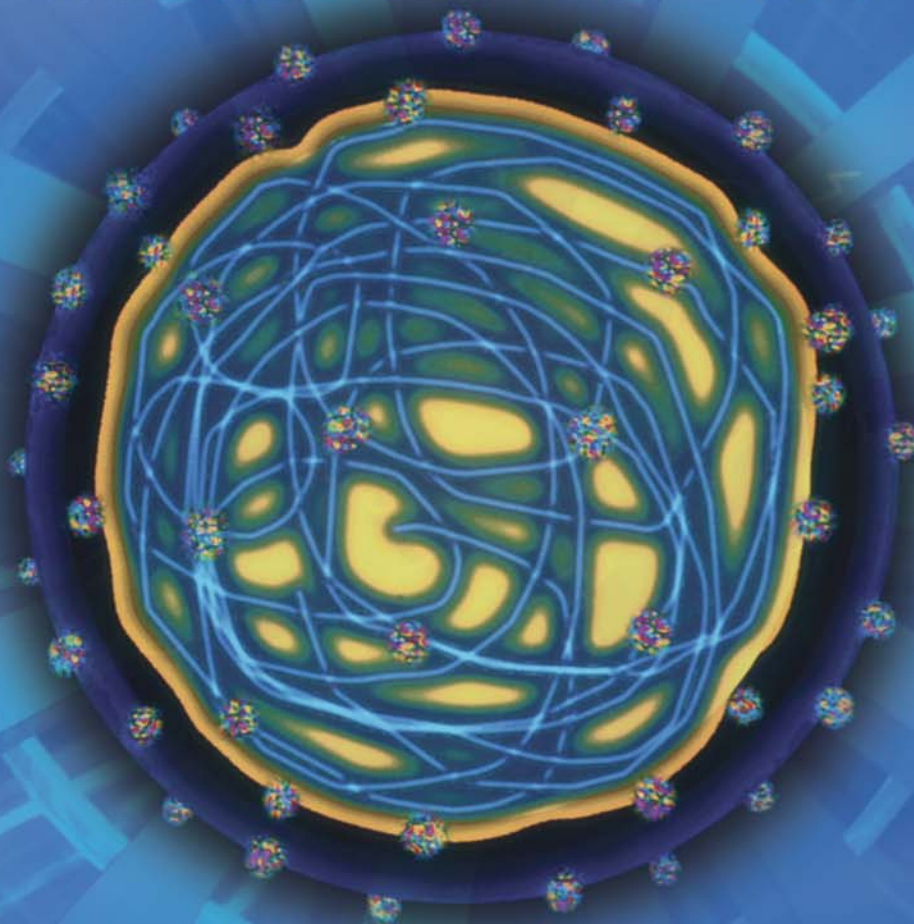


**Genetic Systems™ HIV-1/HIV-2 PLUS O EIA**

**YOU AND YOUR PATIENTS  
DESERVE PEACE OF MIND**



**Use the Available HIV-1/HIV-2 Test  
for Donor Screening with the Group O Claim**

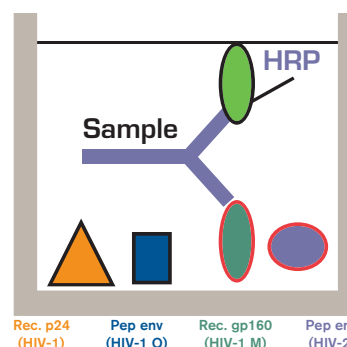
# Genetic Systems™ HIV-1/HIV-2 PLUS O EIA

## Key Benefits

- Superior specificity performance, compared to Genetic Systems™ HIV-1/HIV-2 Peptide EIA, due to direct sandwich assay technology
- Enhances safety of the blood supply with group O detection

## Superior Specificity Performance Due to Direct Sandwich Assay Technology

Immunoglobulins from the sample bind to antigens on the solid phase and also to similar HRP-conjugated antigens in solutions.



*“The Food and Drug Administration (FDA) has requested all manufacturers of HIV test kits to modify existing kits to achieve enhanced sensitivity for HIV-1 group O. In the interests of the public health, we encourage manufacturers to respond to this request as expeditiously as possible.”*

-Edward Tabor, MD

Director, Division of Transfusion Transmitted Diseases, FDA  
Letter to industry, July 30, 1997

## Sensitivity\*

|                      |                  |
|----------------------|------------------|
| <b>HIV-1 Group M</b> | 100% Sensitivity |
| <b>HIV-1 Group O</b> | 100% Sensitivity |
| <b>HIV-2</b>         | 100% Sensitivity |

\* Source: Clinical trial data, on file.

Cadaveric claim: see Package Insert for manual testing options.

## Specificity\*

In a beta trial, matched samples were tested on both the GS HIV-1/HIV-2 Peptide and GS HIV-1/HIV-2 PLUS O assays with the automated Ortho Summit™ System.

| Assay                         | Total Samples | No. IR | IR%   | No. RR | RR%   | Specificity |
|-------------------------------|---------------|--------|-------|--------|-------|-------------|
| <b>GS HIV-1/HIV-2 Peptide</b> | 24,247**      | 47     | 0.19% | 41     | 0.17% | 99.83%      |
| <b>GS HIV-1/HIV-2 PLUS O</b>  | 24,247**      | 52     | 0.21% | 19     | 0.08% | 99.92%      |

\* Source: Beta trial data, on file. \*\* 3 additional samples that were RR and confirmed positive by Western Blot were removed from specificity calculations.

## Description

## Product Code

Genetic Systems™ HIV-1/HIV-2 PLUS O EIA – 480 tests 32588  
Genetic Systems™ HIV-1/HIV-2 PLUS O EIA – 4800 tests 25256

*For 4800 test kit, Wash and Stopping Solutions must be ordered separately.*

Wash Solution for 4800 tests 25261  
Stopping Solution for 4800 tests 25260

To place an order, please contact customer service at 1-800-828-6316 or order on-line at [www.orthoclinical.com](http://www.orthoclinical.com)

[www.orthoclinical.com](http://www.orthoclinical.com)

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