

(19)



(11)

EP 3 546 939 A3

(12)

EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
06.11.2019 Bulletin 2019/45

(51) Int Cl.:
G01N 33/53 (2006.01)

(43) Date of publication A2:
02.10.2019 Bulletin 2019/40

(21) Application number: **19175712.9**

(22) Date of filing: **21.12.2010**

(84) Designated Contracting States:
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB
GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO
PL PT RO RS SE SI SK SM TR**

(30) Priority: **23.12.2009 US 28988009 P**

(62) Document number(s) of the earlier application(s) in
accordance with Art. 76 EPC:
10838413.2 / 2 517 012

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(54) **AN ASSAY FOR MEASURING CELL-MEDIATED IMMUNORESPONSIVENESS**

(57) The present invention relates generally to the field of immunological-based diagnostic assays. More particularly, the present invention contemplates a method for measuring cell-mediated immunoresponsiveness. The present invention further enables determination of the immunosuppressive effects of disease conditions,

therapeutic agents and environmental contaminants. The assay of the present invention is also capable of integration into pathology architecture to provide a diagnostic reporting system and to facilitate point of care clinical management.

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EUROPEAN SEARCH REPORT

Application Number
EP 19 17 5712

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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	CARON GERSENDE ET AL: "Direct stimulation of human T cells via TLR5 and TLR7/8: Flagellin and R-848 up-regulate proliferation and IFN-gamma production by memory CD4(+) T cells", JOURNAL OF IMMUNOLOGY, vol. 175, no. 3, August 2005 (2005-08), pages 1551-1557, XP002712773, ISSN: 0022-1767 * the whole document *	1,5-7,9, 15,16	INV. G01N33/53
A	MEINHARD SCHILLER ET AL: "Immune response modifiers ? mode of action", EXPERIMENTAL DERMATOLOGY, vol. 15, no. 5, 1 May 2006 (2006-05-01), pages 331-341, XP055078748, ISSN: 0906-6705, DOI: 10.1111/j.0906-6705.2006.00414.x * the whole document *	1,4-16	
			TECHNICAL FIELDS SEARCHED (IPC)
			G01N
The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 13 June 2019	Examiner Lanzrein, Markus
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	

EPO FORM 1503 03/02 (P04C01)



Application Number

EP 19 17 5712

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, 13-16(completely); 4-12(partially)

☐ 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

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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, 13-16(completely); 4-12(partially)

A method for measuring cell-mediated immune response activity in a subject, said method comprising contacting a sample source of lymphocytes from the subject with one or more agents which potentiate the adaptive and innate immune systems and measuring the presence or elevation in the level of an immune effector molecule from immune cells wherein the presence or level of the immune effector molecule is indicative of the level of cell-mediated responsiveness of the subject.

2. claims: 2(completely); 4-12(partially)

A method for determining whether an agent induces immunosuppression in a subject, the method comprising contacting a sample source of lymphocytes from the subject after exposure to the agent with one or more potentiators which stimulate adaptive and innate immunity and measuring the presence and level of an effector molecule from the lymphocytes wherein the level of the effector molecule determines the level of immunosuppression induced by the agent.

3. claims: 3(completely); 4-12(partially)

A method for detecting whether a disease condition is inducing immunosuppression in a subject the method comprising contacting a sample source of lymphocytes from the subject with a disease condition with one or more agents which potentiate adaptive and innate immunity and measuring the presence or level of an immune effector molecule from the lymphocytes wherein the level of the immune effector molecule is indicative of the extent of immunosuppression induced or associated with the disease condition.

4. claim: 17

A method of allowing a user to determine the status of cell-mediated immunoresponsiveness of a subject, the method including:

(a) receiving data in the form of levels or concentrations of an immune effector molecule which relative to a control provide a correlation to the state of cell-mediated immunoresponsiveness from the user via a communications network, the immune effector molecule measured after exposure of lymphocytes to one or more agents which potentiate adaptive and innate immune responses;

**LACK OF UNITY OF INVENTION
SHEET B**

Application Number

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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:

- (b) processing the subject data via univariate or multivariate analysis to provide an immunoresponsiveness value;
- (c) determining the status of the subject in accordance with the results of the immunoresponsiveness value in comparison with predetermined values; and
- (d) transferring an indication of the status of the subject to the user via the communications network.

专利名称(译)	测试细胞介导的免疫功能		
公开(公告)号	EP3546939A3	公开(公告)日	2019-11-06
申请号	EP2019175712	申请日	2010-12-21
[标]申请(专利权)人(译)	塞尔雷斯蒂斯有限公司		
申请(专利权)人(译)	CELLESTIS有限公司		
当前申请(专利权)人(译)	CELLESTIS有限公司		
[标]发明人	BOYLE JEFF DE LAS HERAS RACHEL		
发明人	BOYLE, JEFF DE LAS HERAS, RACHEL		
IPC分类号	G01N33/53		
CPC分类号	A61P37/02 G01N33/5047 G01N33/56972 Y02A90/22 Y02A90/24 Y02A90/26 G01N33/53		
代理机构(译)	Bohmann , ARMIN K.		
优先权	61/289880 2009-12-23 US PCT/AU2010/001717 2010-12-21 WO		
其他公开文献	EP3546939A2		
外部链接	Espacenet		

摘要(译)

本发明总体上涉及基于免疫学的诊断测定法领域。更特别地，本发明涉及一种用于测量细胞介导的免疫应答性的方法。本发明还使得能够确定疾病状况，治疗剂和环境污染物的免疫抑制作用。本发明的测定法还能够整合到病理学体系中以提供诊断报告系统并促进护理点临床管理。

		EUROPEAN SEARCH REPORT		Application Number EP 19 17 5712
DOCUMENTS CONSIDERED TO BE RELEVANT				
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claims	CLASSIFICATION OF THE DISCUSSION (IPC)	
X	CARON GERSENDE ET AL.: "Direct stimulation of human T cells via TLR5 and TLR7/8: Flagellin and R-848 up-regulate proliferation and IFN-gamma production by memory CD4(+) T cells". JOURNAL OF IMMUNOLOGY, vol. 175, no. 3, August 2005 (2005-08), pages 1551-1557, XP002712773, ISSN: 0022-1767 * the whole document *	1,5-7,9,15,16	INV. G01N33/53	
A	MEINHARD SCHILLER ET AL.: "Immune response modifiers: 7 mode of action". EXPERIMENTAL DERMATOLOGY, vol. 15, no. 5, 1 May 2006 (2006-05-01), pages 331-341, XP055675748, ISSN: 0950-6705, DOI: 10.1111/j.0950-6705.2006.00414.x * the whole document *	1,4-16	TECHNICAL FIELDS SEARCHED (IPC) G01N	
-The present search report has been drawn up for all claims				
1	Place of search Munich	Date of completion of the search 13 June 2019	Examiner Lanzrein, Markus	
CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if considered with another document of the same category Z: document cited for other reasons F: intermediate document				
2: theory or principle underlying the invention C: prior art document, but published on, or D: prior art document, but not published on, or E: document cited for other reasons F: member of the same patent family, corresponding document				