

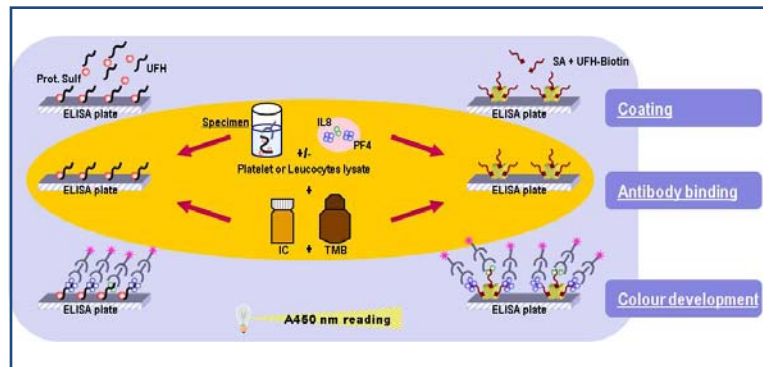
Heparin Induced Thrombocytopenia (HIT)

ZYMUTEST HIA kits offer a range of immuno-assays designed for testing heparin dependent antibodies, involved in the development of Heparin Induced Thrombocytopenia (HIT) or Heparin Induced Thrombocytopenia and Thrombosis (HITT).

ZYMUTEST HIA, IGAM (RK040D) measures the total antibodies, offering 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.

ZYMUTEST HIA, IgG (RK040A) measures only the IgG isotype, which is reported to be the most strongly associated with the clinical complications of heparin dependent antibodies (HIT/HITT). It allows to confirm HIT/HITT diagnosis or its clinical suspicion. However, some cases associated with only IgM and/or IgA isotypes can be missed.

ZYMUTEST HIA, IgG, IgM and IgA (RK040E) is designed for the full isotyping of heparin dependent antibodies. The main applications are to characterize the isotype distribution in patients with a risk or a suspicion of HIT/HITT, or for research investigations.



Complete disposable 96 well Elisa plate (3x32 tests)

ELISA FOR HEPARIN INDUCED ANTIBODIES (HIT)

ZYMUTEST HIA, IgG

IVD

CE, 510(k)

#RK040A

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.

Presentation

12x8 test kit
2x HIA Sample Diluent
3x HIA IgG positive Control
3x Negative control
3x Platelet lysate
3x Anti-IgG (Fc γ)-HRP IC
1x Conjugate Diluent
1x 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

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 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)

ZYMUTEST HIA, IgM

IVD

CE

#RK040B

Enzyme immuno-assay designed for measuring heparin-dependent antibodies of the IgM isotype, in human plasma or serum, or in any biological fluid where these antibodies must be measured.

Presentation	Assay characteristics	Applications
12x8 test kit 2x HIA Sample Diluent 3x HIA IgM positive Control 3x Negative control 3x Platelet lysate 3x Anti-IgM (μ)-HRP IC 1x Conjugate Diluent 1x Wash Solution 1x TMB 1x 0.45M Sulfuric Acid	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%	Measurement of human heparin-dependent antibodies of the IgM isotype, in research or prospective studies on the risk of HIT development during heparin therapy.

ELISA FOR HEPARIN INDUCED ANTIBODIES (HIT)

ZYMUTEST HIA, IgA

IVD

CE

#RK040C

Enzyme immuno-assay designed for measuring heparin-dependent antibodies of the IgA isotype, in human plasma or serum, or in any biological fluid where these antibodies must be measured.

Presentation	Assay characteristics	Applications
12x8 test kit 2x HIA Sample Diluent 3x HIA IgA positive Control 3x Negative control 3x Platelet lysate 3x Anti- IgA (α)-HRP IC 1x Conjugate Diluent 1x Wash Solution 1x TMB 1x 0.45M Sulfuric Acid	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%	Measurement of human heparin-dependent antibodies of the IgA isotype, in research or prospective studies on development of HIT during heparin therapy.

ELISA FOR HEPARIN INDUCED ANTIBODIES (HIT), SCREENING ASSAY

ZYMUTEST HIA IgGAM

IVD

CE, 510(k)

#RK040D

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.

Presentation	Assay characteristics	Applications
12x8 test kit 2x HIA Sample Diluent 3x HIA IgGAM positive Control 3x Negative control 3x Platelet lysate 3x Anti-IgG ($\text{Fc}\gamma$)- IgM (μ)- IgA(α)-HRP IC 1x Conjugate Diluent 1x Wash Solution 1x TMB 1x 0.45M Sulfuric Acid	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%	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.

ELISA FOR HEPARIN INDUCED ANTIBODIES (HIT), FULL ISOTYPING

ZYMUTEST HIA IgG, IgA, IgM

IVD

CE

#RK040E

Enzyme immuno-assay designed for specifically measuring heparin-dependent antibodies of IgG, or IgM, or IgA isotype, in human plasma or serum, or in any biological fluid where these antibodies must be measured. Specific isotyping assay. Assay designed for the full isotyping of heparin dependant antibodies, applications to characterization of isotype distribution in patients with a risk or a suspicion of HIT/HITT, or for research investigations.

Presentation

- 12x8 test kit
- 2x HIA Sample Diluent
- Positive Controls (IgG, IgA and IgM)
- 3x Negative control
- 3x Platelet lysate
- Anti-IgG (Fc γ)/IgM (μ)/IgA (α)-HRP IC (1 each)
- 1x Conjugate Diluent
- 1x 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%

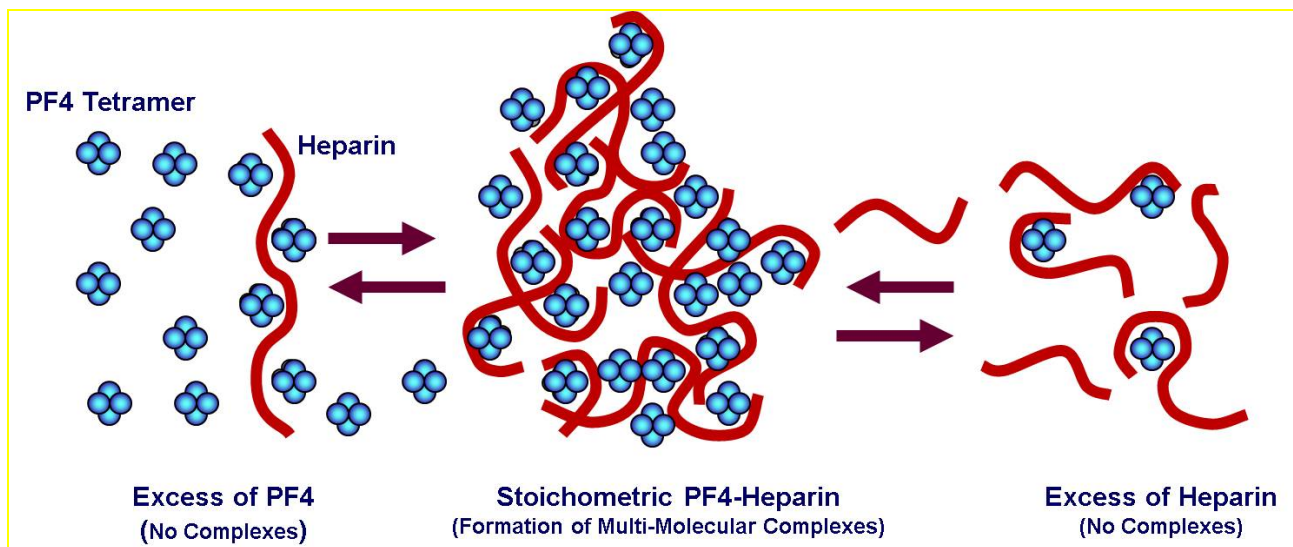
Applications

Complete isotyping of Heparin dependent antibodies, as a primary approach in research applications or as a second intention assay for characterizing patients measured positive with the ZYMUTEST HIA IgGAM, screening assay (# RK040D).

Note: The kit allows running 32 tests for each specific isotype.

NEW

Presentation with individual strips, small package
(see next page)



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

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

ZYMUTEST HIA Mono Strip, IgG

RUO

CE in progress

#RK041A

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 (Fc γ)-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 in progress

#RK041D

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 (Fc γ)- 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%
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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.