



NEW

recomLine HTLV-1 & HTLV-2 IgG

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG antibodies against human T-lymphotropic virus type 1 (HTLV-1) and type 2 (HTLV-2).

The human T-lymphotropic virus (HTLV) is a retrovirus, which can cause rare but severe diseases like adult T-cell leukemia (ATL) or HTLV-1 associated myelopathy/tropical spastic paraparesis (HAM/TSP) in humans. Several HTLV types are known of which HTLV-1 and HTLV-2 are the most prevalent ones. It is possible to discriminate between HTLV-1 and HTLV-2 with molecular and serological diagnostic methods.

HTLV prevalence greatly varies by region and is highest in endemic areas like Japan, South America, the Caribbean and certain parts of Africa. In Europe a relevant prevalence can be found in countries with historical ties to these regions, but also for example in Romania. The total number of HTLV-infected persons can only be roughly estimated, the numbers are incomplete and range up to a total of more than 20 million cases worldwide.

The virus depends on a direct cell-cell contact to establish an infection. Due to this, blood plasma is not considered as an infective agent. Vertical mother to child transmission, especially during breastfeeding, is one of the most common routes of infection. Moreover, transmission through unprotected sexual contact, drug use and contaminated blood products or transplants is also relevant.

Since there is no curative therapy for HTLV, diagnostics is key to contain the virus. Only by the means of fast and reliable diagnostics the risk of vertical transmission through infected mothers can be reduced and safety of blood products and transplants can be guaranteed. Usually HTLV diagnostic is performed in two steps: A positive or ambiguous result of a serological screening test is followed by a confirmatory assay, such as a line immunoassay.

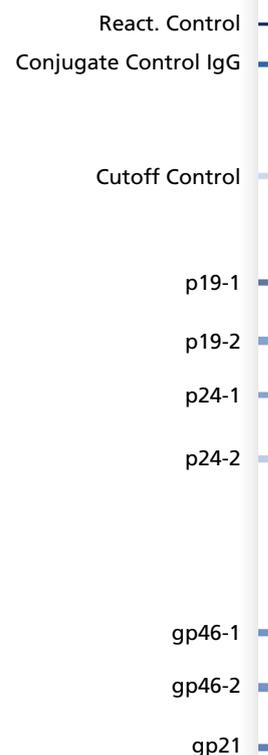
The *recomLine* HTLV-1 & HTLV-2 IgG is a qualitative test for the detection of IgG antibodies against HTLV-1 as well as HTLV-2 in human serum or plasma. The test is able to discriminate between virus type 1 and type 2 on one strip, therefore it is ideal for a simple and safe confirmation of screening results.

Product advantages

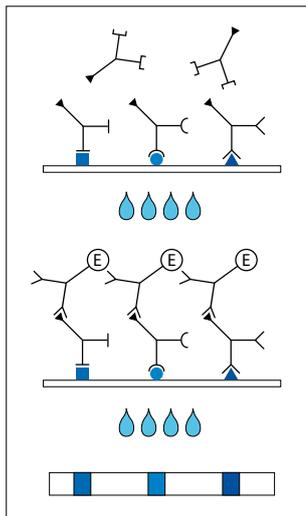
- **Recombinant antigens:** Clear results interpretation due to easily readable bands
- **Very precise typing** of HTLV-1 and HTLV-2 on one test strip
- **Safe:** 100% sensitivity and control bands on every strip
- **Easy test procedure:** Simple processing of the test and individualized automatization solutions
- **Simple and objective evaluation and documentation** by use of the *recomScan* evaluation software
- **CE-label:** The *recomLine* HTLV-1 & HTLV-2 IgG meets the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Recombinant HTLV antigens

Antigen	Genomic region	Function/localization
gp46-1 / gp46-2	ENV HTLV-1 / ENV HTLV-2	External glycoprotein, part of the HTLV envelope
gp21	ENV (Type unspecific)	Part of the HTLV envelope
p24-1 / p24-2	GAG HTLV-1 / GAG HTLV-2	Capsid protein
p19-1 / p19-2	GAG HTLV-1 / GAG HTLV-2	Matrix protein



Test principle and procedure



- 1st Incubation** A test strip loaded with HTLV-1/HTLV-2 antigens is incubated with diluted serum or plasma in a dish for **3 hours**.
- wash 3 times
- 2nd Incubation** Peroxidase conjugated anti-human antibodies (IgG specific) are added. Incubate for **45 minutes**.
- wash 3 times
- Color reaction** **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips adhered by antibodies.

Evaluation

Diagnostic sensitivity

<i>recomLine</i> HTLV-1 & HTLV-2 IgG	HTLV-1 (n = 206)	HTLV-2 (n = 110)
Negative	0	0
Borderline	2	7
Positive	204	103
Sensitivity	100 %*	100 %*

* Including borderline results

Differentiation between HTLV-1 and HTLV-2

<i>recomLine</i> HTLV-1 & HTLV-2 IgG	HTLV-1 (n = 204)	HTLV-2 (n = 103)
Positive for HTLV-1	204	0
Positive for HTLV-2	0	101
Differentiation not possible	0	2
Correct differentiation	100 %	98 %

Diagnostic specificity

<i>recomLine</i> HTLV-1 & HTLV-2 IgG	Blood donor (n = 200)	Clinical samples* (n = 239)	Potentially interfering samples** (n = 80)
Negative	193	235	79
Borderline	7	4	1
Positive	0	0	0
Specificity	96.5 %	98.3 %	98.8 %

* Including samples from patients with acute hepatitis, recent EBV infection, various autoimmune diseases, pregnant women and samples from the laboratory routine

** Including lipemic, hemolytic, icteric and RF-positive samples

Article no.

5272 *recomLine* HTLV-1 & HTLV-2 IgG
Reagents for 20 determinations

Storage

At +2°C to +8°C