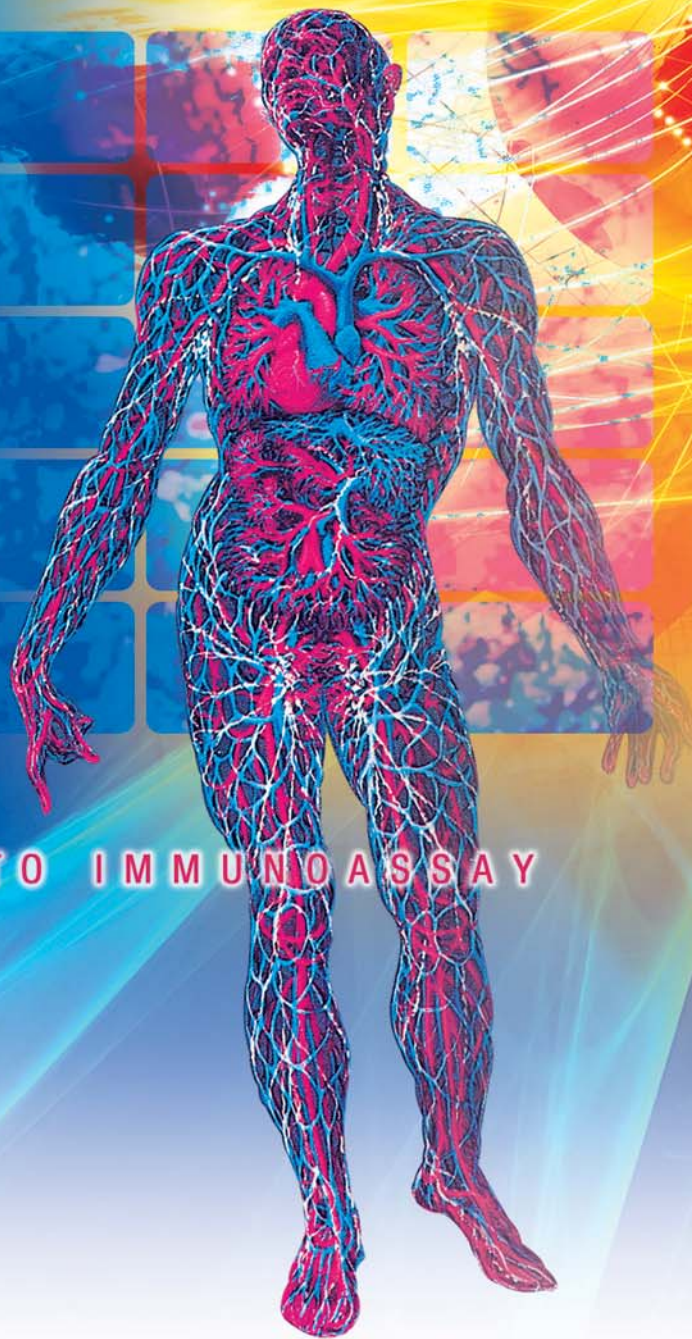
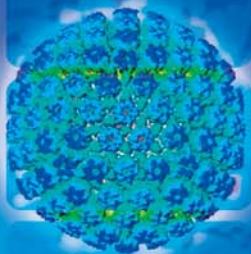


PATHOZYME VIRO™ HSV-2 IgG

A sensitive and specific enzyme immunoassay for the detection of type-specific IgG antibodies against Herpes Simplex Virus Type 2 in human serum.



BRINGING INNOVATION TO IMMUNOASSAY



omega

DIAGNOSTICS

PATHOZYME VIRO™ HSV-2 IgG

Herpes Simplex Virus Type 2 (HSV-2) is a common human pathogen with a world-wide distribution that has historically been associated with Genital Herpes infections. It is closely related to Herpes Simplex Virus Type 1 (HSV-1), which is mostly associated with Herpes infections of the face, nose and tongue. A recent study showed that primary genital infections are equally likely to be caused by HSV-1 or HSV-2 (ref. 1). Primary infections are often characterised by the appearance of sores within 2 weeks and may be accompanied by flu-like symptoms and swollen glands. Infection is for life and several recurrent episodes may occur within a year. Recurrence rates for HSV-2 are up to four times those for HSV-1 (ref. 2). Serious and potentially fatal complications of HSV-2 infection can occur when neonates are infected in the birth canal. Infection with HSV-2 increases the risk of acquiring the Human Immunodeficiency Virus (ref. 3).

High specificity

(100% - no false positives). Use of short peptide sequences gives no cross reactivity with other antibodies

High sensitivity

96% compared with Western Blotting

Microplate format

Breakwell strips for maximum flexibility and minimal wastage

Ready-to-use colour-coded reagents

For ease of use

Controls ready-to-use

No need to dilute controls

Rapid

Test completed with 1h 45min total incubation

Results easily calculated

and expressed as an index for ease of comparison

Shelf-life

1 year.

Principle of the test

Almost all proteins induced by herpes simplex virus types 1 and 2 are very closely related and show considerable serological cross-reactivity. However, one glycoprotein designated gG2 that is induced by HSV-2, can be distinguished serologically from the equivalent HSV-1 glycoprotein gG1 (refs. 4-8). Type-specific serological assays that distinguish between antibodies in human sera directed against these two glycoproteins have been developed (ref.9).

Immunodominant epitopes on gG2 have been mapped (refs.10 - 13) and offer the possibility of peptide-based type-specific-serodiagnosis of HSV-2 infections (refs 11,15,16). Branched peptides are superior to monomeric peptides for the detection of low amounts of antibodies (ref. 14).

Calculation of results

Calculate the average OD of the Low Positive Control. This is the cut-off value of the assay. Divide the sample OD by the cut-off value to obtain the Sample Index.

A Sample Index greater than 1.1 indicates a positive sample. A Sample Index lower than 0.9 indicates a negative sample.

Evaluation Data - Internal

STUDY 1: comparison with an ELISA method from another manufacturer. 285 unselected sera were screened using both this kit and HerpeSelect® 2 ELISA IgG kits (Focus Diagnostics, Cypress CA USA) according to the manufacturer's instructions.

The results were as follows.

Omega PATHOZYME VIRO™ HSV-2 IgG		Focus HerpeSelect®2 ELISA IgG		
		Positive	Equivocal	Negative
Omega PATHOZYME VIRO™ HSV-2 IgG	Positive	79	0	1
	Negative	2	1	202

From this data the correlation coefficient between the two methods is 98.6%

STUDY 2: sensitivity and specificity.

Sera were screened by Western Blotting and/or a monoclonal antibody blocking test (ref. 17) to identify 54 sera that were positive for antibodies against HSV-2 and 170 sera that were negative for antibodies against HSV-2. These sera were screened using Omega PATHOZYME™ VIRO HSV-2 ELISA IgG.

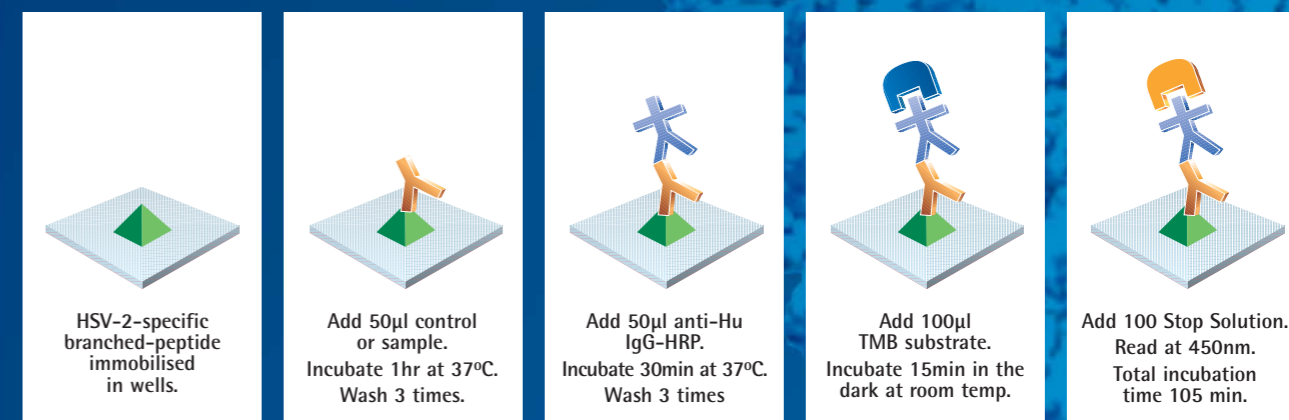
The results were as follows.

Omega PATHOZYME VIRO™ HSV-2 IgG		Western Blot and/or Monoclonal Antibody	
		Positive	Negative
Omega PATHOZYME VIRO™ HSV-2 IgG	Positive	52	0
	Negative	2	170

From this data the sensitivity is 96.3% and the specificity is 100%.

The coefficient of variation of PATHOZYME VIRO™ HSV-2 IgG is less than or equal to 10%.

Protocol for PATHOZYME VIRO™ HSV-2 IgG



Evaluation Data - External

An evaluation was performed at the Clinical Virology Laboratory of the Manchester Medical Microbiology Partnership, Manchester (UK) using 218 unselected sera. The sera were screened in the Omega PATHOZYME VIRO™ HSV-2 IgG kit, the HerpeSelect® 2 ELISA IgG kit (Focus Diagnostics, Cypress CA USA, Product code EL0920G) and the bioelisa HSV-2 IgG kit (BIOKIT, S.A., Barcelona, Spain, Product code 3000-1028). All assays were performed according to the manufacturer's instructions. Of the 218 samples, 31 were positive in all three kits and 164 were negative in all three kits. The remaining 23 samples gave results that were discordant between the three kits.

The detailed results were as follows.

Omega PATHOZYME VIRO™ HSV-2 IgG		Focus HerpeSelect®2 ELISA IgG		
		Positive	Equivocal	Negative
Omega PATHOZYME VIRO™ HSV-2 IgG	Positive	42	1	4
	Equivocal	0	0	2
	Negative	3	1	165

Omega PATHOZYME VIRO™ HSV-2 IgG		bioelisa HSV-2 IgG		
		Positive	Equivocal	Negative
Omega PATHOZYME VIRO™ HSV-2 IgG	Positive	31	0	16
	Equivocal	0	0	2
	Negative	3	0	166

bioelisa HSV-2 IgG		Focus HerpeSelect®2 ELISA IgG		
		Positive	Equivocal	Negative
bioelisa HSV-2 IgG	Positive	33	0	1
	Equivocal	0	0	0
	Negative	12	2	170

From this data the correlation coefficient between the kits are: Omega/Focus = 95.0%, Omega/BIOKIT = 90.4% and Focus/BIOKIT = 93.1%.

The 23 samples that gave discordant results were analysed by Western Blotting. Unambiguous profiles were obtained for 22 of the samples of which 21 were HSV-2 positive and one was HSV-2 negative. Of the HSV-2 positive samples, 3/21 (14%) were scored positive by BIOKIT, 14/21 (67%) were scored positive by Focus and 16/21 (76%) were scored positive by Omega. No false positives were detected by any of the three kits.

Patents

The contents of this kit are protected by the following patents: European Patent, no. 0994121, US Patent no. 5,965,357, and other patents pending.

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Ordering information

Description: PATHOZYME VIRO™ HSV-2 IgG
Code: OD697
Product to be stored at 2°C to 8°C



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