



## VWR® DISPOSABLE SEROLOGICAL PIPETS

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

|                                  |                                |
|----------------------------------|--------------------------------|
| <b>North American Catalog No</b> | 89130-898                      |
| <b>Lot Number:</b>               | 11218015                       |
| <b>Description:</b>              | VWR PIPETTE SERO 10ML PR CS200 |
| <b>Manufacturing Date:</b>       | 4/22/2018                      |
| <b>Expiration Date:</b>          | 4/21/2021                      |

### 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:** <math>\leq 0.1\text{ EU/mL}</math> (<math>\leq 4\text{ EU/device}</math>)

**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:** <math>\leq 0.1\text{ EU/mL}</math> (<math>\leq 4\text{ EU/device}</math>)

**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:



Linda K. Shine  
 Manager - Supplier Qualification  
 Global Compliance  
 VWR International LLC

Date: May 16, 2018