

# CORE HIV 1 & 2

## TEST PERFORMANCE

### 1. Diagnostic specificity:

A total of 1204 samples were tested with the Core HIV 1&2 at two European Blood Transfusion Centres. 3 samples were found repeatedly positive.

**The diagnostic specificity is determined as 99.75%.**

### 2. Diagnostic sensitivity:

500 HIV positive samples were tested with the Core HIV 1&2, all of them were found positive.

**The diagnostic sensitivity is determined as 100%.**

HIV Type	Number of samples tested	Core HIV1&2	
		negative	positive
HIV-1	360	0	360
HIV-2	100	0	100
HIV-1 subtype non-B*	40	0	40

\*(including subtype-O)

### 3. Possible Interferences:

The table below shows the results of the Core HIV 1&2 tested on a variety of samples containing possibly interfering substances:

Sample type	Number of samples tested	Core HIV1&2	
		negative	positive
clinical specimens	200	200	0
pregnant women	200	200	0
related infections (*)	100	98	2
Rheumatoid Factor positive	7	7	0
Multipara	1	1	0
anti-E coli positive	2	2	0

(\*) The results were negative for samples containing HBs Ag (15), anti-HCV (12), anti-HTLV (14), anti-HSV (16), anti-VZV (4) and anti-EBV (4). One of the 20 anti-CMV samples and one of the 15 anti-HAV samples were found false positive.

### 4. Seroconversion panels

The sensitivity, evaluated on 30 commercially available seroconversion panels (Boston Biomedica Inc.), is comparable to HIV Antibody detection ELISA's registered in major European countries.

Features :

✓ CE Marked	✓ Specificity: 99.75%
✓ 3rd. Generation Double Antigen Sandwich assay.	✓ Detects All subtypes including subtype-O
✓ Serum / Plasma / Whole Blood	✓ Results in few minutes.
✓ Sensitivity: 100%	✓ 24 months shelf life stored between 4°C and 30°C

Distributed By :



0459