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(54) **METHODS OF IDENTIFYING AN INDIVIDUAL AS TO BE TREATED BY CHEMOTHERAPY BASED ON MARKER MOLECULES AND RELATED USES**

VERFAHREN ZUR IDENTIFIKATION EINER EINZELPERSON DAHINGEHEND, DASS SIE DURCH CHEMOTHERAPIE ZU BEHANDELN IST, AUF BASIS VON MARKERMOLEKÜLEN UND VERWANDTE VERWENDUNGEN

PROCÉDÉS D'IDENTIFICATION D'UN INDIVIDU DEVANT ÊTRE TRAITÉ PAR CHIMIOTHÉRAPIE EN SE BASANT SUR DES MOLÉCULES DE MARQUEURS ET UTILISATIONS ASSOCIÉES

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- (56) References cited:
- MULEYTH ET AL: "50: Do preoperatively elevated CYFRA 21-1 or CEA values qualify for adjuvant chemotherapy in completely resected stage I NSCLC patients?", **ANTICANCER RESEARCH - INTERNATIONAL JOURNAL OF CANCER RESEARCH AND TREATMENT; 12TH INTERNATIONAL HAMBURG SYMPOSIUM ON TUMOR MARKERS, INTERNATIONAL INSTITUTE OF ANTICANCER RESEARCH, GR; HAMBURG, GERMANY**, vol. 23, no. 6B, 1 November 2003 (2003-11-01), page 4507, XP008179384, ISSN: 0250-7005
 - MULEY T ET AL: "Increased CYFRA 21-1 and CEA Levels are Negative Predictors of Outcome in p-Stage I NSCLC", **ANTICANCER RESEARCH - INTERNATIONAL JOURNAL OF CANCER RESEARCH AND TREATMENT, INTERNATIONAL INSTITUTE OF ANTICANCER RESEARCH, GR**, vol. 23, no. 5B, 1 September 2003 (2003-09-01), pages 4085-4093, XP008153792, ISSN: 0250-7005
 - TAKESHI HANAGIRI ET AL: "Preoperative CYFRA 21-1 and CEA as prognostic factors in patients with stage I non-small cell lung cancer", **LUNG CANCER, ELSEVIER, AMSTERDAM, NL**, vol. 74, no. 1, 6 February 2011 (2011-02-06), pages 112-117, XP028288128, ISSN: 0169-5002, DOI: 10.1016/J.LUNGCAN.2011.02.001 [retrieved on 2011-02-22]
 - MULEY T ET AL: "Tumor volume and tumor marker index based on CYFRA 21-1 and CEA are strong prognostic factors in operated early stage NSCLC", **LUNG CANCER, ELSEVIER, AMSTERDAM, NL**, vol. 60, no. 3, 1 June 2008 (2008-06-01), pages 408-415, XP022691011, ISSN: 0169-5002, DOI: 10.1016/J.LUNGCAN.2007.10.026 [retrieved on 2008-02-20]
 - Jan Kulpa ET AL: "Carcinoembryonic Antigen, Squamous Cell Carcinoma Antigen, CYFRA 21-1, and Neuron-specific Enolase in Squamous Cell Lung Cancer Patients", **Clinical Chemistry**, 1 November 2002 (2002-11-01), pages 1931-1937, XP055257310, United States Retrieved from the Internet:
 URL:<http://www.clinchem.org/content/48/11/1931.full.pdf> [retrieved on 2016-03-10]
 - BLANKENBURG FLORIAN ET AL: "Preoperative CYFRA 21-1 and CEA as prognostic factors in patients with stage I non-small cell lung cancer: external validation of a prognostic score", **TUMOUR BIOLOGY : THE JOURNAL OF THE INTERNATIONAL SOCIETY FOR ONCODEVELOPMENTAL BIOLOGY AND MEDICINE, INTERNATIONAL SOCIETY FOR ONCODEVELOPMENTAL BIOLOGY AND MEDICINE, SWITZERLAND**, vol. 29, no. 4, 1 January 2008 (2008-01-01), pages 272-277, XP008179382, ISSN: 1423-0380, DOI: 10.1159/000152945 [retrieved on 2008-09-09]
 - EBERT W ET AL: "Cytokeratin 19 fragment CYFRA 21-1 compared with carcinoembryonic antigen, squamous cell carcinoma antigen and neuron-specific enolase in lung cancer. Results of an international multicentre study", **EUROPEAN JOURNAL OF CLINICAL CHEMISTRY AND CLINICAL BIOCHEMISTRY, WALTER DE GRUYTER, BERLIN, DE**, vol. 32, no. 3, 1 March 1994 (1994-03-01), pages 189-199, XP008179383, ISSN: 0939-4974, DOI: 10.1515/CCLM.1994.32.3.189 [retrieved on 2009-09-16]
 - Macmillan ET AL: "Evaluation of a new tumour marker in patients with non-small-cell lung cancer: Cyfra 21.1", **Br. J. Cancer**, 1 January 1994 (1994-01-01), pages 525-528, XP055257295, Retrieved from the Internet:
 URL:<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1968860/pdf/brjcancer00193-0119.pdf> [retrieved on 2016-03-21]
 - D. MORO ET AL: "CEA, CYFRA21-1 and SCC in non-small cell lung cancer", **LUNG CANCER.**, vol. 13, no. 2, 1 October 1995 (1995-10-01), pages 169-176, XP055257391, NL ISSN: 0169-5002, DOI: 10.1016/0169-5002(95)00485-8
 - WIESKOPF B ET AL: "Cyfra 21-1 as a biologic marker of non-small cell lung cancer. Evaluation of sensitivity, specificity, and prognostic role", **CHEST, AMERICAN COLLEGE OF CHEST PHYSICIANS, US**, vol. 108, no. 1, 1 July 1995 (1995-07-01), pages 163-169, XP002448261, ISSN: 0012-3692
 - M Plebani ET AL: "Clinical evaluation of seven tumour markers in lung cancer diagnosis: can any combination improve the results?", , 1 January 1995 (1995-01-01), pages 170-173, XP055257408, Retrieved from the Internet:
 URL:<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2034156/pdf/brjcancer00041-0174.pdf> [retrieved on 2016-03-10]

- **YOSHIKI KOZU ET AL: "Prognostic significance of postoperative serum carcinoembryonic antigen levels in patients with completely resected pathological-stage I non-small cell lung cancer", JOURNAL OF CARDIOTHORACIC SURGERY, BIOMED CENTRAL LTD, LO, vol. 8, no. 1, 22 April 2013 (2013-04-22), page 106, XP021145750, ISSN: 1749-8090, DOI: 10.1186/1749-8090-8-106**