STRECK

Quality Control Certificate of Analysis

TITLE Cell-Free DNA BCT® IVD 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® IVD

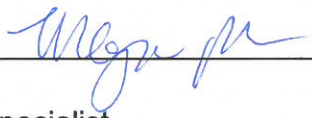
LOT #: 63310331

DATE OF MANUFACTURE: 2026-09-29

EXPIRATION DATE: 2028-03-29

ACTIVITY*(Specification Range 2.30 – 3.46): 3.27

QUALITY CONTROL APPROVAL: Megan Ratliff
(Print)

QUALITY CONTROL APPROVAL: 
(Signature)

TITLE: Quality Control Product Specialist

DATE: 2026-11-18

This product was manufactured in compliance with all current, applicable regulatory requirements and standards. For In Vitro Diagnostic Use. Performance characteristics have only been established on the Guardant360 CDx assay.

This product has been validated per the ISO 6710 standard.

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 as measured via Streck's proprietary test method.