

HIT DIAGNOSTIC WORKFLOW

Your HIT screen came back positive. *Now what?*

A positive PF4/heparin screen is a question, not an answer. Rapid screening immunoassays exist to **rule HIT out** — but a positive result detects anti-PF4/heparin antibodies broadly, sweeping in IgM and IgA classes that don't activate platelets. So a positive screen leaves the question that matters unanswered: **is this the antibody that actually causes disease?**

01

SCREEN — BROAD

Rapid screening immunoassay

Sensitive, with strong negative predictive value — good for *ruling out*. But a positive flags every isotype, pathogenic or not.

positive?



02

VERIFY — SPECIFIC

ZYMUTEST™ HIA IgG

Isolates the one antibody class capable of driving platelet activation — sharpening the result before the next clinical decision.

ZYMUTEST™ HIA IgG

IGG-SPECIFIC ANTI-PF4/HEPARIN ANTIBODY ELISA

Pathogenic isotype only

An Fcy-specific conjugate measures IgG — the isotype tied to platelet activation in HIT — not clinically silent IgM/IgA.

Built-in confirmation

A heparin-inhibition step (>50% signal drop with excess heparin) confirms binding is genuinely heparin-dependent.

Low HIT volume? The 32-test **MonoStrip (RK041A)** runs a handful of samples without committing a full 96-well plate — the 96-test **RK040A** scales when you need it.

FDA 510(K)-CLEARED · K071255 | **CE-IVD** | MANUAL OR AUTOMATED ELISA | PLASMA OR SERUM

EVALUATION DATA — SPECIFICITY

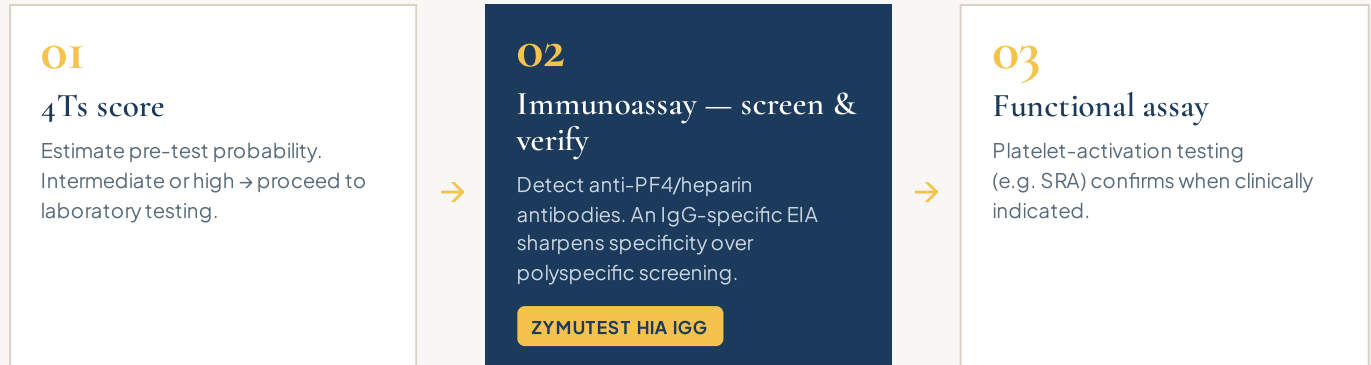
~90%

vs ~77% — global-isotype ELISA

IgG-specific detection lifted clinical specificity to ~90% — **without meaningful loss of sensitivity for clinically significant, IgG-mediated HIT.**[†] Fewer false alarms; fewer unnecessary functional send-outs.

Screen broadly. • *Verify specifically.*

— WHERE IT FITS — THE GUIDELINE-BACKED WORKFLOW



Workflow per **ASH 2018** guidelines (Cuker et al., *Blood Advances*). **ASH 2024** guidance concurs that IgG-specific EIAs deliver greater diagnostic specificity than polyspecific assays — positioning the IgG-specific immunoassay as the natural verify step before a functional send-out.

Specifications

Method	IgG-specific anti-PF4/heparin antibody ELISA (Fcγ-specific conjugate)
Formats	RK040A — 96 tests · RK041A MonoStrip — 32 tests
Sample	Citrated or EDTA plasma, or serum
Platform	Manual, or automated on open ELISA processors (lab-validated application)
Detection	Microplate reader at 450 nm
Assay time	~2.5 h, batched — minimal hands-on; walk-away on automation
Confirmation	Built-in heparin-inhibition step (>50% signal drop)
In kit	Positive & negative controls, cell lysate, all reagents
Storage	2–8°C · usable across a 2-month in-use window

Why labs make the switch

→ Cut the false alarms

IgG-specific detection lifts clinical specificity over polyspecific screening — fewer positives that aren't HIT.

→ Fewer functional send-outs

A sharper verify step reduces unnecessary, costly SRA referrals and shortens the path to an answer.

→ Right-sized & bench-ready

The 32-test MonoStrip suits low HIT volumes; manual or automated on open ELISA systems, with onboarding support.

INDEPENDENTLY EVALUATED IN *N Engl J Med* 2021 · *Thrombosis Research* 2011 · *ASH Blood VTH* 2025

BEYOND HIT — WHERE RAPID PLATFORMS FALL SHORT

In independent evaluations of **VITT and anti-PF4 disorders**, rapid and chemiluminescent platforms (AcuStar, LIA, STic, PaGIA) showed **poor sensitivity**, while anti-PF4 **ELISAs detected the antibodies** — HYPHEN's assay among those named in UK NEQAS. As "vaccine-induced" VITT gives way to **virus-induced, VITT-like anti-PF4 disorders**, keeping an ELISA on the bench keeps these on the menu.

Platton et al., *JTH* 2021 · UK NEQAS (Reilly-Stitt et al.), *JTH* 2021 · Greinacher et al., *NEJM* 2021. ZYMUTEST™ HIA IgG is cleared for HIT, not VITT; anti-PF4 ELISA-positive samples should be confirmed by a functional platelet-activation assay.

MEET US AT OUR BOOTH

Request an *evaluation kit*.

Put ZYMUTEST™ HIA IgG on your own bench. Talk through a workflow fit and pricing with our team. Contact **Maria Waldron**, Director of Sales.

Visit our **booth**