

Certificate of Analysis



Filter Cup 500ML R_{TYPE}

Catalog Number: PC652-0024

Batch Number: 210118-319

Expiry Date: 2024-01-18

Membrane: PES 0.22 μm

Flow Rate

Flow rate of this product has been tested no less than 800 ml/min with deionized water under -70KPa.

Sterilization

Product labeled as sterile is irradiated and dosimetrically released upon ISO11137 recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. GeneDireX, Inc. products labeled sterile meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

Non-Pyrogenic

Products labeled non-pyrogenic have been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and company guidelines. The acceptance level for product is less than 0.5 EU/ml.

DNase & RNase Free

This product has been tested and is free of any detectable DNase / RNase contamination.

Max. Vacuum Pressure

The max. vacuum pressure of this lot product has been validated. The acceptance level for product is not less than 0.09MPa and no any distortion or damaged.

Quality Control Testing

Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.