

Certificate of Conformity

VWR Catalogue Number	See List
Description	Reagent Reservoirs
Country of Origin	Manufactured in Mexico
Date of Issue (yyyy-mm-dd)	2024-09-02

25 mL

Catalogue Number	Material	Sterility
613-1174	Polystyrene	Sterile
613-1175	Polystyrene	Sterile
613-1176	Polystyrene	Non-Sterile
613-1177	Polystyrene, 3 divisions	Non-Sterile
613-1178	Polystyrene, 3 divisions	Sterile
613-1179	Polystyrene, 3 divisions	Sterile

50 mL

Catalogue Number	Material	Sterility
613-1184	White Polystyrene	Sterile
613-1183	White Polystyrene	Sterile
613-1180	White Polystyrene	Non-Sterile
613-1181	Natural Polystyrene	Sterile
613-1182	Natural Polystyrene	Sterile
613-1185	Polyvinyl Chloride	Non-Sterile
613-1186	Polyvinyl Chloride	Sterile
613-1187	Polyvinyl Chloride	Sterile

100 mL

Catalogue Number	Material	Sterility
613-1171	Polystyrene	Sterile
613-1172	Polystyrene	Sterile
613-1173	Polystyrene	Non-Sterile

Quality System Compliance

Products are manufactured under the **ISO 9001:2015** and **ANSI/AAMI ISO 11137** standards. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements. Inspected according to level S4 AQL 0.4 sampling plan per ANSI/ASQ Z1.4-2008 standard.

PCR Inhibitor: Products are tested via PCR amplification and gel electrophoresis analysis.

Functional Testing: Each product is inspected at regular intervals to our set specifications to ensure the proper form, fit and function. Functional testing for tips includes a test for leaking and an accuracy test using the maximum volume of the tip. Accuracy and precision are then printed on the pack boxes in the form of the CV value.

Traceability: Products are manufactured with the Lot number, Part number and expiration date, clearly printed on the pack and case box labels. Pipette tip racks are labelled with the lot number, Part number and tip size, on the front of the lid for an extra level of traceability.

Product Specifications

Material	See table above.
Sterilization	Product labelled as sterile are irradiated and dose released upon ISO 11137-2:2013 recommended practices in effect at the time of validation meet a minimum requirement of 10^{-3} SAL with a specified dose range of 3.0 kGy – 20 kGy. (which is not applicable for non-sterile products).
ATP Assay	Products are tested via luminescence detection (detection limit 2.5×10^{-10} mg/ μ L) for the presence of ATP and the assay resulted with a value of 2.5×10^{-10} to 7.2×10^{-9} mg/ μ L.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination. Test sensitivity is 10^{-7} Kunitz units/ μ L. and the specification level is $< 10^{-7}$ Kunitz units/ μ L.

DNA Statement	Product is DNA free.
Nucleic Acid Free	Products are tested for nucleic acid by electrophoretic detection method with a limit of 10 ng. As a result no amplicons were detected.
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE).
Cytotoxicity	This product is free of cytotoxicity effects.
Non-Pyrogenic Statement	The acceptance level for product is 0.06 EU/mL (LAL Gel Clot Method). and the specification level is < 0.06 EU/ml.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	This product is free of Bisphenol A.
DEHP Statement	Please see RoHS information below.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed.
REACH Statement	No substances as listed on >Substance of Very High Concern< candidate list published 2024-01-23 are used in manufacturing of the raw materials used to produce this product. No routinely analysis is performed.
Storage Conditions	Store in a Room temperature.
Shelf Life	5 years

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
 This document has been produced electronically and is valid without a signature.

Version History

Sl.no	Version number	Description	Month & Year
1	1.0	Created General CoC using new layout	06-2021
2	1.1	DNA statement added	08-2023
3	2.0	Updated sterilization, DNase RNase, Non-Pyrogenic Statement, Reach Date	05-2024
4	3.0	Shelf life information updated	09-2024
5	3.1	Included Function testing, and Traceability and Nucleic acid	02-2025