



- (51) **International Patent Classification:**
G01N 37/00 (2006.01)
- (21) **International Application Number:**
PCT/US2012/030709
- (22) **International Filing Date:**
27 March 2012 (27.03.2012)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
13/074,649 29 March 2011 (29.03.2011) US
- (71) **Applicant (for all designated States except US):** **BIO-RAD LABORATORIES, INC.** [US/US]; 1000 Alfred Nobel Drive, Hercules, California 94547 (US).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** **KUCHIPUDI, Lakshmi** [IN/US]; 1000 Alfred Nobel Dr., Hercules, California 94547 (US). **PARVIN, Curtis** [US/US]; 1000 Alfred Nobel Dr., Hercules, CA 94547 (US). **YUNDT-PACHECO, John** [US/US]; 1000 Alfred Nobel Dr., Hercules, California 94547 (US).
- (74) **Agents:** **BOYD, David** et al.; Eighth Floor, Two Embarcadero Center, San Francisco, California 94111 (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).

[Continued on next page]

(54) **Title:** SYSTEM AND METHOD FOR PRODUCING STATISTICALLY VALID ASSAY MEANS AND RANGES FOR QUALITY CONTROL MATERIALS

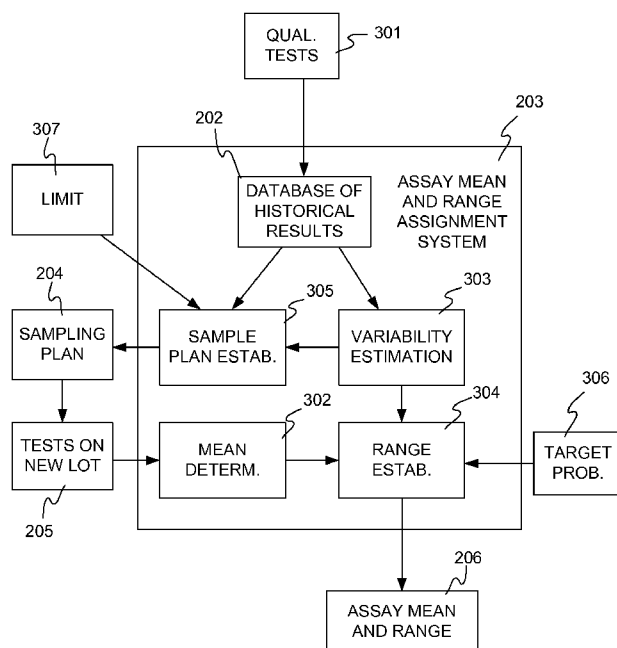


FIG. 3

(57) **Abstract:** A method of establishing statistically valid assay means and ranges for quality control materials, used to qualify medical testing machines, utilizes tests on a new lot of quality control material to establish an assay mean, and uses data from a database of historical test results to establish an assay range. The system may estimate the variability of test results from prior lot data, and then compute the limits of the assay range such that a new test on a new lot of the quality control material will be expected to fall within the range with a specified probability. Because historical data is used to estimate the test variability, the number of new tests required to specify a statistically valid mean and range may be dramatically reduced, as compared with establishing the mean and range based only on tests of the new lot of material.

**Declarations under Rule 4.17:**

- *as to the identity of the inventor (Rule 4.17(i))*
- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:

24 April 2014

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/30709

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01N 37/00 (2012.01)

USPC - 702/81

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC (8) - G01N 37/00 (2012.01)

USPC - 702/81

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 702/81,85,182-185,188 (See Keywords Below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST (PGPB,USPT,USOC,EPAB,JPAB), Google Scholar

Search Terms: Quality, control, sample, test, previous, history, past, statistical, variability, variance, deviation, target, achieve, designate, probability, possibility, range, limit, threshold, within, instrument, lab, internal, between, external, global, sampling plan, average....

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004/0220761 A1 (YUNDT-PACHECO), 04 November 2004 (04.11.2004), entire document, especially Abstract; para [0028]-[0031], [0037]-[0040], 0056]-[0060], [0061]-[0065]	1-21
Y	US 6,278,401 B1 (WIGREN), 21 August 2001 (21.08.2001), entire document, Abstract; col 3, ln 30 to col 4, ln 40; col 5, ln 10-56	1-13 and 15-21
Y	US 6,821,792 B1 (SONDERMAN et al.), 23 November 2004 (23.11.2004), entire document, especially Abstract; col 4, ln 16 to col 5, ln 12; col 5, ln 50 to col 6, ln 17	5, 14, 18-19

☐ Further documents are listed in the continuation of Box C.



* 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

12 June 2012 (12.06.2012)

Date of mailing of the international search report

20 JUN 2012

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:

Lee W. Young

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774