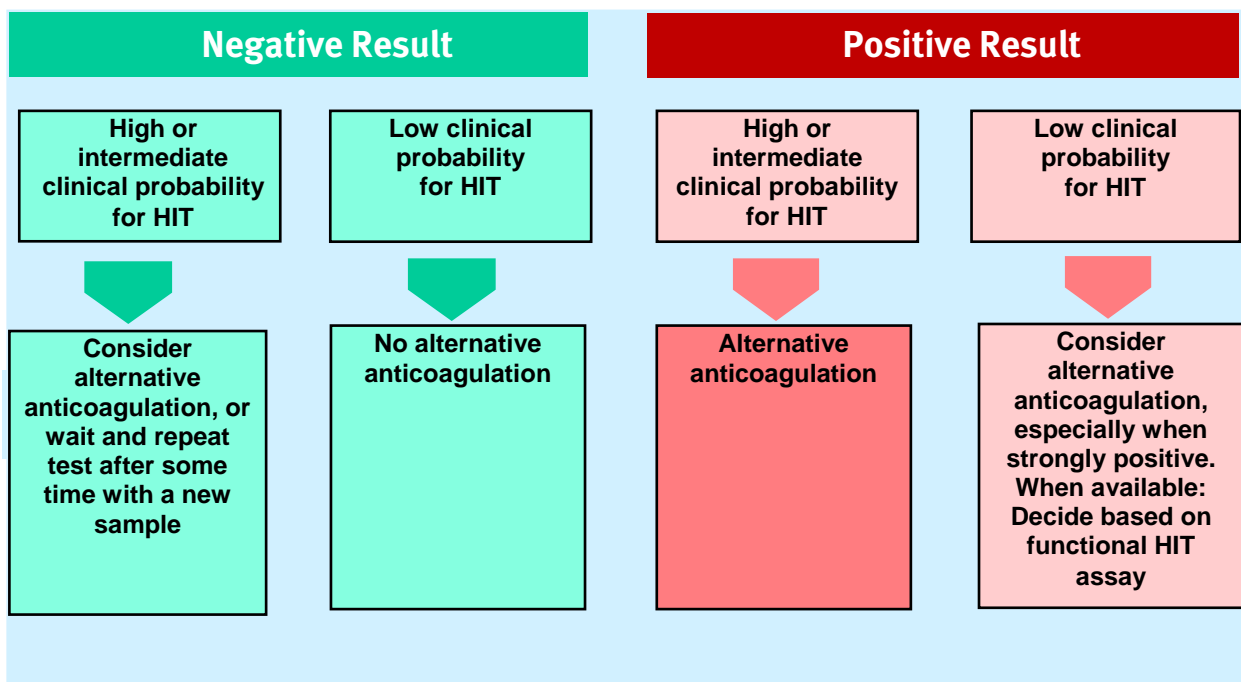
## Performance data for Milenia® QuickLine HIT

Milenia® QuickLine HIT was tested in internal and external investigations with a plurality of well characterized samples from patients that had been tested for suspected HIT II based on clinical factors with a functional test.

A study with 455 samples revealed a high degree of congruent results with ELISA and the functional HIPA-Test. The evaluation of Milenia® QuickLine HIT results was made by visual inspection. All HIT-positive patients based on the functional assay were correctly identified. Milenia® QuickLine HIT shows a tendency for less false positive results compared to other commercial IgG specific ELISA tests.

<b>NPV</b>	<b>100 %</b>	<b>PPV</b>	<b>54 %</b>
<b>Specificity</b>	<b>93 %</b>	<b>Sensitivity</b>	<b>100 %</b>

HIT II is not a laboratory diagnosis. Clinical data, e.g. the 4-t-score, are very important for selecting the best strategy for therapy, especially if heparin needs to be replaced by alternative anticoagulants. The algorithm below could serve as a model (for information only and without responsibility) how to use the QuickLine results in clinical decision processes. In a complex syndrome such as HIT II, any decision has to consider the overall clinical pictures and risk factors. The detection of HIT antibodies with immunoassays does not reliably confirm a diagnosis of HIT. This is only possible with functional assays. However, there is evidence that a strong signal in immunoassays is associated with a high probability for HIT.



## Milenia® QuickLine HIT

### Advantages:

- Small sample volume
- Results in a few minutes
- Rapid results with the potential to expedite medical decision-making
- Easy interpretation
- Ready-to-use reagents

### Specificity:

- Detection of IgG antibodies, the relevant species in HIT
- No cross-reactivity with IgA and IgM
- ELISA –like quality results
- Standardized antigen: PF<sub>4</sub> / polyanion
- No positive samples missed in a clinical study on 455 samples with suspected HIT

## References

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## Order Information

Parameter	Order Code	Package Size
Milenia® QuickLine HIT	MQHIT 1	20 tests
Milenia® QuickLine HIT	MQHIT Z	5 tests

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**Fax number ++49 641 948883 – 80**

I am interested in testing your products, please contact me

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