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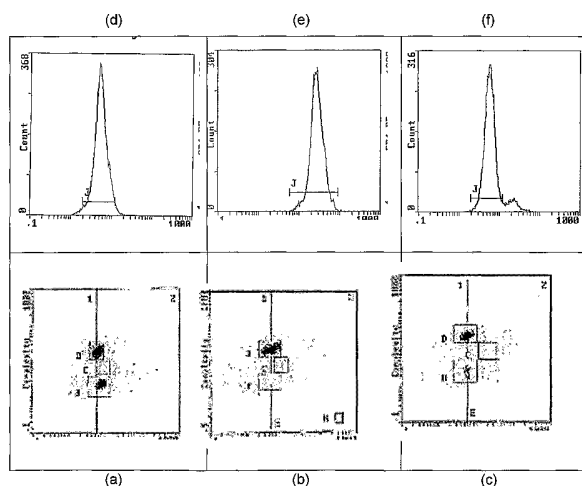
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(54) Title: A METHOD FOR DIAGNOSING AND MONITORING CELLULAR RESERVOIRS OF DISEASE



(57) Abstract: The invention provides an assay for diagnosing and/or monitoring a viral infection or disease in a patient, the assay including the steps of mixing a sample of leucocytes with a fluorescent cell membrane-permeable dye which stains RNA or both DNA and RNA within the leucocytes; identifying from all the leucocytes at least two of the three major sub-populations of leucocytes selected from the group consisting of monocytes, granulocytes and lymphocytes; determining the fluorescence intensity for each of the identified sub-populations; and comparing the fluorescence intensity of at least two cell sub-populations to each other to obtain at least one of the following ratios: granulocytes : monocytes, monocytes : lymphocytes, and granulocytes lymphocytes. The viral infection may be HIV and the disease may be AIDS. The invention also provides a method of monitoring the cellular viral, parasitic or bacterial reservoir of a patient with a viral or bacterial infection by the steps described above. A kit for performing the assay or method is also provided.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

International application No  
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**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. G01N33/50 G01N1/30 G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, EMBASE, BIOSIS, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/069421 A (IMMUNIVEST CORPORATION; DROOG, ERIK; TIBBE, ARJAN; GREVE, JAN; GOHEL,) 21 August 2003 (2003-08-21)	1-12,14, 15,18-47
Y	-----	16,17
Y	HERTOGHE T ET AL: "T cell activation, apoptosis and cytokine dysregulation in the.(co)pathogenesis of HIV and pulmonary tuberculosis (TB)." CLINICAL AND EXPERIMENTAL IMMUNOLOGY. DEC 2000, vol. 122, no. 3, December 2000 (2000-12), pages 350-357, XP002382850 ISSN: 0009-9104 table 1  -----  -/--	16,17

Further documents are listed in the continuation of Box C.

See patent family annex.

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| <p>* Special categories of cited documents :</p> <ul style="list-style-type: none"> <li>*A* document defining the general state of the art which is not considered to be of particular relevance</li> <li>*E* earlier document but published on or after the international filing date</li> <li>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>*O* document referring to an oral disclosure, use, exhibition or other means</li> <li>*P* document published prior to the international filing date but later than the priority date claimed</li> </ul> | <ul style="list-style-type: none"> <li>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>*G* document member of the same patent family</li> </ul> |
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  <b>Rosin, O</b>
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## INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	<p>MELAMED M R ET AL: "Blood granulocyte staining with acridine orange. Changes with infection."            THE JOURNAL OF HISTOCHEMISTRY AND CYTOCHEMISTRY : OFFICIAL JOURNAL OF THE HISTOCHEMISTRY SOCIETY. JUL 1974,            vol. 22, no. 7, July 1974 (1974-07), pages 526-530, XP008064724            ISSN: 0022-1554            figures 1-3</p>	<p>1,2,5-9,            14,15,            18,19,            26,            29-37,            41-47</p>
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Y	<p>PATTERSON BRUCE K ET AL: "Detection of HIV-RNA-positive monocytes in peripheral blood of HIV-positive patients by simultaneous flow cytometric analysis of intracellular HIV RNA and cellular immunophenotype"            CYTOMETRY,            vol. 31, no. 4, 1 April 1998 (1998-04-01), pages 265-274, XP008064777            ISSN: 0196-4763            abstract; figures 3-5; table 2</p>	<p>13</p>
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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