

Certificate of Quality Commitment

This certifies that the pipet tips, PCR tubes and other bio-research products manufactured by Molecular BioProducts, Inc., are subject to the industry's highest standards of quality at every level of production. From raw materials to the finished product, all components of each manufacturing lot are fully traceable and produced in a controlled environment.

Molecular BioProducts, Inc. guarantees that manufacturing lots meet the industry's highest standards for molding precision and clarity, and are certified free of RNase, DNase, DNA and pyrogen contamination by MBP and/or independent laboratories. Typical testing protocols are described on the reverse side of this certificate.

Satisfaction Guaranteed

Dedicated to customer service and quality manufacturing, Molecular BioProducts, Inc. guarantees its products will be free of defects in materials and workmanship and will replace any product that fails to perform as promised. Contact our Customer Service Department for details.

MBP[®]

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President



Limitation of Liability: MBP's entire liability with respect to this product shall be limited to the price of the product. In no event shall Molecular BioProducts, Inc., its agents or employees, be liable for direct, indirect, special, consequential or incidental damages arising out of the use of, or inability to use this product or arising out of any defect in the product, even if MBP has been advised of the possibility of such damages. Pure is a trademark of MBP; MBP is a registered trademark of Molecular BioProducts, Inc., San Diego, California. ©MBP 2002.

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Typical Test Protocols Used In Product Certification

DNA Contamination

PCR reactions are prepared for positive and negative testing for multiple types of DNA contamination. Positive reactions are prepared with single-copy DNA BRCA-1, human total genomic DNA as template, 2.5 units of Taq polymerase, dNTPs and 2 mM MgCl₂. Negative reactions are the same as above except for the use of multi-copy mitochondrial D-loop DNA and no template. After 40 cycles, the results are assayed by agarose electrophoresis. In the negative reaction, the absence of a PCR product band of 368 bp indicates freedom from human DNA contamination. For positive reactions, a visible 368 bp band indicates a successful reaction. Sensitivity level is 30 picograms, multi-copy.

RNase and DNase Detection

For RNase detection, 7.5 kb poly-A tailed RNA is diluted in distilled, RNase/DNase free water. For DNase detection, 1.0 kb DNA ladder is diluted in distilled, RNase/DNase free water. In separate tests, tips from each manufacturing lot are bathed in the water and then used to aspirate a given aliquot which is incubated at 37°C for one hour and compared to a control. No degradation following electrophoresis indicates freedom from contamination.

Pyrogen Detection

Products are directly tested for endotoxins by the Limulus Ameobocyte Lysate (LAL) gel clot assay according to USP/FDA guidelines for medical devices. Sensitivity is 0.06 EU/ml.

Bioburden

Sampled products are immersed in 1X phosphate buffer and shaken for 15 minutes on a reciprocal shaker at 25-30°C. The entire extract is sterile filtered with a 0.45 micron filter which is then incubated for 3-7 days at 37°C in the presence of total count media tryptic soy broth. The number of colony forming units determines applied dosage for electron beam sterilization.

PCR Inhibition

PCR reactions are prepared with primers specific for human mitochondrial D-loop DNA, one unit of Taq polymerase, dNTPs, 2 mM MgCl₂ and 0.2 µg of total human genomic DNA used as template. After 40 cycles, the results are assayed by agarose electrophoresis. The presence of a PCR product band of 368 bp indicates freedom from PCR inhibitors.

Product Sterilization

Those products designated as pre-sterilized are irradiated by electron beam. Dosage levels are determined through bioburden testing of individual manufacturing lots and are verified via an Aluminum Calorimeter.

Verification of Sterility

Following applicable USP 23 guidelines, sampled products are aseptically transferred to fluid thioglycollate and tryptic soy broth and shaken for 15 minutes on a mechanical shaker. The media are incubated for not less than 14 days while being examined for growth. If no growth is observed, the article being tested meets the requirements for sterility.

To receive a certificate of analysis for a specific lot number, contact our Customer Service department.

*PCR process is covered by patents owned by Hoffman-La Roche Ltd.