

A VISUAL IMMUNOASSAY FOR HTLV- I/II SEROLOGIC DIAGNOSIS

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INTRODUCTION

Human T-cell lymphotropic virus types I and II (HTLV-I/II) have been detected worldwide (1). HTLV-I is associated with adult T-cell leukemia/lymphoma and neurological disorders (2). AuBIODOT™ is a Visual Immunoassay (VIA) system developed in our Center, that uses opaque-white polystyrene slide-like antigen-coated supports, recombinant Protein A-colloidal gold as immunoprobe, and signal amplification with silver ion developers. The system was specially developed for manual operation and visual reading of results, and has been successfully applied to HIV-1/2, HCV and *Toxoplasma gondii* serodiagnosis (3). HTLV-I viral transmembrane protein p21e has been used in ELISA and Western blot assays for HTLV-I/II with high sensitivity and specificity (4). Synthetic peptides (SP) from different proteins of HTLV-I have been also used for HTLV-I diagnosis, and peptides from p19 and gp46 have demonstrated good sensitivity and specificity (5). In this work we evaluated the use of recombinant p21e and a synthetic peptide with epitopes from p19 and gp46 proteins in the AuBIODOT™ format.

MATERIALS AND METHODS

Recombinant p21e (rp21) was obtained from genetically engineered *Escherichia coli*, and purified by reverse phase-HPLC. A SP containing immunodominant epitopes from the *core* and *env* regions of HTLV-I (p19 and p46) was obtained by the Tea Bags Method (6). Polystyrene slides and AuBIODOT™ reagents were the same as previously described (3). The slides were coated with rp21 and SP using 50 mM carbonate-bicarbonate buffer, pH 9.6, for 3 h at 37°C. Two well-characterized panels from Perú comprising 115 samples (47 positives and 68 negatives) and 336 samples (51 positives and 285 negatives), and one from the Cuban Retroviral Reference Laboratory (46 positives and 438 negatives) were

used in the evaluation of the system. In these panels, negative samples were from different sources, 120 African from Angola and Ethiopia, 18 lepers, 45 HIV seropositives, and 608 healthy blood donors (170 from Perú and 438 Cubans).

RESULTS AND DISCUSSION

Results of the evaluation of the VIA differs from one serum panel to the other. In the two panels from Perú, all the positives samples were detected, but five negative samples (3 Africans and 2 blood donors) from one of the panels gave positive signals. The resulting sensitivity and specificity for these two panels were 100% and 98.5%, respectively. With samples from the Cuban Retroviral Reference Laboratory, one of the 46 positive sera resulted negative, and 8 from 438 negative samples gave positive results, for a 97.82% sensitivity, and 98.17% specificity. Overall, our AuBIODOT™ anti HTLV-I/II system has a 99.3% sensitivity and 98.3% specificity. These results are better than those reported with commercially available ELISA system (7). The AuBIODOT™ anti HTLV-I/II system allows easy and accurate serodiagnosis of infection, due to the possibility of visual reading and low laboratory requirements, coupled to its high sensitivity and adequate specificity.

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