

# AlteClean™

Selecting the correct purity level of your sample storage consumables is critical for protecting the integrity of your samples. AltemisLab can help you make an informed decision on which purity level is correct for your samples and workflow, and by questioning if sterile products are still necessary given the advances in production and clean room manufacturing processes.

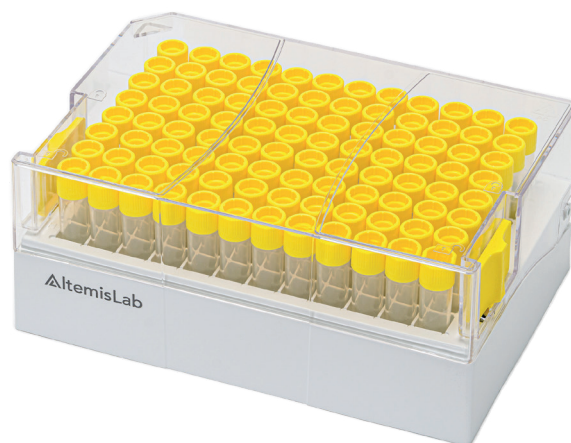
## What is the difference between AlteClean™ and Sterile products?

### AlteClean™

Manufactured in a clean room environment and certified free of non-viable biologics. AlteClean consumables exhibit no detectable DNA, RNA, DNase, RNase, or endotoxins.

### Sterile

Sterility is defined as free from living organisms. Sterilization and autoclaving eliminate viable organisms, though non-viable contaminants may remain.



## What is Sterility Assurance?

At present, a sterility assurance level (SAL) of  $10^{-3}$  or  $10^{-6}$  is generally accepted for laboratory consumables that require sterilisation. A SAL of  $10^{-6}$  means that the survival rate will only be 1 viable microorganism in 1,000,000.

## Which purity level is correct for my application?

AltemisLab is committed to providing products which meet the highest standards of quality.

Every application has varying acceptable levels of viable and non-viable biological materials and choosing the correct purity level for your application is essential to protect your precious samples from degradation and contamination.

Purity level guidance by application

AlteClean™		AlteClean™ Sterile
DNA & RNA sequencing	Molecular Biology	Cell Culture
Genomics	Gene Therapy	Microbiology
Proteomics	Biotherapeutics	Plant or Animal derived products

## AlteClean™

All AlteTubes are manufactured from Medical Grade Virgin Polypropylene in a certified class 100,000 (or ISO 8) clean room, with processes in place that eliminate the opportunity for human contact with the products. Access by personnel to the clean room is only granted when wearing gown, gloves, face mask, hairnet and over shoes. No material that could cause contamination is allowed in the clean room environment. Products are processed and sealed prior to leaving the clean room environment, to ensure they remain contamination free, before the final outer packaging process is completed.

Periodic testing of the manufacturing processes ensures our products are free from the following contaminants:

### Endotoxin (Pyrogens):

AlteTubes have been tested according to ISO 10993-5:2009, USP, Biological Reactivity Test, In Vitro with Limulus Amebocyte Lysate (LAL) reagent. No pyrogens were detected.

Results: Test sample extraction had an undetectable level of endotoxin at <0.25 Eu/mL.

AlteTubes, including all components used in the packaging, are free of; **lead (Pb), cadmium (Cd), mercury (Hg), and hexavalent chromium (Cr6+).**

This product does not contain **phthalates.**

This product does not contain **latex.**

This product does not contain **Bisphenol A (BPA).**

### PCR Inhibitors

qPCR and rt-qPCR testing confirms AlteTubes are free from **DNA, DNase, RNA and RNase.**

## AlteClean™ Sterile

AlteClean™ Sterile products meet the AlteClean™ specifications for non-viable contaminants and have also been Electron Beam (E-beam) treated, meeting a minimum requirement of  $10^{-6}$  SAL (Sterility Assurance Level).

E-Beam Sterilisation is a form of ionizing energy that is characterized by its low penetration and high-dosage rates. The beam, a concentrated, highly charged stream of electrons, is generated by accelerators capable of producing continuous or pulsed beams. As the product/material being sterilized passes the E-Beam, energy from the electrons is absorbed, altering various chemical bonds, damaging the DNA, and destroying the reproductive capabilities of the micro-organisms.

