



Certificate of Quality

LLG-Cryotubes

The LLG-Cryotubes are manufactured in a clean room environment, class 7 according to ISO 14644; class 10,000 as for F. S. 209 standard.

We hereby certify that the LLG-Cryotubes are completely free of:

- **human DNA**
- **PCR inhibition**
- **DNase**
- **RNase**
- **Pyrogens**
- **ATP**

The control and the certification is done by an external laboratory.

Human DNA:	<i>Method:</i>	Polymerase Chain Reaction
	<i>Limit:</i>	< 2 pgless than one human cell
DNase	<i>Method:</i>	DNA digestion
	<i>Limit:</i>	not detectable (LOD 1.0×10^{-6} Kunitz-units)
RNase	<i>Method:</i>	RNA digestion
	<i>Limit:</i>	not detectable (LOD 1.0×10^{-9} Kunitz-units)
PCR Inhibition:	<i>Method:</i>	Polymerase Chain
	<i>Limit:</i>	Reaction Less than 10 targets amplifiable
Endotoxin:	<i>Test method:</i>	Kinetic-turbidimetric LAL test (FDA Guideline)
	<i>Limit:</i>	<0.001 EE(EU;I.E.; I.U.)/ml
ATP	<i>Test method:</i>	Pre-sterilization test /Bioburden test
	<i>Limit:</i>	< 5.5×10^{-12} mg

- The material has passed the United States Pharmacopeia testing including Class VI tests.
- Material has successfully passed the biological tests according to ISO 10993 - external communicating devices for indirect blood contact for a prolonged period.
- Products certified as STERILE were treated with a validated method to provide a Sterility Assurance Level (SAL) of 10^{-6} .

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