

VWR® DISPOSABLE SEROLOGICAL PIPETS, POLYSTYRENE, STERILE, PLUGGED

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

North American Catalog No:	89130-898
Lot Number:	17018038
Description:	VWR PIPETTE SERO 10ML PR CS200
Manufacturing Date:	June 19, 2018
Expiration Date:	June 18, 2021

Component Materials:

Pipette	Polystyrene, meets USP Cytotoxicity Test <87>.
Mouthpiece Plug	Polyester, meets USP Cytotoxicity Test <87>.
Ink	meets USP Cytotoxicity Test <87>.

Volumetric Accuracy:

This product has been tested and is accurate within +/- 2% at stated full volume.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

<u>Test/Procedure</u>	<u>Results</u>
Visual Attributes	Pass
Volumetric Accuracy	Pass
Packaging	Pass

Sterilization: The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 "Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization".

Sterility Assurance Level: SAL 10⁻³

Pyrogens: The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing".

Results: <= 0.1 EU/mL (<= 4 EU/device)

DNase/RNase: The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing".

Results: <= 0.1 EU/mL (<= 4 EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy: This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

This document has been produced electronically and is valid without a signature.

Signed on behalf of VWR International:

Michael J. Mascali, RPh, FASCP, ASQ CMQ – OE
SVP Compliance
VWR International LLC

Date: July 05, 2018