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National Institute of Environmental Health Sciences, NIH
Interagency Coordinating Committee on the
Validation of Alternative Methods
William S. Stokes
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Nomination of a test method to ICCVAM

Dear Dr. Stokes,

The Monocyte-Activation Test comprises methods to detect pyrogen contaminations in pharmaceutical products, medical devices, and other samples. The test bears the chance to fully replace the Rabbit Pyrogen Test and for that purpose has been incorporated in the European Pharmacopoeia in 2010. In the recent Test Method Evaluation Report (NIH Publication Number 08-6392) the ICCVAM concluded that the presented validation database was inadequate for such a definitive statement. The report, however, also stated that the methods could be applicable for the detection of a wider range of endotoxin and non-endotoxin pyrogens and test materials, provided that they are adequately validated for such uses. We nominate the Monocyte-Activation Test with cryo-preserved human blood to ICCVAM for the additional evaluation studies based on the protocols proposed by the ICCVAM. Please find the details for the nomination in the attached document.

Sincerely yours

Biotest AG

ppa.


/s/

Dr. Bodo Holtkamp
Senior Director Molecular Biology

ppa.


/s/

Peter Unglaube
Vice President Production and R&D

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