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(54) **Immunoassay device with immuno-reference electrode**

(57) An electrochemical immunosensor system with reduced interference, comprising: a first immunosensor that generates an electrochemical signal based on the formation of a sandwich between an immobilized antibody, a target analyte and a labeled antibody, wherein a portion of the signal arises from non-specific binding of the labeled antibody in the region of the first immunosensor, and a second immunosensor that acts as a immuno-

reference sensor and generates a signal that is the same as or predictably related to the degree of non-specific binding which occurs in the region of the first immunosensor, and has an immunocomplex between an immobilized antibody and an endogeneous or exogeneous protein that is in the sample and that is not the target analyte.

EP 2 551 671 A3



EUROPEAN SEARCH REPORT

Application Number
EP 12 17 9659

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 6 451 610 B1 (GORMAN ANNE JESSICA [US] ET AL) 17 September 2002 (2002-09-17)	1,2	INV. G01N33/543
Y	* column 8 - column 9; example 1 *	3-6	
X	US 6 322 963 B1 (BAUER ALAN JOSEPH [IL]) 27 November 2001 (2001-11-27)	1-4,6	
Y	* columns 13,14,20; figure 6; examples 8,10 *	5	
X	EP 0 213 343 A2 (NOVA BIOMEDICAL CORP [US]) 11 March 1987 (1987-03-11)	1,2	
Y	* paragraph [0034] - paragraph [0039] *	3-6	
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (IPC) G01N
Place of search		Date of completion of the search	Examiner
Munich		27 November 2012	Pinheiro Vieira, E
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EPO FORM 1503 03.02 (P04C01)



Application Number

EP 12 17 9659

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:
- 1-6
- ☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).



LACK OF UNITY OF INVENTION
SHEET B

Application Number

EP 12 17 9659

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-6

Immunoassay device for measuring an analyte in blood while reducing interference associated with leukocytes comprising adding a salt reagent to a whole-blood sample for an immunoassay device to increase the ionic strength of the sample and thereby reduce interference from the buffy coat when the sample contacts the immunosensor.

2. claims: 7-11

An immunosensor system for blood with reduced interference comprising a first immunosensor that generates a signal based on the formation of a sandwich between an immobilized antibody, a target analyte and a labeled antibody, wherein a portion of the signal arises from non-specific binding of the labeled antibody in the region of the first immunosensor, and a second immunosensor that acts as an immuno-reference sensor and generates a signal that is the same as or predictably related to the degree of non-specific binding which occurs in the region of the first immunosensor, and has an immunocomplex between an immobilized antibody and an endogenous or exogenous protein that is in the sample and that is not the target analyte, and method using the same.

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 12 17 9659

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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27-11-2012

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专利名称(译)	免疫分析装置，带免疫参比电极		
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发明人	MILLER, CARY JAMES CAMPBELL, JOHN LEWIS EMERSON		
IPC分类号	G01N33/543 G01N G01N27/00 G01N33/53 G01N33/537		
CPC分类号	G01N33/5438 Y10S436/807		
优先权	PCT/US2004/029498 2004-09-09 WO 10/658529 2003-09-10 US		
其他公开文献	EP2551671B1 EP2551671A2		
外部链接	Espacenet		

摘要(译)

一种干扰减少的电化学免疫传感器系统，包括：第一免疫传感器，其基于在固定化抗体，靶分析物和标记抗体之间形成夹心而产生电化学信号，其中一部分信号源自非特异性结合。第一免疫传感器区域中的标记抗体和第二免疫传感器，其充当免疫参考传感器并产生与在该区域中发生的非特异性结合程度相同或可预测地相关的信号。第一个免疫传感器，并且在固定的抗体和样品中的内源或外源蛋白质之间具有免疫复合物，该蛋白质不是靶分析物。

EUROPEAN SEARCH REPORT		Application Number EP 12 17 9659																
<p>DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category</th> <th>Citation of document with indication, where appropriate, of relevant passages</th> <th>Relevant to claim</th> <th>CLASSIFICATION OF THE APPLICATION (IPC)</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 6 451 610 B1 (GORMAN ANNE JESSICA [US] ET AL) 17 September 2002 (2002-09-17) * column 8 - column 9; example 1 *</td> <td>1,2 3-6</td> <td>INV. G01N33/543</td> </tr> <tr> <td>X</td> <td>US 6 322 963 B1 (BAUER ALAN JOSEPH [IL]) 27 November 2001 (2001-11-27) * columns 13,14,20; figure 6; examples 8,10 *</td> <td>1-4,6 5</td> <td></td> </tr> <tr> <td>X</td> <td>EP 0 213 343 A2 (NOVA BIOMEDICAL CORP [US]) 11 March 1987 (1987-03-11) * paragraph [0034] - paragraph [0039] *</td> <td>1,2 3-6</td> <td></td> </tr> </tbody> </table>			Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)	X	US 6 451 610 B1 (GORMAN ANNE JESSICA [US] ET AL) 17 September 2002 (2002-09-17) * column 8 - column 9; example 1 *	1,2 3-6	INV. G01N33/543	X	US 6 322 963 B1 (BAUER ALAN JOSEPH [IL]) 27 November 2001 (2001-11-27) * columns 13,14,20; figure 6; examples 8,10 *	1-4,6 5		X	EP 0 213 343 A2 (NOVA BIOMEDICAL CORP [US]) 11 March 1987 (1987-03-11) * paragraph [0034] - paragraph [0039] *	1,2 3-6	
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<p>TECHNICAL FIELD (IPC)</p> <p>G01N</p>																		
<p>1. The present search report has been drawn up for all reasons.</p> <p>Place of search: Munich Date of completion of the search: 27 November 2012 Searcher: Pinheiro Vieira, E</p> <p>CATEGORY OF CITED DOCUMENTS</p> <p>X: particularly relevant if (other) alone Y: particularly relevant if considered with another O: document of the same category A: non-relevant document I: intermediate document</p> <p>Z: theory or principle underlying the invention C: earlier related document, but published on, or after, the filing date D: document cited for its application E: document cited for other reasons A: member of the same patent family, corresponding document</p>																		