

CERTIFICATE OF QUALITY

Thermo Fisher Scientific certifies that this product meets the following criteria

Sterile

Sterile products have been gamma irradiated and meet a minimum requirement of 10^{-3} SAL (Sterility Assurance Level).

Cytotoxicity

This material was tested and shown to be non-cytotoxic as part of our initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

PCR Inhibitors

Deoxyribonucleic Acid (DNA): <0.6ng human genome DNA
Ribonuclease (RNase): This product is certified to be free of RNase contamination at the level of 1.9×10^{-10} Kunitz unit/ μ L

Deoxyribonuclease (DNase): This product is certified to be free of DNase contamination at the level of 8×10^{-7} Kunitz unit/ μ L

Endotoxin (Pyrogen)

This product is certified to be non-pyrogenic at a level of <0.05 EU/mL per USP <85>



Barry Srolis
Senior Quality Manager

Manufactured under an ISO 13485 registered
Quality Management System

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