Sterilization and Purity Certificate – Qualitix® pipette tips

Socorex® certifies that pipette tip products are free of detectable DNase, RNase, Pyrogen (Endotoxins) and ATP. Filter tip products are additionally certified as free of detectable human DNA and Protease. Quality controls performed on each lot by independent laboratories according to procedures below. Sterile products have a Sterility Assurance Level (SAL) of 10^{-6} using a continuously audited process.

Sterility SAL (sterility assurance level): 10^{-6}

Sterilization ref:
Ph. Eur. (European Pharmocopeia) and USP (United States Pharmacopeia)

Method:
Products are irradiated with a dose range of 12-35kGy.

Validation: Quarterly bioburden and sterility audits

Sterility test ref:
USP <71> Sterility Tests
ISO 11137 Sterilization of Health Care Products- Radiation

Method:
Minimum 100 samples,14 days incubation at 28-32°C

Validation: No growth detected

Deoxyribonuclease (DNase) < 10^{-7} Kunitz Units

Test ref: Labcon, Laboratory SOP 09-0004 v8, 2017

Method: Incubation on agarose gel of DNA molecular scale. Test performed on DNase-free water exposed to product.

1) Product from tested lot
2) Product plus 10^{-7} K Unit of DNase
3) Negative control
4) Positive control

Validation: No degradation on agarose gel of the DNA molecular scale in samples 1) and 3), degradation in samples 2) and 4)

Ribonuclease (RNase) < 10^{-9} Kunitz Units

Test ref: Labcon, Laboratory SOP 09-0003 v9, 2017

Method: Incubation on agarose gel of RNA molecular scale. Test performed on RNase-free water exposed to product.

1) Product from tested lot
2) Product plus 10^{-9} K Unit of RNase
3) Negative control
4) Positive control

Validation: No degradation on agarose gel of RNA molecular scale in samples 1) and 3), degradation in samples 2) and 4)

Pyrogen (endotoxins) < 0.05 IU or EU/mL, < 0.5 IU or EU/ item tested

Test ref: LAL turbidometric method, European Pharmacopeia 9th edition (2017), and United States Pharmacopeia 40 NF 35 (2017), chapter 85

Method: Preparation of a standard curve from 5 IU (or EU/mL) to 5 10^{-2} IU (or EU/mL). Bacterial endotoxin rates determined using plate reader measurements at 405 nm.
Test performed on Pyrogen-free water exposed to product.

1) Product from tested lot
2) Product plus 0.5 IU (or EU/mL) of endotoxin
3) Negative control

Validation: Less than 0.05EU in sample 1) and 3), detection in sample 2)

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Adenosine Triphosphate (ATP) < $2X10^{-12}$ mg/ul

Test ref: Labcon, Laboratory SOP 09-0028 v2, 2017

Method: Detection of surface ATP using the 3M Clean-Trace NG Luminometer and ATP Clean-Trace Swabs. Test performed on swab that has contacted surface of product.

1) Product from tested lot
2) Product plus $2X10^{-12}$ mg/ul of ATP
3) Negative control

Validation: Relative light units (RLU) results indicating less than $2X10^{-12}$ mg/ul of surface ATP.

Human Deoxyribonucleic Acid (DNA) < 1 pg (filter tips only)

Test ref: Labcon, Laboratory SOP 09-0017 v7, 2017

Method: Amplification by PCR of "Alu" genomic area in human DNA. Migration of PCR product on agarose gel. Test performed on DNA-free water exposed to product.

1) Product from tested lot
2) Product plus 1 pg of Human DNA,
3) Negative control
4) Positive control

Validation: No DNA amplification in samples 1) and 3) compared to amplification in samples 2) and 4)

Protease < 2ng protease activity (filter tips only)

Test ref: Labcon, Laboratory SOP 09-0019 v7, 2017

Method: Incubation on polyacrylamide gel of protein molecular scale. Test performed on protease-free water exposed to product.

1) Product from tested lot
2) Product plus 2ng/ul Proteinase K
3) Negative control
4) Positive control

Validation: No degradation on polyacrylamide gel of protein molecular scale in samples 1) and 3), degradation in samples 2) and 4)

LOT SPECIFIC CERTIFICATE AVAILABLE FROM SOCOREX@SOCOREX.COM

SOCOREX SWISS

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DNA-RNase-DNase-Pyrogen-free CERTIFIED