Quality Certificate

VWR® MICROCENTRIFUGE TUBES, POLYPROPYLENE

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	87003-294
Lot Number:	639927-D23401
Description:	VWR Tube Microcent Natural 1.7 Ml Pk500
Expiration Date:	September 2023

Quality Management System – Complies with the current version of the EN ISO 13485:2016 Standard.

BSE/TSE – Product complies with the latest revision of EMA/410/01 "*Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products*" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Non-Pyrogenic – Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "*Bacterial Endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing*". The acceptance level for product is ≤ 0.02 EU/ml or ≤ 0.8 EU/device.

USP Class VI Testing – All material resin is tested, qualified and shown to be non-toxic as established in the Standard USP Class VI Chapter <87>, "*Biological Reactivity Test, in Vitro*" and Chapter <88>, "*Biological Reactivity Tests, in vivo.*"

Human and Bacterial DNA Free – Tested by PCR method and found to be free of detectable human and bacterial DNA contamination. The assay detection limit is hDNA 0.5pg/ul and bDNA 0.0001pg/ul.

PCR Inhibition - Tested with real time Polymerase Chain Reaction and found no inhibition of real time PCR with a Ct comparison of ≤.5X$CT_{PosCtrl}$-Ct.

DNase/RNase Free – Tested by nuclease assay and found to be free of detectable DNase/RNase contamination. The assay detection limit is $4X10^{-6}$U/ul for DNase and 10^{-10} U/ul for RNase.

Sterility – Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137-3:2017, "*Sterilization of health care products- Radiation*". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-3}.

Quality Control Testing – Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspections and inline tests are:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Fit Form Function Testing – Pass

The product met the manufacturer's high standards of quality at the time of batch/lot release.

Signed:

Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: October 15, 2020