Performance of the LIAISON® XL murex recHTLV-I/II assay

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SPECIALISED MEDICAL PATHOLOGY

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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 LIAISON® XL murex recHTLV-I/II assay (DiaSorin, Saluggia, Italy) was compared to that of ARCHITECT rHTLV- I/II (Abbott, Wiesbaden, Germany), used routinely in our laboratory.

Materials and Methods

Assay design

The LIAISON® XL MUREX recHTLV-I/II assay uses two steps chemiluminescence immunoassay (CLI A) technology for the qualitative determination of specific antibodies to Human T-cell Lymphotropic Virus (HTLV) type I and type II in human serum or plasma samples. This assay use a recombinant antigen (gp21) specific for transmembrane region of HTLV-I/II and two synthetic peptides (gp46) specific for outer envelope region of HTLV-I or HTLV-II (**Fig 1a and 1b**).

Fig. 1a

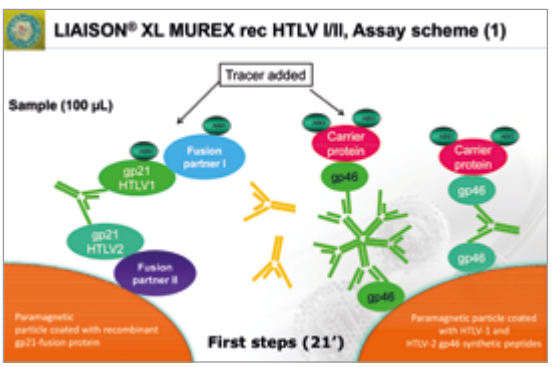
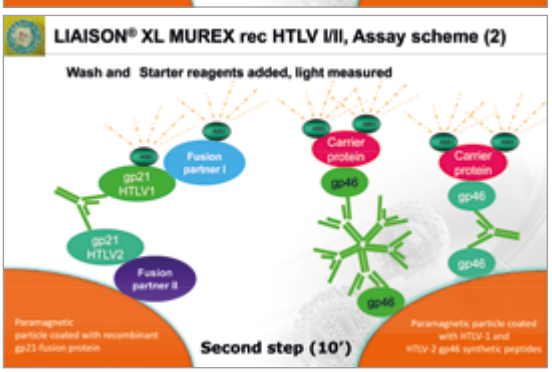


Fig. 1b



Specimens

During a 2 weeks period, all unselected serum samples (N=663) submitted to the laboratory for HTLV testing were examined by LIAISON® XL murex recHTLV-I/II assay. These samples were mainly provided from couples requesting inclusion in an assisted fertility program, donor's organs and patients from French Overseas Departments (Martinique, Guadeloupe and French Guyana).

Samples that were discordant were tested by INNO-LIA HTLV I/II Score (Fujirebio Europe N.V, Gent, Belgium), a line immunoassay using antigens derived from HTLV I and HTLV II immunodominant proteins, for confirmation.

Sensitivity was evaluated using 49 frozen HTLV-I positive serum specimens (confirmed by Immunoblot INNO-LIA HTLV I/II Score).

Results

Among 663 routine samples, 658 samples were negative with ARCHITECT and LIAISON® XL.
5 and 3 samples were reactive with ARCHITECT and LIAISON® XL respectively.
The results are summarized in the following table 1. >>>

Table 1

LIAISON® XL murex recHTLV-I/II	ARCHITECT rHTLV- I/II		
	Positive	Negative	Total
Positive	3	0	3
Negative	2	658	660
Total	5	658	663

LIAISON® XL murex recHTLV-I/II and ARCHITECT rHTLV had an overall agreement of 99.7% with 100% negative agreement.
The 2 discrepancies samples (weakly reactive with ARCHITECT) were not confirmed by immunoblot (**table 2**).

Table 2: Results of Immunoblot INNO-LIA. >>>

In addition, all 49 positive HTLV-I samples were detected by both assays.

Table 2

	ARCHITECT	LIAISON® XL	INNO-LIA HTLV I/II Score						
Patient	Cutoff = 1	Cutoff = 1	gag p19 I/II	gap p24 I/II	env gp46 I/II	env gp21I/II	gag p19 I	env gp46 I	env gp46 II
1	1.1	0.27	-	-	-	-	-	-	-
2	2.1	0.48	+	-	-	-	-	-	-

Conclusions

**The HTLV assay performance of LIAISON® (120 - 171 tests/h) and ARCHITECT (100 tests/h) were equivalent.
LIAISON® XL murex recHTLV-I/II assay demonstrated very good specificity and sensitivity. It was appropriate for the large-scale screening of samples for HTLV-1/2 antibodies.**