

Press Release

PCR-based “Hygiene Screening System” for rapid identification of bacterial colonies in hygiene monitoring: BIOTECON Diagnostics GmbH and BIOTEST AG start worldwide sales cooperation

In order to enhance the worldwide launch of its innovative **Hygiene Screening System**, **BIOTECON Diagnostics GmbH** Potsdam, Germany has started a global sales cooperation with the **Business Unit Microbiology of BIOTEST AG** in Eppelheim, Germany.

In September 2009 the dedicated sales force for the microbiological product range of Biotest AG will start to sell the system for rapid identification of microorganisms from hygiene monitoring samples. *Corynebacterium*, *Staphylococcus*, *Micrococcus*, *Kocuria*, and *Kytococcus* can be detected in a simple procedure starting from a single bacterial colony.

“The strength of our Hygiene Screening System lies in a focused product development based on clients’ needs, continuous quality control and excellent performance which is now combined with Biotest’s strength to reach the specific market with its worldwide sales force” emphasizes Alois Schneiderbauer, Chief Business Officer of BIOTECON Diagnostics.

“For our Global Business Unit Microbiology the new molecular biological detection system is a perfect addition to our broad product range in the field of environmental monitoring, including microbial air samplers and Contact Slides. Our customers in the pharmaceutical industry will benefit from this rapid microbiology method for the identification of bacterial colonies grown on our solid media which are optimized for monitoring tests” comments Dr. Frank Schulze, Executive Vice President of the Global Business Unit Microbiology at Biotest AG.

BIOTECON Diagnostics developed the Hygiene Screening System to meet the need for a fast and specific method for environmental monitoring in the pharmaceutical industry. A monitoring study with several pharmaceutical companies revealed that up to 80% of the microorganisms isolated from samples derived from the pharmaceutical environment (personnel, air and surface) belong to the genera *Staphylococcus*, *Micrococcus* and *Corynebacterium*. The method is based on a fast real-time PCR (polymerase chain reaction) technology. A stepwise assignment to either one or other of the mentioned genera is possible within a single PCR reaction in less than two hours.

Since 2004, the usage of more sensitive and specific tests has been recommended by the European Pharmacopoeia (E.P., Chapters 5.1.6 and 2.6.1) and by the FDA Aseptic Guideline with reference to molecular biological methods. There is a need for new methods because most of the conventional methods are time-consuming and sometimes show an insufficient accuracy. The Hygiene Screening System achieves these recommendations by providing an innovative method which allows fast and accurate identification.

BIOTECON Diagnostics GmbH with its headquarter in Potsdam / Berlin (Germany) has been a competent partner for molecular biological and microbiological issues for more than ten years. The focus is the development, production and marketing of PCR-based rapid detection systems. BIOTECON Diagnostics offers solutions for the food and beverages industry as well as for pharmaceutical and cosmetics manufacturers.

Biotest AG is a company that researches and manufactures pharmaceutical, biotherapeutic and diagnostic products and has specialized in the areas of application of immunology and haematology. In its Plasma Protein segment, Biotest develops and markets immunoglobulins, coagulation factors and albumins based on human blood plasma. These are used for diseases of the immune and haematopoietic systems. In the Biotherapeutic segment, Biotest researches into the clinical development of monoclonal antibodies, including in the indications of rheumatoid arthritis and cancer of plasma cells. The products of the Microbiological Monitoring segment are primarily used in hygiene monitoring, while those of Medical Diagnostics are used, for example, in blood transfusions and transplants. Biotest has around 2,000 employees worldwide. The preference shares of Biotest AG are listed in the SDAX on the Frankfurt stock exchange.

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