

## VWR® DISPOSABLE SEROLOGICAL PIPETS, POLYSTYRENE, STERILE, PLUGGED

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

<b>North American Catalog No:</b>	89130-896
<b>Lot Number:</b>	35018013
<b>Description:</b>	VWR Pipette Sero 5ml Pr Cs200
<b>Manufacturing Date:</b>	December 16, 2018
<b>Expiration Date:</b>	December 15, 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<sup>-3</sup>

**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<sup>-7</sup> Kunitz units/uL for DNase and 10<sup>-9</sup> 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