NEWS RELEASE – FOR IMMEDIATE RELEASE

Contact Information:

Institute of Biotechnology AS CR, v. v. i.
Peter Sebo, Ph.D., director
Phone: +420 (241) 063 613
Fax: +420 (241) 063 610
Email: btu-office@img.cas.cz
http://www.ibt.cas.cz/en

American Association for Clinical Chemistry (AACC)
Peter Patterson
Phone: (202) 835-8744
Fax: (202) 833-4576
Email: ppatterson@aacc.org
www.aacc.org

International Scientists Secure Quality in Molecular Diagnostics

Consensus Guideline Reached For Quantitative Polymerase Chain Reaction

PRAGUE, April 1, 2009 — Institute of Biotechnology of the Academy of Sciences of the Czech Republic, v.v.i. (IBT) and the American Association for Clinical Chemistry (AACC), announced today that a consensus guideline for a key laboratory method called qPCR (or quantitative polymerase chain reaction) was published by a group of international scientists representing the medical and research fields.

qPCR is extensively used in diagnostic testing, from pathogen detection to cancer prognosis, and new studies using qPCR are published at an ever-increasing rate. The consensus guideline, the first of its kind for this technique, provides a minimum set of information that researchers must provide in order for their qPCR data to be considered for publication. The goal is to increase the transparency and quality of studies, so that experiments using qPCR can be accurately reproduced by others, and the scientific community can assess the quality and validity of those studies more readily.

Authors of this guideline, including Professor Stephen A. Bustin at the Institute of Cell and Molecular Science, Queen Mary, University of London, recognized that there was a widespread problem in how qPCR data were reported and interpreted. "The majority of published qPCR studies do not provide sufficient experimental detail, and scientists reading them have a hard time deciding if the conclusions are valid. For instance, this has contributed to the erroneous reporting of the association between child MMR vaccination and autism," said Dr Bustin. When analyzed correctly, the results proved to be due to poorly implemented experimental technique. Another example is a study on plant genetics that was published in the journal *Science* as the "breakthrough of the year" in 2005. Two years later, this study had to be retracted because of poorly implemented qPCR.

The guideline includes a checklist of essential and desirable steps that should be followed when using qPCR. If followed appropriately, authors should be able to design and report qPCR experiments with greater inherent value, and journal reviewers, editors, and laboratory managers will be able to evaluate the technical quality of the published data against an established yardstick. Most importantly, adherence to this guideline should facilitate the publication of results that will be factually reliable.

"This guideline will enhance quality and reliability of published results, thus spurring the development of new qPCR based molecular diagnostic tests." commented co-author Dr. Mikael Kubista head of the gene expression laboratory at the Institute of Biotechnology AS CR, v. v. i. and founder of the TATAA Biocenters.

"This guideline was created by scientists from five countries who are very knowledgeable in qPCR. The guideline should help us evaluate future qPCR studies that are submitted to our journal," remarked Dr. Nader Rifai, editor of the journal Clinical Chemistry which will publish this guideline in its April, 2009 issue. Full access to the guideline is available online at: www.clinchem.org/cgi/content/full/55/4/611.

BACKGROUND

About quantitative PCR (qPCR):

qPCR is an extension of the polymerase chain reaction invented in 1986 by Kary Mullis, which revolutionized biological research and resulted in him receiving the 1993 Nobel Prize in Chemistry. qPCR allows accurate measurement of DNA by turning a single copy of DNA into millions of copies in less than an hour, and its simplicity has made this technique a quintessential method for scientific research, medical and forensic analysis, as well as for biodefense and food safety applications.

More about the guideline and related information:

1. S.A. Bustin, V. Benes, J.A. Garson, J. Hellemans, J. Huggett, M. Kubista, R. Mueller, T. Nolan, M.W. Pfaffl, G.F. Shipley, J. Vandesompele, and C.T. Wittwer, The MIQE Guidelines: Minimum Information for Publication of Quantitative Real-Time PCR Experiments. *Clinical Chemistry* 55 (2009) 609-620. http://www.clinchem.org/cgi/content/full/55/4/611 (full text)
2. http://www.rdml.org/miqe/
3. Minimum Information for Biological and Biomedical Investigations (www.mibbi.org)

About AACC:

The American Association for Clinical Chemistry (AACC) is a leading professional society dedicated to improving healthcare through laboratory medicine. Its over 9,000 members are clinical laboratory professionals, physicians, research scientists, and others involved in developing tests and directing laboratory operations. AACC brings this community together with programs that advance knowledge, expertise, and innovation. For more information about this topic, or about AACC and its programs and publications, please contact Peter Patterson on the above telephone numbers or at ppatterson@aacc.org.

About IBT:

The Institute of Biotechnology AS CR, v. v. i. is the newest public research institute of the Academy of Sciences of the Czech Republic established on January 1, 2008, and is located at the biomedical research center in Prague-Krč. The primary ambition

of this new institute is to develop cutting-edge basic and oriented research on topics opening for diagnostic and therapeutic applications in human medicine. With presently six research teams and two more being recruited, IBT will serve as a nucleation center of BIOCEV, the planned joined Biotech&Biomed Research Center of the Academy of Sciences with Charles University, to be built at Vestec near Prague by the year 2012, taking advantage of the support of the European Regional Development Funds in frame of the Operational Program R&D for Innovation. For further information, see: http://www.ibt.cas.cz/en