

— ZYMUTEST™ HIA IGG MONOSTRIP · IGG-SPECIFIC HIT ELISA · HYPHEN BIOMED

The full HIT answer — *right-sized for your lab.*

Smaller hospitals see HIT too — just not often enough to justify opening a 96-well plate for one or two samples. The ZYMUTEST™ HIA IgG MonoStrip is the **same FDA-cleared, IgG-specific anti-PF4/heparin ELISA** as the full kit — same antibody specificity, same confirmation step, same **~90% specificity** — supplied in **32 break-apart wells** so you can run a handful of samples without waste. Keep HIT verification **in-house** instead of sending it out.

IGG-SPECIFIC HIT ELISA · HYPHEN BIOMED

ZYMUTEST™ HIA IgG MonoStrip

Anti-PF4/heparin IgG ELISA · 32 tests

- **Identical assay to the 96-test kit (RK040A)** — IgG-specific Fcy conjugate, no clinically silent IgM/IgA.
- Built-in **heparin-inhibition confirmation** (>50% signal drop) — confirms genuinely heparin-dependent binding.
- **~90% specificity** vs ~77% for global-isotype screening — fewer false alarms, fewer SRA send-outs.
- **Break-apart strips** — run one to a few samples at a time, no full-plate commitment or wasted wells.
- **FDA 510(k)-cleared (K071255)** & CE-IVD; manual or automated; plasma or serum.

RK041A · FDA-cleared · CE-IVD

32 tests

WHY THE MONOSTRIP FOR LOWER VOLUME

HIT is intermittent at smaller centers. A 96-well plate forces you to batch or waste wells — so samples get held or sent out, delaying the answer.

The MonoStrip breaks into **small runs**: test today's one or two samples now, store the rest. Same reagents, same controls, same result.

Keeps a sharp **IgG-specific verify step** on your own bench — faster than send-outs, with the costly functional referral reserved for when it's truly needed.

WHERE IT FITS

Low-volume HIT testing

Community & regional hospitals

On-demand / single-sample runs

IgG-specific HIT verification

Reduce SRA send-outs

Manual or automated ELISA

Plasma or serum

4Ts intermediate / high workup

SAME ASSAY — SCALE WHEN YOU NEED TO

ZYMUTEST™ HIA IgG · 96-test

RK040A — the identical IgG-specific assay in a full 96-well plate for higher-volume labs.

Everything in the box

Positive & negative controls, cell lysate and all reagents — ready to run.

Guideline-backed step

IgG-specific EIA is the **ASH-recommended verify step** ahead of a functional (SRA) send-out.

Regulatory: ZYMUTEST™ HIA IgG (RK041A MonoStrip, 32 tests; RK040A, 96 tests) is manufactured by HYPHEN BioMed and is **FDA 510(k)-cleared (K071255)** and **CE-IVD** — an IgG-specific anti-PF4/heparin antibody ELISA for detection of antibodies associated with heparin-induced thrombocytopenia (HIT), on plasma or serum, manual or automated. It is cleared for HIT, not VITT; positive results are interpreted with clinical findings and, when indicated, a functional platelet-activation assay. Specificity figures (~90% IgG-specific vs ~77% global-isotype) are from independent published evaluations (Pouplard et al., Thromb Haemost 2010). Distributed by Aniara Diagnostica in North America and the Nordic & Baltic states. Pricing on request. © 2026 Aniara Diagnostica, Inc.