

# Fit for Purpose designation

## Sterile & PCR ready

Products with the Fit for Purpose designation Sterile & PCR ready are an excellent choice for your most sensitive PCR-based studies. Products with this designation are among the highest quality available and most comprehensively tested to detect impurities. The Thermo Scientific™ Sterile & PCR ready Designation includes combination testing for sterility and elimination of endotoxins, as well as testing for the elimination of RNase, DNase, human DNA, and PCR inhibitors. These products have been tested and meet the following criteria:

Description	Test method	Limit of detection*
<b>Sterile</b>	E-beam or gamma irradiation or EtO gassing	Tested in accordance with ISO 11137; SAL varies by product
<b>Free of endotoxins</b>	Limulus Amebocyte Lysate (LAL) gel clot or Kinetic turbidometric	Tested in accordance with USP 85; sensitivity varies by product
<b>Free of RNase</b>	Nuclease assay	< 1.0 x 10 <sup>-9</sup> Kunitz Units/μl
<b>Free of DNase</b>	Nuclease assay	< 8.0 x 10 <sup>-7</sup> Kunitz Units/μl
<b>Free of human DNA</b>	PCR	< 30pg
<b>Free of PCR inhibitors</b>	PCR	control yield = test yield

\*Above limits of detection apply to FinnTip System Tips produced beginning with lot 22258XX

Products that meet this dual designation are intended to support the extreme demands of PCR-based science where sample material is limited or especially valuable and in applications where any contamination poses enhanced risk to results. Thermo Scientific™ Sterile & PCR ready Fit for Purpose products are recommended for use with the following application areas and techniques:

### Application areas

- Quality control
- Forensic human identification
- Medical research
- Microbiology
- Molecular biology
- Stem cell research
- Transgenic plant/animal studies

### Techniques

- Bacteria and yeast cultures
- Cell and tissue cultures
- DNA analysis (PCR, restriction analysis, hybridization, sequencing, NGS)
- Isolation and storage of DNA, RNA
- Mitochondrial DNA analysis
- RNA analysis



ISO 9001  
Certified

ISO 14001  
Certified

ISO 13485  
Certified

**Luis Perez**  
Director, Quality Assurance  
Laboratory Products

Thermo Fisher Scientific, Inc. Quality Management System is certified in accordance with international Quality Management standards. All sites are certified to one or more Quality Management standards; refer to the [Site ISO Certifications](#) for copies of relevant ISO Certifications.

Changes to manufacturing procedures, packaging, and product specifications are documented and traceable. To receive notifications of product changes, register to receive changes through the following link [www.thermofisher.com/registercustomernotifications](http://www.thermofisher.com/registercustomernotifications).

All products are fully traceable by lot number. For a lot-specific certificate, please Contact Us/Technical Support ([Link](#)) and enter the product name or SKU.

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