



- (51) **International Patent Classification:**  
*G01N 33/48* (2006.01)
- (21) **International Application Number:**  
PCT/US2012/022926
- (22) **International Filing Date:**  
27 January 2012 (27.01.2012)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**  
61/437,618 29 January 2011 (29.01.2011) US  
61/437,613 29 January 2011 (29.01.2011) US  
61/437,621 29 January 2011 (29.01.2011) US
- (71) **Applicant (for all designated States except US):** **ASTUTE MEDICAL, INC.** [US/US]; 3550 General Atomics Court, San Diego, CA 92121 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** **ANDERBERG, Joseph** [US/US]; 470 Delage Court, Encinitas, CA 92024 (US). **GRAY, Jeff** [US/US]; 417 Bay Meadows Way, Solana Beach, CA 92075 (US). **MCPHERSON, Paul** [US/US]; 1449 Elva Court, Encinitas, CA 92024 (US). **NAKAMURA, Kevin** [US/US]; 2409 Newcastle Ave, Cardiff By The Sea, CA 92007 (US). **KAMPF, James, Patrick** [US/US]; 5882 Gablewood Way, San Diego, CA 92130 (US).
- (74) **Agents:** **WHITTAKER, Michael, A.** et al.; Acuity Law Group, P.C., 12707 High Bluff Drive, Suite 200, San Diego, CA 92130 (US).
- (81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**  
— with international search report (Art. 21(3))
- (88) **Date of publication of the international search report:**  
10 April 2014



WO 2012/103450 A3

(54) **Title:** METHODS AND COMPOSITIONS FOR DIAGNOSIS AND PROGNOSIS OF RENAL INJURY AND RENAL FAILURE

(57) **Abstract:** The present invention relates to methods and compositions for monitoring, diagnosis, prognosis, and determination of treatment regimens in subjects suffering from or suspected of having a renal injury. In particular, the invention relates to using a one or more assays configured to detect a kidney injury marker selected from the group consisting of Angiopoietin-related protein 3, Soluble Lymphatic vessel endothelial hyaluronin acid receptor 1, and Vascular endothelial growth factor D as diagnostic and prognostic biomarkers in renal injuries.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/022926

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - G01N 33/48 (2012.01) USPC - 436/86 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8) - G01N 33/48, 33/50, 33/53; A61K 39/395, 48/00; C07K 16/28 (2012.01) USPC - 436/63, 71, 86, 536 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 practicable, search terms used) PatBase, Orbit.com, PubMed		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2010/091236 A1 (ANDERBERG) 12 August 2010 (12.08.2010) entire document	1-5, 7-9, 101-108
Y	Shoji et al. Plasma angiotensin-like protein 3 (ANGPTL3) concentration is associated with uremic dyslipidemia. Atherosclerosis. 207:579-584. 2009. [retrieved on 2012-04-19]. Retrieved from PubMed: <URL:http://www.sciencedirect.com/science/article/pii/S002191500900416X> entire document	1-5, 7-9, 101-108
Y	Han et al. Upregulation of hyaluronan and its binding receptors in an experimental model of chronic cyclosporine nephropathy. Nephrology. 15:216-224. 2010. [retrieved on 2012-04-19]. Retrieved from PubMed: <URL: http://onlinelibrary.wiley.com/doi/10.1111/j.1440-1797.2009.01167.x/abstract;jsessionid=9AD931A20F4EA7C42650E77BD4368FBE.d04t03> entire document	5
A	WO 2010/111746 A1 (SIMMONDS) 07 October 2010 (07.10.2010) entire document	1-5, 7-9, 101-108
A	US 2005/0256075 A1 (ALITALO et al) 17 November 2005 (17.11.2005) entire document	1-5, 7-9, 101-108
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "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) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "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 "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 "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 "&" document member of the same patent family		
Date of the actual completion of the international search 19 April 2012		Date of mailing of the international search report <b>02 MAY 2012</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.: 6, 10-100  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.