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- (71) Applicant (for all designated States except US): LABO-RATORY CORPORATION OF AMERICA HOLD-INGS [US/US]; 430 South Spring Street, Burlington, NC 27215 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): SPERINDE, Jeff [US/US]; 623 Isabella Road, El Granada, CA 94018 (US). WINSLOW, John, William [US/US]; 931 Ventura Street, El Granada, CA 94018 (US). JIN, Xueguang [CN/US]; 4490 Calypso Terrace, Fremont, CA 94555 (US).

- (74) Agents: CALKINS, Charles, W. et al.; Kilpatrick Stockton, LLP, 1001 West Fourth Street, Winston-Salem, NC 27101 (US).
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— with international search report (Art. 21(3))

[Continued on next page]

**(54)** Title: METHODS AND ASSAYS FOR MEASURING p95 AND/OR p95 IN A SAMPLE AND ANTIBODIES SPECIFIC FOR p95

### FIGURE 5a

Veratag Assay Workflow p95 Assay Configuration · slide after antigen retrieval block, add 1° Ab · add 2° Ab, release sterically cell blocked? membrane quantify vtag by CE p185 p95 CE electropherogram capillary proprietary Fluorescence Intensity (RPA) electrophoresis anti-p95 Ab anti-mouse secondary Time Normalize peak areas to internal standard and tumor area Amount Tumor Acea

(57) Abstract: Methods of measuring and/or quantifying the presence and/or amount of p95 and/or p95 complex in a sample utilizing monoclonal antibodies specific for p95 are provided.





- 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))
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## INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - G01N 33/53, 33/48 (2010.01) USPC - 436/501, 63 According to International Patent Classification (IPC) or to both national classification and IPC						
B. FIELI	DS SEARCHED					
Minimum documentation searched (classification system followed by classification symbols) USPC: 436/501, 63						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 436/501, 63 (text search)						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Electronic data bases searched: PubWEST (EPAB, JPAB, USPT, PGPB); Google Scholar; GenCore Sequence Search (AA) Search terms used: p95HER2 (synonyms: p95HER-2, truncated ErbB2, truncated HER2), extracellular "stub" region, antibody, immunoassay, proximity probe, Veritag assay (Etag assay), cancer prognosis (breast, NSCLC), drug resistance, biomarke						
C. DOCU	MENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where ap	ppropriate, of the relevant passages	Relevant to claim No.			
X 	US 2003/0059863 A1 (CLINTON). 27 March 2003 (27. [0023],[0032], [0058], SEQ ID NO: 1.	03.2003). Especially para [0009]-	1-4, 7-9, 21, 22, 24-27, 30-33			
- <del></del>			5, 10-14, 16-19, 23, 28			
^			6, 15, 20, 29			
Υ	US 2004/0241686 A1 (NELSON). 2 December 2004 ( 5,14,19, 23, 28	02.12.2004). Especially SEQ ID NO: 11.	5,14,19, 23,28			
Υ	HUANG et al. Comparison of Central HER-2 Tests with		10-14,16-19			
A	HER-2 Homodimer Measurements Using a Novel Proximity Based Assay. Abstract 40 American College of Pathologist Annual Meeting 25-28 September 2008. Available on the internet: <url: http:="" publications.aspx="" www.hermarkassay.com="">. Especially pg 5, fig 1 and 2.</url:>		15, 20			
Y US 2008/0131883 A1 (ADAMS et al.) 5 June 2008 (0		.06.2008) abstract, para [0410], [0383]	16			
A XIA et al. Truncated ErbB2 receptor (p95ErbB2) is reg formation with ErbB3 yet remains sensitive to the dual 22 January 2004 Oncogene Vol 23 No 3 Pages 646-6		EGFR/ÉrbB2 kinase inhibitor GW572016.	1-33			
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<u>-</u>	rity date claimed	Date of mailing of the international search				
13 April 2010 (13.04.2010)		2.5 MAY				
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International application No.
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Box	No.	I	Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)
1.	With	h regai ied ou	rd to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was ton the basis of a sequence listing filed or furnished:
	a.	(mear	on paper in electronic form
2.	b.	stat	in the international application as filed together with the international application in electronic form subsequently to this Authority for the purposes of search addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required tements that the information in the subsequent or additional copies is identical to that in the application as filed or does go beyond the application as filed, as appropriate, were furnished.
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International application No.
PCT/US 09/66295

C (Continuation). DOGUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
A	SAEZ et al. p95HER-2 predicts worse outcome in patients with HER-2-positive breast cancer. Clin Cancer Res 15 January 2006 Vol 12 No 2 Pages 424-431. Especially abstract.	1-33			
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