

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:	35118011
Description:	VWR Pipette Sero 10ml Pr Cs200
Manufacturing Date:	December 17, 2018
Expiration Date:	December 16, 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: Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10⁻⁷ Kunitz units/uL for DNase and 10⁻⁹ Kunitz units/uL for RNase

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.

Signed:



Jamie Ethier
 VP Global Quality
 VWR, Part of Avantor

Date: January 10, 2019