

TITLE Cell-Free DNA BCT® CE Certificate of Analysis

CERTIFICATE OF ANALYSIS

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

PRODUCT NAME: Cell-Free DNA BCT® CE

LOT #: 32160317

DATE OF MANUFACTURE: 2023-05-15

EXPIRATION DATE: 2025-05-15

ACTIVITY*(Specification Range 2.30 – 3.46): 2.88

QUALITY CONTROL APPROVAL: Hannah Sorensen

(Print)

QUALITY CONTROL APPROVAL: 

(Signature)

TITLE: Quality Control Product Specialist

DATE: 2023-07-27

This product was manufactured in compliance with all current, applicable regulatory requirements and standards.

Cell-Free DNA BCT CE is for Export Only. Not for use in the U.S.

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 internationally recognized standard.

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