(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 May 2005 (26.05.2005)

PCT

(10) International Publication Number
WO 2005/047858 A2

(51) International Patent Classification[7]: G01N

(21) International Application Number:
PCT/US2004/037097

(22) International Filing Date:
8 November 2004 (08.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/518,003 7 November 2003 (07.11.2003) US

(71) Applicant *(for all designated States except US)*: **CAMBREX BIO SCIENCE WALKERSVILLE, INC.** [US/US]; 8830 Biggs Ford Road, Walkersville, MD 21793 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BONEN, Matthew, Richard** [US/US]; 6406 Lakeridge Drive, New Market, MD 21774 (US). **BERZOFSKY, Ronald, Norman** [US/US]; 133 E. Timonium Road, Timonium, MD 21093 (US). **RICHARDSON, Bruce, J.** [US/US]; c/o Lathrop Engineering, 1101 S. Winchester Boulevard B-110, San Jose, CA 95128 (US). **LATHROP, Robert, L., III** [US/US]; c/o Lathrop Engineering, 1101 S. Winchester Boulevard B-110, San Jose, CA 95128 (US). **DEN DULK, Bruce, Rodney** [US/US]; c/o Lathrop Engineering, 1101 S. Winchester Boulevard B-110, San Jose, CA 95128 (US).

(74) Agent: **HANLON, Brian, E.**; Banner & Witcoff, Ltd., 1001 G Street, N.W., 11th Floor, Washington, D.C. 20001-4597 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

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.

WO 2005/047858 A2

(54) Title: ON-LINE APPARATUS AND METHOD FOR DETERMINING ENDOTOXIN LEVELS

(57) Abstract: An apparatus and method for on-line testing for the presence of an endotoxin within a fluid sample from a fluid line. The apparatus is positioned in fluid communication with a fluid line to perform the on-line fluid testing for the presence of at least one endotoxin. The apparatus can include a housing and a fluid sampling system positioned in fluid communication with the fluid line. The fluid sampling system can comprise a valve for controlling the fluid flow from the fluid line into the fluid sampling system. A fluid flow well is positioned within the housing and in fluid communication with the fluid sampling system. A removable assembly can also be secured within the housing. The removable assembly comprises a plurality of wells for receiving used and unused fluid carrying members that can receive samples from the fluid flow well, a plurality of fluid sample receiving wells, and a plurality of vessel retention positions comprising recesses for securely receiving portions of respective fluid vessels. A detecting system is provided for testing a control sample and a sample of the fluid from the fluid line. The results of these tests are compared in order to determine if the fluid sample is carrying any endotoxins. In an embodiment, fluorescence testing of the sample is compared to that of the control in order to determine if the sample includes an endotoxin.