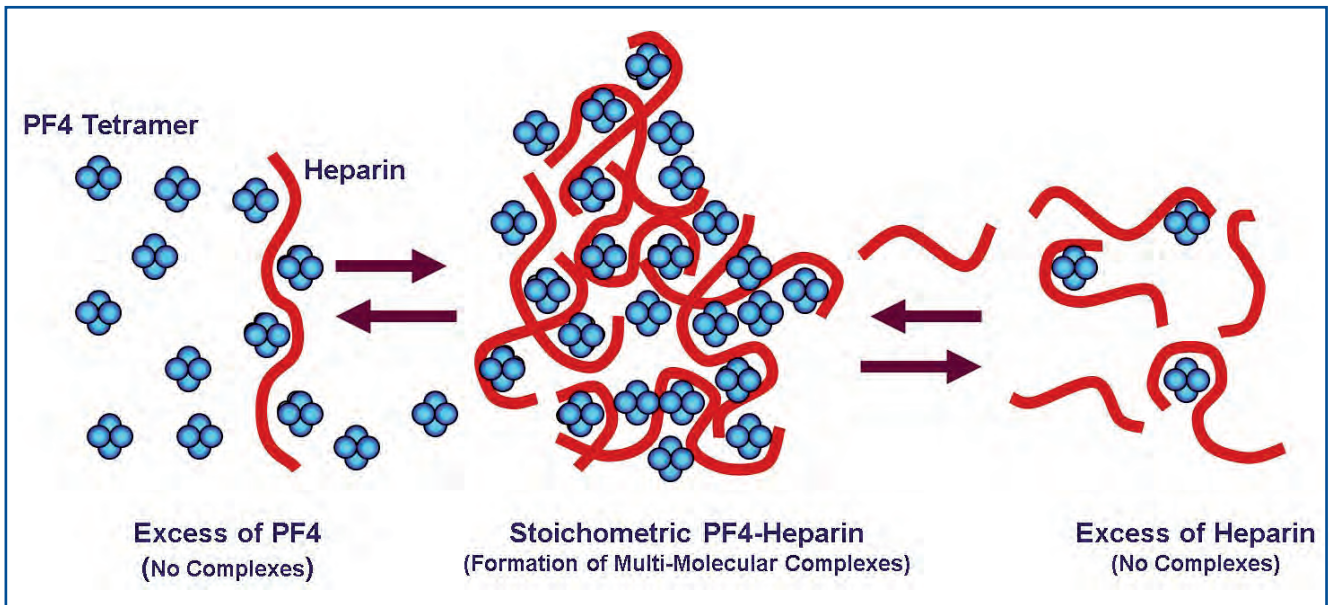




## Presentation with individual strips, small package

(see next page)



Multi molecular PF4-heparin complexes' formation, reactive with heparin dependent antibodies in HIT.



# ANIARA

Manufactured By: HYPHEN BioMed

## Mono Strip disposable HIT (4x8 tests)

ELISA FOR HEPARIN INDUCED ANTIBODIES (HIT), IgG ISOTYPE, MONO-STRIP

ZYMUTEST HIA Mono Strip, IgG

**RUO**

**CE Marked & 510(k) Cleared #ARK041A**

Enzyme Immuno-assay designed for measuring heparin-dependent antibodies of the IgG isotype, in human plasma or serum, or in any biological fluid where these antibodies must be measured. This assay measures only the IgG isotype, reported as the most associated with the clinical complications of heparin dependent antibodies (HIT/HITT), allowing confirmation of the diagnosis of HIT/HITT or its clinical suspicion. However, some cases associated with only IgM and/or IgA isotypes can be missed.

This kit allows individual test as it offers a packaging for 4 individual 8 well strips along with controls.

### Presentation

4 individual 8 well strips  
2x HIA Sample Diluent  
4x HIA IgG positive Control  
4x Negative control  
4x Platelet lysate  
4x Anti-IgG (Fcγ)-HRP IC  
1x Conjugate Diluent  
2x Wash Solution  
1x TMB  
1x 0.45M Sulfuric Acid

### Assay characteristics

Total Assay Time: 2h15  
Cut-off:  $A_{450} > 0.30$   
Dynamic Range:  $A_{450}$  up to 3.0  
Intra-Assay CV: 4 - 6%  
Inter-Assay CV: 5 - 8%

### Applications

Individual test.  
Clinical suspicion of HIT during heparin therapy.  
Heparin-dependent antibodies of the IgG isotype are those strongly associated with the clinical diagnosis of HIT. The ZYMUTEST HIA Mono Strip IgG assay offers then a better specificity for the clinical complication of HIT, but it has less sensitivity as cases associated with only IgM and/or IgA isotypes are missed.

ELISA FOR HEPARIN INDUCED ANTIBODIES (HIT), SCREENING ASSAY, MONO-STRIP

ZYMUTEST HIA Mono strip, IgGAM

**RUO**

**CE Marked & 510(k) Cleared #ARK041D**

Enzyme immuno-assay designed for measuring globally all heparin-dependent antibodies, whether the isotype is: IgG, IgM and IgA, in human plasma or serum, or in any biological fluid where these antibodies must be measured. This assay is proposed as screening, as an early identification of heparin treated patients presenting a risk to develop HIT or HITT. This assay measures the whole of antibodies. It offers the highest sensitivity as all isotypes are detected. It is the preferred assay when an early detection of heparin dependent antibodies is required for assessing the development risk of HIT/HITT.

This kit allows individual test as it offers a packaging for 4 individual 8 well strips along with controls.

### Presentation

4 individual 8 well strips  
2x HIA Sample Diluent  
4x HIA IgGAM positive Control  
4x Negative control  
4x Platelet lysate  
4x Anti-IgG (Fcγ)  
- IgM (μ)- IgA(α)-HRP IC  
1x Conjugate Diluent  
4x Wash Solution  
1x TMB  
1x 0.45M Sulfuric Acid

### Assay characteristics

Total Assay Time: 2h15  
Cut-off:  $A_{450} \geq 0.50$   
Dynamic Range:  $A_{450}$  up to 3.0  
Intra-Assay CV: 4 - 6%  
Inter-Assay CV: 5 - 8%

### Applications

Individual test.  
Assessment of the risk to develop HIT/HITT, in patients treated with heparins (Unfractionated or LMWH): presence of antibodies is a risk indicator for development of HIT/HITT.  
Clinical suspicion of HIT during heparin therapy.



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