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(54) **Agglutination assay**

(57) The invention relates to agglutination assays and related kits, reagents and devices. In particular methods of assaying small analytes having few epitopes are disclosed, by means of using hub moieties to which multiple analytes may be bound by a first epitope, together with a further moiety capable of binding a second analyte

epitope and which is also capable of binding to a detectable particle. Stable agglutinated complexes may be so formed, which may be used as the basis for various assay formats.

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EUROPEAN SEARCH REPORT

Application Number
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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	WO 2004/083859 A1 (PLATFORM DIAGNOSTICS LTD [GB]; BOND DAMIAN JOSEPH PETER [GB]; MINTER S) 30 September 2004 (2004-09-30)	1,3,4, 6-9, 11-15, 17,18, 22-26	INV. G01N33/58 G01N33/543 G01N33/548 G01N33/558
Y	* the whole document, particularly p. 5, p. 8, 3rd para., p. 10, p. 15 last para. - p. 18, fig. 1 - 3 * -----	2,10,19, 20	G01N33/53
X	US 6 274 325 B1 (DEGER ARNO [DE] ET AL) 14 August 2001 (2001-08-14)	3,4,6-9, 11	
Y	* col. 2, lines 32 - 52, col. 3, line 8 - col. 4, line 57, Examples * -----	2,10,19, 20	
X	WO 02/40698 A2 (SURROMED INC [US]) 23 May 2002 (2002-05-23)	1-11,19, 20	
A	* p. 7, line 7 - p. 8, line 20, p. 18, lines 19 - 33, fig. 1 - 4 * -----	12-15, 22-26, 1718	
X	EP 0 293 779 A1 (DAIICHI PURE CHEMICALS CO LTD [JP]) 7 December 1988 (1988-12-07)	1-4, 6-15, 17-20, 22-26	TECHNICAL FIELDS SEARCHED (IPC) G01N
	* Example 1, claims 1, 2 * -----		
X	WO 94/15193 A (SIENNA BIOTECH INC [US]) 7 July 1994 (1994-07-07)	1-4, 6-15,19, 20	
	* p. 8, lines 10 - 26, p. 11, lines 12 - 25, p. 15, line 15 - p. 17, line 2, examples 1, 4 * -----		
X	GB 2 045 431 A (TECHNICON INSTR) 29 October 1980 (1980-10-29)	1-4,6-11	
	* p. 1, col. 1, lines 30 - 60, examples 1, 2 * ----- -/--		
-The present search report has been drawn up for all claims-			
Place of search Munich		Date of completion of the search 29 January 2014	Examiner Hoesel, Heidi
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)



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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:
1-14, 17-20(completely); 22-26(partially)
- 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:
- 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, 3-9, 11-15, 17, 18, 22-26(all partially)

agglutination assays/kits requiring (i) a multivalent reagent capable of binding to a first epitope of the analyte (reagent A) and (ii) a second moiety which comprises a second ligand for the analyte and is bound to a detectable particle (reagent B)

2. claims: 2, 10, 19, 20(completely); 1, 3-9, 11-15, 17, 18, 22-26(partially)

agglutination assays/kits requiring (i) a multivalent reagent capable of binding to a first epitope of the analyte (reagent A) and (ii) a second moiety which comprises a second ligand for the analyte and which is capable of binding to a particle (reagent B)

3. claims: 5(completely); 1-4, 6-15, 17-20, 22-26(partially)

agglutination assays/kits requiring reagents A and B as defined in claim 1, wherein the hub is soluble

4. claims: 1-4, 6-15, 17-20, 22-26(all partially)

agglutination assays/kits requiring reagents A and B as defined in claim 1, wherein the hub is insoluble, e.g. a red blood cell, latex bead, gold sol or an insoluble macromolecule

5. claims: 12-14, 17, 18, 22-26

agglutination assays/kits requiring reagents A and B as defined in claim 1, further comprising a porous carrier e.g. a capillary device

6. claims: 15(completely); 1-14(partially)

agglutination assays products requiring reagents A) and B as defined in claim 1, further comprising one or more of detection means, signal processing means, display means and a power source

7. claim: 16

a device suitable for an agglutination assay requiring a



**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:

porous carrier and reagent A in reconstitutable form as the sole reagent; particles either as hub or as part of reagent B are not required

8. claim: 21

an agglutination assay using reagent A and B as defined in claim 1, and a second moiety capable of binding to a detectable and agglutinable particle, wherein the detectable and agglutinable particle is part of the sample material, and replaces an extraneous particle-based reagent

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

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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
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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