

## 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>                | 18318012                      |
| <b>Description:</b>               | VWR PIPETTE SERO 5ML PR CS200 |
| <b>Manufacturing Date:</b>        | July 02, 2018                 |
| <b>Expiration Date:</b>           | July 01, 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:** 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.

**Signed:**



Jamie Ethier  
VP Global Quality  
VWR, Part of Avantor

**Date:** July 25, 2018