

# Certificate of Analysis



## 10 ml Serological Pipets

Catalog Number: PC510-0200

Batch Number: 220328-329-A

Expiry Date: Mar-2025

### **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.

### **Cytotoxicity**

Testing is conducted to qualify all material resins using USP and ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

### **Graduation accuracy**

Each lot has been taken some samples random from total Lot as representative sample for graduation accuracy and they comply with our product specification. Serological pipets are accurate to +/- 2% at full scale.

### **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.

Yi-Hsing, Yao

Inspector, Quality

Issued on Mar-2022