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(54) Title: CALIBRATOR QUALITY CONTROL CELL DEVICE FOR IMMUNOHISTOCHEMISTRY ASSAY AND METHODS OF USE THEREOF

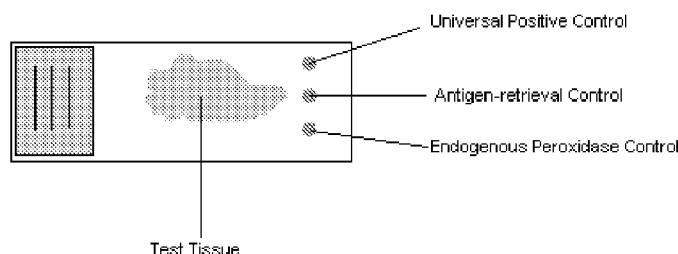


FIG. 4

(57) Abstract: This disclosure relates to immunohistochemistry, and specifically to a quality control device for an immunohistochemistry assay and methods of use thereof. More specifically, disclosed herein is a calibrator cell pellet and methods of use as a control in an immunohistochemistry assay. The calibrator cell pellets are used, in some embodiments, as standards for quantifying the intensity of immunohistochemical staining, for instance for normalizing immunohistochemical staining to a calibrated standard, thereby allowing more accurate quantitation of staining intensity.



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A. CLASSIFICATION OF SUBJECT MATTER**G01N 33/53(2006.01)i, G01N 33/48(2006.01)i, G01N 33/58(2006.01)i, G01N 33/537(2006.01)i**

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 G01 33/53, C12Q 1/68

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

Korean Utility models and applications for Utility models since 1975

Japanese Utility models and applications for Utility models since 1975

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

eKOMPASS(KIPO internal) & keyword: quality control cell, immunohistochemistry assay, universal positive control cell pellet and digital image analysis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/62064 A2 (CYTOLOGIX CORPORATION) 19 OCTOBER 2000 See the whole documents.	1-18
A	US 2007-0141723 A1 (SESHI A. SOMPURAM et al.) 21 JUNE 2007 See the whole documents.	1-18
A	WO 91/05263 A1 (CITY OF HOPE) 18 APRIL 1991 See the whole documents.	1-18
A	US 5,846,749 A (DENNIS J. SLAMON et al.) 8 DECEMBER 1998 See the whole documents.	1-18
A	US 2005-0003458 A1 (MATHEW MOORE et al.) 6 JANUARY 2005 See the whole documents.	1-18
A	KR 10-0650162 B1 (CHEOL MIN KIM et al.) 20 NOVEMBER 2006 See the whole documents.	1-18



Further documents are listed in the continuation of Box C.



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INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/US2008/085841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2000-062064 A2	19.10.2000	AU 2000-43545 A1	14.04.2000
		EP 1169643 A2	09.01.2002
		US 2006-0127956 A1	15.06.2006
		US 2003-166261 A1	04.09.2003
		US 06281004 B1	28.08.2001
		US 07011940 B1	14.03.2006
		US 06855490 B2	15.02.2005
		WO 2000-062064 A3	19.10.2000
US 2007-0141723 A1	21.06.2007	None	
WO 1991-005263 A1	18.04.1991	CA 2091678 C	22.04.2003
		EP 0445277 A4	16.10.1991
		EP 0445277 A1	11.09.1991
		EP 0550553 A1	14.07.1993
		EP 0953648 A3	12.09.2007
		EP 0953648 A2	03.11.1999
		EP 0445277 B1	31.07.1996
		EP 0550553 B1	12.07.2000
		GB 2263480 A	28.07.1993
		JP 03-895366 B2	22.12.2006
		JP 08-507784 A	20.08.1996
		KR 10-0372934 B1	07.02.2003
		US 5837261 A	17.11.1998
		US 5665362 A	09.09.1997
		US 05610022 A1	11.03.1997
		US 05837261 A1	17.11.1998
		US 06541009 B1	01.04.2003
		US 5610022 A	11.03.1997
		US 05665362 A1	09.09.1997
		WO 1994-021807 A3	29.09.1994
		WO 1992-005263 A1	02.04.1992
US 5846749 A	08.12.1998	None	
US 2005-0003458 A1	06.01.2005	AU 2002-14137 A1	08.11.2001
		AU 2002-339101 A1	10.06.2003
		AU 2000-18766 B2	22.12.1999
		AU 2000-18768 A1	22.12.1999
		AU 2000-18768 B2	22.12.1999
		AU 2000-18679 A1	21.12.1999
		AU 2000-18679 B2	21.12.1999
		AU 2000-18687 A1	22.12.1999
		AU 2000-18687 B2	22.12.1999
		AU 2000-18688 A1	22.12.1999
		AU 2000-18688 B2	22.12.1999
		AU 2000-18689 A1	22.12.1999
		AU 2000-18689 B2	22.12.1999

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/085841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		AU 2002-212537 B2	08.11.2001
		AU 2002-214137 B2	08.11.2001
		AU 2002-339101 A1	05.11.2002
		AU 2001-10442 A1	27.10.2000
		AU 2001-10442 B2	27.10.2000
		AU 2003-255716 A1	11.07.2003
		AU 772586 B2	29.04.2004
		AU 766437 B2	16.10.2003
		AU 772327 B2	22.04.2004
		AU 772473 B2	29.04.2004
		AU 765292 B2	11.09.2003
		AU 766855 B2	23.10.2003
		AU 2002-212537 B2	05.04.2007
		AU 2002-214137 B2	04.01.2007
		AU 2000-18766 A1	22.12.1999
		CA 2459053 A1	26.08.2004
		CA 2564290 C	29.01.2008
		CA 2509317 A1	08.12.2005
		CA 2557965 A1	29.06.2000
		CA 2557965 C	19.08.2008
		CA 2565202 A1	29.06.2000
		CA 2393744 A1	28.06.2001
		CA 2393744 C	27.05.2008
		CA 2428479 A1	16.05.2002
		CA 2428479 C	04.07.2006
		CA 2445033 A1	17.10.2002
		CA 2452857 A1	05.06.2003
		CA 2461851 A1	25.09.2004
		CA 2461851 C	27.11.2007
		CA 2461855 A1	25.09.2004
		CA 2461855 C	20.05.2008
		CA 2462031 A1	25.09.2004
		CA 2462031 C	27.11.2007
		CA 2460829 A1	22.01.2004
		CA 2460829 C	09.09.2008
		CA 2511628 A1	27.01.2006
		CA 2519325 A1	30.03.2006
		CA 2560501 A1	29.06.2000
		CA 2560501 C	25.03.2008
		CA 2473216 A1	09.01.2005
		CA 2473216 C	20.11.2007
		CA 2497854 C	15.08.2006
		CA 2497854 A1	29.06.2000
		CA 2537867 A1	16.05.2002
		CA 2537867 C	20.03.2007
		CA 2356130 A1	29.06.2000
		CA 2356131 A1	29.06.2000
		CA 2356131 C	29.01.2008
		CA 2356144 A1	29.06.2000
		CA 2356144 C	12.12.2006

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/085841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		CA 2356148 A1	29.06.2000
		CA 2356148 C	04.10.2005
		CA 2356194 A1	29.06.2000
		CA 2356194 C	27.02.2007
		CA 2441814 A1	26.09.2002
		CA 2564290 A1	29.06.2000
		CA 2459053 C	10.07.2007
		EP 1151180 A1	07.11.2001
		EP 1510651 A2	02.03.2005
		EP 1144802 B1	08.12.2004
		EP 1144802 A2	17.10.2001
		EP 1505251 A2	09.02.2005
		EP 1582274 A2	05.10.2005
		EP 1242714 A1	25.09.2002
		EP 1413709 A2	28.04.2004
		EP 1147287 A2	24.10.2001
		EP 1147287 B1	17.08.2005
		EP 1333963 A2	13.08.2003
		EP 1333963 B1	10.01.2007
		EP 1141515 A1	10.10.2001
		EP 1141517 B1	08.12.2004
		EP 1141517 A1	10.10.2001
		EP 1141518 B1	26.10.2005
		EP 1141518 A1	10.10.2001
		EP 1659259 A1	24.05.2006
		EP 1510651 B1	02.07.2008
		GB 2382832 A	11.06.2003
		GB 2383065 A	18.06.2003
		GB 2383361 A	25.06.2003
		GB 2415001 A	14.12.2005
		GB 2415453 A	28.12.2005
		GB 2416551 A	01.02.2006
		GB 2403749 A	12.01.2005
		GB 2346400 A	09.08.2000
		GB 2345308 A	05.07.2000
		GB 2418683 A	05.04.2006
		GB 2428717 A	07.02.2007
		GB 2346909 A	23.08.2000
		GB 2347445 A	06.09.2000
		GB 2346632 A	16.08.2000
		US 06712151 B2	30.03.2004
		US 2003-0024711 A1	06.02.2003
		US 2002-0175474 A1	28.11.2002
		US 06688400 B2	10.02.2004
		US 2002-0195256 A1	26.12.2002
		US 2004-0177974 A1	16.09.2004
		US 06976536 B2	20.12.2005
		US 06598678 B1	29.07.2003
		US 2005-0011650 A1	20.01.2005
		US 07373990 B2	20.05.2008

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/085841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2003-0062171 A1	03.04.2003
		US 06752215 B2	22.06.2004
		US 06543552 B1	08.04.2003
		US 2003-0132032 A1	17.07.2003
		US 06742606 B2	01.06.2004
		US 2004-0131812 A1	08.07.2004
		US 07093653 B2	22.08.2006
		US 2004-0149454 A1	05.08.2004
		US 07168497 B2	30.01.2007
		US 2005-0005668 A1	13.01.2005
		US 07188687 B2	13.03.2007
		US 2005-0121232 A1	09.06.2005
		US 06851475 B2	08.02.2005
		US 2003-0188868 A1	09.10.2003
		US 2005-0155771 A1	21.07.2005
		US 07086478 B2	08.08.2006
		US 2008-0202753 A1	28.08.2008
		US 2002-0060079 A1	23.05.2002
		US 06425444 B1	30.07.2002
		US 2002-0079106 A1	27.06.2002
		US 06457532 B1	01.10.2002
		US 06527049 B2	04.03.2003
		US 2002-0145281 A1	10.10.2002
		US 06698517 B2	02.03.2004
		US 2002-0079100 A1	27.06.2002
		US 2006-0065408 A1	30.03.2006
		US 07275602 B2	02.10.2007
		US 06578630 B2	17.06.2003
		US 2001-0045284 A1	29.11.2001
		US 2005-0161222 A1	28.07.2005
		US 07267175 B2	11.09.2007
		US 2004-0159466 A1	19.08.2004
		US 2008-0017387 A1	24.01.2008
		US 06446323 B1	10.09.2002
		US 2002-0112338 A1	22.08.2002
		US 2003-0136561 A1	24.07.2003
		US 06923261 B2	02.08.2005
		US 2004-0055756 A1	25.03.2004
		US 07322420 B2	29.01.2008
		US 2004-0163823 A1	26.08.2004
		US 2005-0016738 A1	27.01.2005
		US 07234532 B2	26.06.2007
		US 2003-0042028 A1	06.03.2003
		US 2002-0166664 A1	14.11.2002
		US 06695063 B2	24.02.2004
		US 2003-0106698 A1	12.06.2003
		US 06899181 B2	31.05.2005
		US 2005-0252662 A1	17.11.2005
		US 07124821 B2	24.10.2006
		US 2003-0042022 A1	06.03.2003
		US 06702029 B2	09.03.2004

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/085841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		US 2002-0166668 A1	14. 11. 2002
		US 2003-0019638 A1	30. 01. 2003
		US 06702030 B2	09. 03. 2004
		US 2004-0079528 A1	29. 04. 2004
		US 06976539 B2	20. 12. 2005
		US 2004-0216506 A1	04. 11. 2004
		US 2004-0216878 A1	04. 11. 2004
		US 2004-0216925 A1	04. 11. 2004
		US 07117957 B2	10. 10. 2006
		US 07124826 B2	24. 10. 2006
		US 2004-0226723 A1	18. 11. 2004
		US 2004-0251035 A1	16. 12. 2004
		US 07350585 B2	01. 04. 2008
		US 06325148 B1	04. 12. 2001
		US 06712142 B2	30. 03. 2004
		US 2002-0185274 A1	12. 12. 2002
		US 06708769 B2	23. 03. 2004
		US 2001-0040054 A1	15. 11. 2001
		US 06902000 B2	07. 06. 2005
		US 2004-0173355 A1	09. 09. 2004
		US 07004257 B2	28. 02. 2006
		US 2005-0077046 A1	14. 04. 2005
		US 07367404 B2	06. 05. 2008
		US 2005-0127673 A1	16. 06. 2005
		WO 2002-075107 A1	26. 09. 2002
		WO 2000-037767 A2	29. 06. 2000
		WO 2000-037768 A1	29. 06. 2000
		WO 2000-037771 A1	29. 06. 2000
		WO 2000-037772 A1	29. 06. 2000
		WO 2000-037773 A1	29. 06. 2000
		WO 2003-046335 A1	05. 06. 2003
		WO 2004-007893 A2	22. 01. 2004
		WO 2002-081863 A1	17. 10. 2002
		WO 2003-029608 A1	10. 04. 2003
		WO 2001-046551 A1	28. 06. 2001
		WO 2002-038343 A2	16. 05. 2002
		WO 2003-021080 A1	13. 03. 2003
		WO 2000-037766 A2	29. 06. 2000
KR 10-0650162 B1	20. 11. 2006	KR 2005-0015407 A	21. 02. 2005
		US 2006-0134792 A1	22. 06. 2006
		WO 2005-012573 A1	10. 02. 2005