

Certificate of product line quality

ART Pipette Tips product family

Thermo Fisher Scientific certifies that the Thermo Scientific™ ART™ Pipette Tips product family has been manufactured in accordance with established manufacturing guidelines and product specifications*. These products are subject to rigorous quality inspections and conform to the highest internally established quality requirements as well as external standards as listed below.

The following quality control criteria apply to the aforementioned product family:



Item	Description	Certified quality	Sterile	Sterile & PCR ready	Forensic ready
Materials	Products are produced with high grade polypropylene resins. Tips are produced with virgin polypropylene resin. Thermo Fisher Scientific does not use any latex or animal-based products or by-products for the manufacturing or packaging of its products	■	■	■	■
Filter tip	A filter within the disposable tip that serves to prevent aerosol contamination when pipetting.			■	■
Functional testing	Products undergo continuous quality controls regarding product function; this includes dimensional checks for visual inspection and functional inspection (weight of liquid).	■	■	■	■
Sterility	For the Sterile products contained in the ART Tip portfolio they are sterilized by E-beam irradiation according to ISO 11137;10 ⁶ Sterility Assurance Level (SAL); a five (5)-year shelf life from the date of manufacture is recommended; unless specified on the label.		■	■	■
Sterilization dose audit	Audited in accordance with the requirements contained in ISO 11137.		■	■	■
Non-pyrogenic / Endotoxin	Products are tested for the presence of endotoxins using the Limulus Amebocyte Lysate (LAL) gel clot assay according to current FDA regulations. Products with endotoxin levels below 0.06 EU/ml are certified endotoxin-free.	■	■	■	■
Animal components	<p>Bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathies (TSE) (EMEA 410/01 compliant) regulatory statements. Our suppliers state the following concerning animal origin and TSE/BSE:</p> <ul style="list-style-type: none"> When manufacturing the raw material (polypropylene), they do not use or intentionally add any ingredients of animal origin. Therefore the product is to be considered safe to use in food, pharmaceutical, and cosmetic contact applications with respect to TSE/BSE transmissions. Tallow-derived additives may be used in the manufacturing of the raw material (polypropylene). <p>The specifications of resins are available for more information regarding the additives or any other substances that may be used by the manufacturers. Product specifications may change without notice.</p>	■	■	■	■

*This certification includes only the tips and not the packaging.

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ART Pipette Tips product family (continued)



Item	Description	Certified quality	Sterile	Sterile & PCR ready	Forensic ready
Bisphenol A (BPA) free*	BPA has not been used in the manufacturing process of the plastic in question.	■	■	■	■
Adenosine triphosphate (ATP) free	Products are tested for the presence of ATP using a luciferase-based detection assay. Products with ATP levels below the experimental baseline value are certified ATP-free in the range $<10^{-13}$ mg/ μ L.	■	■	■	■
Nucleases	This product is certified to be free of detectable Ribonuclease (RNase) / Deoxyribonuclease (DNase) contamination. This test is performed using the nuclease assay method with a detection limit of 10^{-9} Kunitz unit/ μ l for RNase and 10^{-7} Kunitz unit/ μ l for DNase.	■	■	■	■
Polymerase chain reaction (PCR) inhibitors	Products are tested for the presence of PCR inhibitors by amplification of a human DNA target sequence. PCR is performed including the appropriate controls and all reactions are analyzed by gel electrophoresis. Test and control reactions must amplify the expected DNA fragment with equivalent yield and purity to verify that the product is free of detectable PCR inhibitors.	■	■	■	■
DNA	Products are tested for DNA contamination using Polymerase Chain Reaction (PCR*). Test reactions, including the appropriate positive and negative controls are prepared with primers specific for human and mouse DNA targets. PCR is performed using the manufacturer's recommended reaction conditions and all PCR products are analyzed by gel electrophoresis. The absence of amplicons in the test reactions indicates that the product is free from detectable DNA contamination. DNA free per the Lower Limit of Detection per <30 pg.	■	■	■	■
Validated in the human identification workflow	Exhibits a high degree of accuracy, precision and reproducibility for forensic applications such as DNA quantification, short tandem repeats (STR) amplification, and genotyping assays.				■

*This certification includes only the tips and not the packaging.

Available in Fit for Purpose



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.

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.

For any additional information or inquires, Contact Us for Support ([Link](#)) and choose the appropriate option.

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Learn more at thermofisher.com/fitforpurpose

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