

# Performance of the Lumipulse® G HTLV-I/II assay



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## Background

There are two types of HTLV: HTLV-I and HTLV-II. HTLV-I is associated with adult T-cell lymphoblastic leukemia and B-cell chronic lymphocytic leukemia and a demyelinating disease called HTLV-I associated myelopathy/Tropical spastic paraparesis (HAM/TSP). HTLV-I infection is endemic in south Japan, the Caribbean, in some regions of Africa, Central and South America and also found in Melanesia and central and northern Australia. It is estimated that 15-20 million people are currently infected with human T-cell lymphotropic virus type 1

(HTLV-1) worldwide. HTLV-II is less common and is associated with neoplasias of the CD8 T lymphocytes. HTLV-II is endemic to a number of indigenous American Indian populations.

Transmission of both HTLV I and II occurs through sexual contact, exposure to blood, transfusion of infected cellular blood components and perinatally, probably by breast feeding.

## Aim

In this study, the performance of a new HTLV assay (Lumipulse® G HTLV-I/II, Fujirebio Europe N.V, Gent Belgium) was compared to that of LIAISON® XL murex rechTLV-I/II

II (DiaSorin, Saluggia, Italy) and ARCHITECT rHTLV- I/II assay (Abbott, Wiesbaden, Germany), used routinely in our laboratory.

## Methods

343 unselected serum samples submitted to the laboratory for HTLV testing were examined also by LIAISON® XL assay and Lumipulse® assay. Samples that were discordant were tested by INNO-LIA HTLV I/II Score (Fujirebio) for confirmation. Sensitivity was evaluated using 61 frozen HTLV positive specimens (56 HTLV-I and

5 HTLV-II positive samples, confirmed by Immunoblot INNO-LIA HTLV I/II Score) and a HTLV I/II Mixed Titer AccuSet Performance Panel (0820-0192) of SeraCare (21 samples).

## Results

Among 343 routine samples, 338, 339 and 340 samples were negative with ARCHITECT, LIAISON® and Lumipulse® respectively. Three, 4 and 5 samples were reactive with Lumipulse®, LIAISON® and ARCHITECT respectively.

Results from the Performance panel dilution series showed the greater sensitivity of Lumipulse® for detecting HTLV-I antibodies. In contrast the LIAISON® had a greater sensitivity for detecting HTLV-II. Architect was less sensitive (table 3).

The results are summarized in the following Table 1.

Lumipulse® G HTLV-I/II	Architect rHTLV- I/II		LIAISON® XL murex rechTLV-I/II	
	Positive	Negative	Positive	Negative
Positive	3	0	3	0
Negative	2	338	1	339

### Percent Agreement

Positive	60% (3/5)	98.9% (3/4)
Negative	100% (338/338)	100% (339/339)
Overall	99.4% (341/343)	99.7% (342/343)

- Lumipulse® had an overall agreement of 99.4% and 99.7% with ARCHITECT and LIAISON® respectively.
- Lumipulse® had 100% negative agreement with ARCHITECT and LIAISON®.

The 3 discrepancies samples (2 and 1 weakly reactive with ARCHITECT and LIAISON) were not confirmed by immunoblot (Table 2).

Table 2: Results of Immunoblot INNO-LIA.

Patient	A	B	C	INNO-LIA HTLV I/II Score						
	Cutoff = 1			gag p19 I/II	gap p24 I/II	env gp46 I/II	env gp21 I/II	gag p19 I	env gp46 I	env gp46 II
1	0.30	1.10	0.81	-	-	-	-	-	-	-
2	0.20	2.10	0.48	+	-	-	-	-	-	-
3	0.10	0.10	1.30	-	-	-	-	-	-	-

A: Lumipulse®; B: Architect; C: LIAISON® XL

Table 3: Dilution of Performance panel

HTLV Performance panel SeraCare (0820-0192)		Dilution	HTLV Fujirébio	Abbott Architect	LIAISON XL
Panel Member	Type of HTLV		Cutoff = 1.0		
01	I	1:250	1.3	1.0	1.5
02	I	1:1300	1.7	0.6	1.2
03	I	1:450	1.1	0.9	1.0
04	I	1:200	1.3	1.0	1.3
05	I	1:100	1.1	0.9	1.2
06	I	1:500	1.3	1.9	1.1
07	I	1:4000	1.0	0.6	0.9
08	I	1:30000	1.4	0.6	1.1
09	I	1:10000	1.0	0.6	1.0
10	I	1:20000	1.2	0.6	1.0
11	I	1:100	1.4	1.5	2.0
12	II	1:300	0.8	1.1	3.0
13	II	1:300	1.1	0.9	1.5
14	II	1:1500	1.2	1.3	2.0
15	II	1:2500	1.0	1.1	1.2
16	II	1:100	0.8	1.0	2.0
17	II	1:500	1.1	1.4	1.4
18	II	1:500	1.1	1.2	1.4
19	II	1:150	0.9	1.0	1.2
20	II	1:600	1.2	0.6	1.5
21	Negative		0.1	0.2	0.32

In addition, all 61 positive HTLV samples (56 HTLV-I and 5, HTLV-II) were detected by both assays.

## Conclusions

- The HTLV assay performance of ARCHITECT, LIAISON® and Lumipulse® were equivalent.
- Lumipulse® G HTLV-I/II assay, performed on Lumipulse® G 1200 instrument, demonstrated very good specificity and sensitivity.
- It was appropriate for the large-scale screening of samples for HTLV-1/2 antibodies.