Certificate of Compliance

Catalogue number(s)	**BCVE-20-500 (case of 500) / BCVE-20-050 (bag of 50)**
Description	**Bluechiip Enabled Cryovial, 2mL, External Thread**
Lot ID	**21P1084400**
Manufacturing Date	**08/2021**
Expiry Date	**08/2026**

Bluechiip Enabled™ Cryovials are produced in an ISO Class 8 Clean Room, in accordance with ISO 14644. An independent accredited Laboratory performs periodic tests on the various purity parameters.

Human DNA Free – Tested by Polymerase Chain Reaction (PCR) method and found to be free of detectable of Human DNA contamination. The assay detection limit is hDNA 2pg (less than one human cell).

DNase/RNase Free – Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-6} Kunitz-units/ul for DNase and 10^{-9} Kunitz-units/ul for RNase.

PCR Inhibitors Free – Tested by PCR. The assay detection limit is less than 10 targets amplifiable.

Endotoxin Free – Tested by Kinetic turbidimetric LAL test (FDA Guideline). The assay detection limit is <0.001 EE(EU;I.E.; I.U.)/ml

ATP Free – Tested by Pre-sterilization test / Bioburden test. The assay detection limit is < 5.5 x 10^{-12} mg

Non-Pyrogenic - Validated per European Pharmacopoeia criteria for pyrogens and meets the requirements for classification as non-pyrogenic. The acceptance level for product is ≤ 0.1 EU/mL.

Non-Cytotoxic / Non-Haemolytic - The raw material used has passed the United States Pharmacopeia (USP) testing including Class VI tests. The raw material used has successfully passed the biological tests according to ISO 10993 - external communicating devices for indirect blood contact for a prolonged period. The raw material does not use or intentionally incorporate any of the following materials: Cadmium, Chromium (VI), Lead, Mercury.

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137. Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Product Attribute - Validated for compliance to IATA PI 650; does not leak at a pressure differential of 95kPa in the range of -40°C to +55°C.

CE Conformity – Product meets the essential requirements of Council Directive 98/79/EC pertaining to in-vitro diagnostics (IVDD). Pathway of conformity per Annex III

FDA registered business and products – Bluechiip Limited is registered in the FDA database and Bluechiip Enabled Cryovials are registered under the FMH Product Code, Regulation Number 864.3250 (sterile specimen container)

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. This product met Bluechiip Limited high standards of quality at the time of batch/lot release, in accordance with our ISO9001 certified quality management system.

Signature

Scott Turner

Engineering and Quality Manager

Form CER-1043-01

SAMPLE