



# Minimize Risks in Endotoxin Testing

Smart Pipetting Solutions

Simplifying Progress

**SARTORIUS**



# Are You Testing Your Medical Devices with Endotoxin-Free Pipette Tips?

## Guarantee Consistently Reliable Endotoxin Testing Results with Purity-Certified Pipette Tips

Endotoxins can be a risk to patient safety. Even a low endotoxin concentration in the blood stream can produce inflammation in the human body; therefore, preventing endotoxin exposure to your patients is important.

To prevent patient exposure to endotoxins, frequent and reliable testing for endotoxin levels on medical devices is required. The LAL method, is one such reliable test method used to guarantee patient safety and the risk-free use of medical devices. An alternative method is the recombinant Factor C (rFC) assay that is completely animal-free.

Depending on the intended use, US Pharmacopeia (USP) chapter 161 states that all final sterilized products, such as medical devices, must be tested for endotoxin levels, usually by batch, and describes endotoxin release limits as follows for products that come into contact with:

- the cardiovascular system or they lymphatic system – 0.5 EU/mL or 20 EU/device
- the cerebrospinal fluid - 0.06 EU/mL or 2.15 EU/device

## New Application Note: Are You GLP/GMP Compliant When it Comes to pipetting

Are you following methods for current Good Laboratory Practice (cGLP) or current Good Manufacturing Practice (cGMP)?

Our new application note introduces tools and principles that can help you with these demanding requirements, especially when it comes to your pipetting practices. A pipette is a precision measuring apparatus that has a significant influence on your lab results, but it can also be your companion in ensuring compliance.



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# Endotoxin Facts - What You Need To Know

## What Are Endotoxins and Where Do They Enter the Life-Cycle?

Endotoxins are lipopolysaccharide complexes natively located on the outer membrane of Gram-negative bacteria. They can cause several clinical conditions, of which the most severe example is septic shock. Endotoxins, as a product of bacterial death, can be found wherever bacterial growth is possible. Inactivation and destabilization of endotoxins is difficult because they have high heat-tolerance and the ability to tolerate extreme pH values. Also, their removal is tedious as the lipopolysaccharides contain a hydrophobic lipid moiety and a hydrophilic phosphate group.

Therefore, the most effective way to achieve an endotoxin-free level for products is to avoid exposure to the possible sources of endotoxins in the first place

Laboratory consumables as a source of endotoxin contamination should be taken seriously, as it has been shown endotoxin contaminated test tubes can compromise the reliability of clinical biomarker assay measurement. (Newhall et al. (2010). Evidence for Endotoxin Contamination in Plastic Na<sup>+</sup>-Heparin Blood Collection Tube Lots. *Clinical Chemistry* 56; 1483-1491)

## Five Vital Questions to Ask Yourself about Endotoxin Testing Before Buying Pipettes and Consumables?

- Are your pipette tips tested and certified with sufficiently low endotoxin-free limits?
- Does the packaging of tips protect the purity of tips through transportation to your lab bench?
- Do you have clear standard operating procedures (SOPs), for example, for pipetting protocols and maintenance?
- Do your instruments support the avoidance of errors in pipetting?
- Are the users trained in correct pipetting technique, and do they understand the effect of poor technique on their results?



# Pipetting in Endotoxin Testing

## The Effects of Endotoxin Contamination

Did you know that endotoxin contamination of lab consumables can influence your assay results?

Pipetting is an integral part of the endotoxin testing workflow for medical devices. To minimize potential sources of endotoxin contamination, use endotoxin-free consumables, such as pipette tips, within the testing workflow.

Pipette tips that are not manufactured in an automated process can contain endotoxins that cause false endotoxin test results and contaminate samples. Highly automated processes minimize human contact with the raw materials and the final product during the entire manufacturing process, thus minimize endotoxin contamination risk. Sartorius pipette tips are manufactured in a highly automated process and in a clean room environment, and go through a lot-specific testing with an endotoxin test limit of <math><0.005\text{ EU/ml}</math>, which is 100 times lower than the regulatory requirement. All Sartorius endotoxin-free tips are supplied with purity certificates. Before purchasing endotoxin-free pipette tips, check the test limits for endotoxin-free certification of pipette tips to ensure they are low enough to match your test needs.

## The Effects of Pipetting Technique

Pipetting errors are a common source of variance in testing procedures. For example, variance in endotoxin testing standard curves can have a deleterious effect on the reliability of test results.

The pre-programmable protocols of electronic pipettes can reduce user error in pipetting steps. Using the same manufacturer's pipette tips with your pipettes ensures the perfect fit, thus reducing leakage, accuracy, and precision performance promised for the pipette.

To ensure the most reliable results, take care of your pipettes and calibrate them regularly. Sartorius also offers certified and accredited pipette calibration services.



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# Purity Certified Pipette Tips

## Endotoxin-free Pipette Tips

Sartorius pipette tips are tested and certified to be endotoxin free, so they fit into workflows of medical device QC labs. Sartorius manufactures pipette tips according to ISO 14644-1 in a certified ISO 8 cleanroom environment to maintain the highest quality and purity standards. Only the best plastic materials are selected, and our automated manufacturing process is strictly controlled from beginning to end in line with GMP to reliably prevent contamination by human contact. An independent laboratory checks every tip lot to ensure the absence of DNase, RNase, and endotoxins with a test limit of 100 times lower than the regulatory requirement.

## Optifit Pipette Tips

Sartorius Optifit tips ensure perfect fitting and leak-tight sealing on Sartorius pipettes for maximum pipetting accuracy and reproducibility. The color coding of the tip trays enable you to easily match them to their color-coded Sartorius pipette.

- Tips are packed in single tray racks with an air-tight wrapping to protect the tips from endotoxins
- DNase-, RNase-, and endotoxin-free production processes reliably protect your sample from contamination
- The highest quality pure polypropylene is used as raw material to ensure material purity
- Lot-specific purity certificate



# Accurate and Precise Pipettes

Sartorius pipettes are a perfect choice for endotoxin testing of medical devices, as they have been designed with cleanliness, accuracy, and ease-of-use in mind. The pipettes are easy to clean with the lower parts of the pipette being easy to remove. They are also easy to calibrate and are equipped with a volume lock to ensure that your dispensing volume is as intended. In addition, the Picus® Nxt has a calibration reminder feature so that you don't forget your next calibration expiry date.

## Tacta® Mechanical Pipette – Perfectly Balanced

Tacta® is the new premium mechanical pipette with superb comfort and reliability. Tacta® makes pipetting effortless and safe, while producing accurate and reliable results time after time.

Experience the benefits of Tacta®:

- Fully autoclavable pipette for best contamination control
- Reliable results, even over lengthy pipetting periods
- Controlled and smooth tip ejection with the new Sartorius Optiject technology
- Comfortable to hold due to the ergonomically designed handle
- The unique Sartorius Optilock system provides flexibility for volume adjustment and locking
- Calibration adjustment to provide accurate results for various liquid types
- Easy to clean, with only three parts to disassemble

## Picus® Nxt Electronic Pipette – Highly Sophisticated and Ergonomic

Picus® Nxt is the lightest and smallest electronic pipette on the market. Its ergonomic design, fully electronic operation, and advanced functionalities ensure an easy and comfortable pipetting experience.

Experience the benefits of Picus® Nxt:

- Fully electronic operations guarantee accurate and precise pipetting results, regardless of user skill level
- The extensive range of pipetting modes, from diluting and titrating to serial dispensing, makes pipetting tasks quick and easy
- User-definable protocols speed up routine pipetting sequences and add reliability on standard curve pipetting
- Certificate of accredited 3-point calibration (ISO 17025 and ISO 8655) conforms to the strictest regulations
- Maintenance and calibration reminders alert you when service is required
- Possibility to lock the pipette and prevent the use, for instance, in case of contamination
- Uniquely lightweight (weighs only 100 grams) and streamlined design for effortless pipetting



# Additional Resources

View these resources to help you find information-rich solutions.

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Cleaning and Decontamination Guide  
for Sartorius Pipettes



[View Guide](#)

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Application Note: Pipette Calibration  
and Standards



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Practical Selection Guide: Set up Pipetting  
Quality Control Program for Your Lab



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Poster: Get the most out of your  
electronic pipette



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Poster: Pipette cleaning - your pipette  
and samples are precious



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Poster: ABC of the pipette tip purity



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Brochure: High Quality Pipette Tips  
for Consistent and Reliable Results



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Brochure: Tacta® Mechanical Pipettes –  
Perfectly Balanced



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Brochure: Picus® and Picus® NxT  
Electronic Pipettes



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