
TITLE CERTIFICATE OF ANALYSIS – CELL-FREE DNA BCT

CERTIFICATE OF ANALYSIS

The following released product satisfies Streck product specifications for product performance and appearance.

PRODUCT NAME: Cell-Free DNA BCT®

LOT #: 63001315

DATE OF MANUFACTURE: 2017-02-27

EXPIRATION DATE: 2019-02-15

ACTIVITY*(Specification Range 2.30 – 3.46): 2.96

QUALITY CONTROL APPROVAL: Barb Spencer
Print

QUALITY CONTROL APPROVAL: Barb Spencer
(Signature)

TITLE: QC Product Specialist

DATE: 06/29/2017

This product was manufactured under FDA QSR, ISO 9001/ISO 13485 and CDMR conditions. This product has not been cleared by the U.S. Food and Drug Administration for In Vitro Diagnostic use. The product is For Research Use Only. Not for use in diagnostic procedures.

This product has been sterilized. The Sterilization Process has been established and validated in accordance with ISO 11137, Sterilization of Healthcare Products. All established dosage requirements are traceable to this nationally recognized standard.

*Reflects the active ingredient concentration in Cell-Free DNA BCT as measured via Streck's proprietary test method.