

A family silhouette consisting of a man, a woman, and a young child, standing on a beach and holding hands. They are positioned in the lower center of the frame, looking out at a vast, starry night sky. The Milky Way galaxy is prominently visible, arching across the sky from the upper left towards the right. The colors of the sky transition from deep blue at the top to lighter blue and purple near the horizon, where a hint of sunset or sunrise is visible. The overall mood is one of wonder and exploration.

Seeing Beyond Limits

PF4 Family of Products

THE SOURCE FOR HIT ANTIBODY DETECTION

PF4 Enhanced[®] assay and PF4 IgG assay are qualitative solid phase enzyme linked immunosorbent assays (ELISA) designed to detect antibodies reactive with platelet factor 4 (PF4) when it is complexed to polyanionic compounds such as Polyvinyl Sulfonate (PVS). These antibodies are found in some patients undergoing heparin therapy. Immucor offers highly sensitive, flexible ELISA kit formats with options to detect either IgG/AM or IgG-only antibodies.^{1, 2}





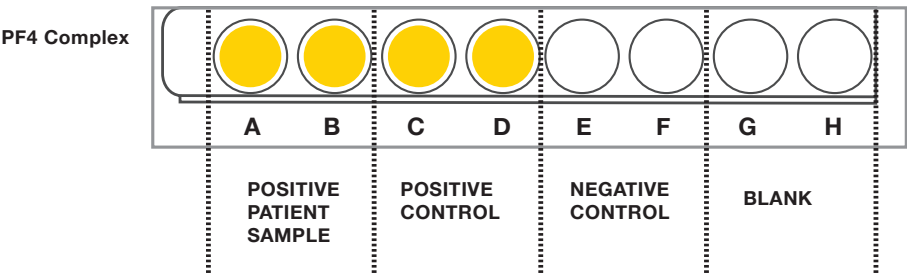
PF4 Family of Products

Immucor's PF4 product line offers the following features

- ELISA kit format detects heparin-induced PF4 antibodies
- Heparin neutralization step reduces false positives relative to heparin-dependent antibody reactivity
- A close relationship between the OD value of the ELISA result and likelihood that a patient has clinical HIT has been reported by several laboratories^{3, 4}
- Serum, sodium citrate (plasma)* and ACD** sample types supported
- Most published test method on the market with proven cost effectiveness
- FDA cleared, CE marked, Health Canada licensed

* 3.2% sodium citrate (plasma)
 ** PF4 IgG assay only

Strip Configuration



Maximum Flexibility

- Feasibility to utilize third party automated ELISA liquid handler systems has been established⁵
- IgG-Specific or Enhanced (IgG/IgA/IgM) kits available
- Two kit sizes available for maximum flexibility –13 test or 45 test kit configurations

Ordering Information

| Catalog #/Order # | Description | Size | Avg. Shelf Life | Storage |
|-------------------|---------------|--------------------------|-----------------|-----------|
| X-HAT13/303287 | PF4 ENHANCED® | Maximum 13 Tests Per Kit | 2 Years | 2° to 8°C |
| X-HAT45/303288 | PF4 ENHANCED® | Maximum 45 Tests Per Kit | 2 Years | 2° to 8°C |
| HAT13G/303289 | PF4 IgG | Maximum 13 Tests Per Kit | 2 Years | 2° to 8°C |
| HAT45G/303290 | PF4 IgG | Maximum 45 Tests Per Kit | 2 Years | 2° to 8°C |



High sensitivity assures confidence in results

In a published study utilizing Immucor's test kit, a total of 63 patients were identified as HIT positive.⁶

- In 61 patients (97% of study population), the ELISA results occurred in the setting of thrombocytopenia (platelet count $<150\,000\text{ mm}^{-3}$)
- In 58 patients (92% of the study population), there was at least a 50% fall in platelet count from baseline consistent with the clinical diagnosis of HIT



A published retrospective study of 299 patients, compared the Serotonin Release Assay (SRA) to commercially available tests.⁷

- Each commercial kit outperformed the SRA test with a positive cut off of $4T > 4$.
- Analyzing results by 4T Score reveal that two assays LIFECODES and STAGO perform above 88% concordant with scores of 7 or 8.
- HemosIL HIT-Ab and SRA were below 24% concordant with these highly scored clinical samples.

Technologies Compared

| | Immucor PF4 ELISA Family | Latex Enhanced Turbidimetric Assay | Chemiluminescent Immunoassay |
|-------------------------------------|---------------------------------------|------------------------------------|------------------------------|
| Sample Type | ACD*, Sodium Citrated Plasma or Serum | Citrated Plasma | Citrated Plasma or Serum |
| Plate Coating | PF4 and Polyvinyl Sulfonate | PF4 and Polyvinyl Sulfonate | PF4 and Polyvinyl Sulfonate |
| End Point | OD Value | Units/mL | Units/mL |
| Heparin Confirmation Step Available | Yes | No | No |
| IgG/A/M Kit Available | Yes | Yes | Yes |
| IgG Specific Kit Available | Yes | No | Yes |
| Multiple Kit Sizes Available | Yes | No | No |

* PF4 IgG assay only

REFERENCES

- ¹ PF4 Enhanced for in vitro diagnostic use [package insert], Waukesha, WI; Immucor GTI Diagnostics, Inc.
- ² PF4 IgG for in vitro diagnostic use [package insert], Waukesha, WI; Immucor GTI Diagnostics, Inc.
- ³ Zwicker, J. I., Uhl, L., Huang, W.-Y., Shaz, B. H. and Bauer, K. A. (2004), Thrombosis and ELISA optical density values in hospitalized patients with heparin-induced thrombocytopenia. *Journal of Thrombosis and Haemostasis*, 2: 2133–2137.
- ⁴ Warkentin, T. E., Sheppard, J. I., Moore, J. C., Sigouin, C. S. and Kelton, J. G. (2008), Quantitative interpretation of optical density measurements using PF4-dependent enzyme-immunoassays. *Journal of Thrombosis and Haemostasis*, 6: 1304–1312. doi:10.1111/j.1538-7836.2008.03025.
- ⁵ C. Cronin, F. Lucas, V. Ricchiuti. Full Automation of Heparin Induced Thrombocytopenia ELISA Assay on DYNEX DSX ELISA Platform [AACC abstract A-309] *Clinical Chemistry Vol. 60, No. 10, Supplement*, 2014
- ⁶ Zwicker JI, Uhl L, Huang WY, Shaz BH, Bauer KA. Thrombosis and ELISA optical density values in hospitalized patients with heparin-induced thrombocytopenia. *J Thromb Haemost*. 2004 Dec;2(12):2133–7.
- ⁷ M. Refaai, F. Kara, H. McRae, K. Refaai, R. Whitmarsh, M. Spigarelli Retrospective Evaluation of HIT Pre-test Probability & Association with HIT assays [ISLH Poster May 2019] *Int. Jnl. Lab. Hem*. 2019 41 (Suppl. 2) 1-204



To learn more or to set up a demo with one of our Transplant Business Managers,
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