Anti-y-H2A Antibody and Method for **Detecting DNA Double-Stranded Breaks**

William M. Bonner, Efthimia P. Rogakou (NCI)

Serial No. 09/351,721 filed 12 Jul 1999

There presently exist assays for determining DNA breakage due to stresses such as radiation and toxins. These include the TUNEL assay and single cell gel electrophoresis, among others. The difficulty in using these and other assays arises in that a great number of DNA breaks are necessary for adequate detection of the breakage. Since only 40 double-stranded breaks in the DNA leads to cell death, it is evident that there is a need for an assay with greater specificity.

The NIH announces a new technology which relates to such an improvement over current DNA detection assays, with the ability to be sensitive enough to detect a single DNA double-stranded break in a cell's nucleus. This method for detection uses antibodies directed against a synthetic phosphorylated peptide containing the mammalian γ-H2AX C-terminal sequence for deletion of DNA double-stranded breaks. It centers on the activity of the H2A histone. In response to a DNA break, H2A can become phosphorylated in great numbers and provide protection for the break site to assist in repair. The antibody and method available show specificity for this occurrence and thus allow detection at levels much lower than are presently needed by other detection techniques. Use of such technology could be widespread, both as a diagnostic tool and with specific DNA breakage-related disease and syndrome research.

Dated: August 29, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 00-22881 Filed 9-6-00; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious

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ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/ 496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A High Yield Pertussis Vaccine **Production Strain and Method for Making Same**

Tod J. Merkel, Jerry M. Keith and Xiaoming Yang (NIDCR) DHHS Reference No. E-159-99/0 filed 26 Jun 2000

Licensing Contact: Uri Reichman; 301/ 496–7736 ext. 240; e-mail:

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Pertussis Toxin (PT) in its chemically detoxified forms has emerged as the most promising acellular vaccine against Bordetella pertussis (B. pertussis), the organism responsible for whooping cough. Genetically detoxified forms of PT have recently been demonstrated as potential vaccine candidates against this organism, and may offer the advantages of enhanced stability and ease of manufacturing. The need for production of large quantities of PT and its genetically detoxified forms keeps growing, but the current methods of production of the toxin from B. pertussis have proven to be rather cumbersome and inefficient, resulting in poor yields and impure form of the desired protein. The present invention provides for a new way to circumvent these difficulties and renders the process more amenable to industrial needs. The present invention describes the development of a new genetically engineered strain of Bordetella bronchiseptica, named BBPT, which grows at a high rate relative to B. pertussis, and is capable of producing wild type or genetically detoxified form of PT in pure form, with high yields and in a cost effective fashion. The high degree of purity of the product is achieved due to the knockout of the filamentous hemagglutinin (FHA) gene in this new strain. The presence of the FHA protein, which is inherent in the conventional methods of production, requires extra purification steps, thus

resulting in poor and inconsistent yields of the toxin. The BBPT strain of the present invention may play a major role in the acceleration of programs dedicated to the development of improved and efficacious vaccines against B. pertussis.

Activation of Antigen Presenting Cells to Respond To a Selected Antigen

Polly Matzinger, Stefania Gallucci, Martijn Lolkema (NIAID) DHHS Reference No. E-018-00/0 filed 25 Oct 1999

Licensing Contact: Peter Soukas; 301/ 496-7056 ext. 268; e-mail: soukasp@od.nih.gov

The inventors have found that alpha interferon and the supernatant of necrotic cells can act as adjuvants when co-injected along with a protein, such as OVA, to initiate a primary in vivo immune response in mice. The compositions of the present invention can induce dendritic cells to activate and become good Antigen Presenting Cells (APCs) and consequently initiate an immune response. The advantage of these adjuvants is that they are more physiological and they allow for repeated vaccination, which current adjuvant technology makes difficult due to the side effects of the adjuvants. The invention also provides uses and applications for the adjuvants, including, but not limited to, transplant rejection, spontaneous tumor rejection, some forms of spontaneous abortion, and some forms of autoimmunity. The invention is further described in Nature Medicine 1999 Nov; 5(11):1249-55.

Dated: August 29, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 00-22882 Filed 9-6-00; 8:45 am] BILLING CODE 4140-01-P

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