Ethics Declaration

[Product Name/Description]

Code No.	**[Product Code]**
Lot No.	**[Lot No]**

SPECIMEN/MATERIAL COLLECTION SUMMARY

Country of origin [Specify]

Material/Collection Type [Select from: Clinical Remnants, Custom Sample Collection, Disease State Plasma, Blood & Plasma Products]

Data Type

☐ **Identified** *(Specimens/material for which the Receiver and/or the study investigator can link private information to the individual from whom the material was obtained)*

☐ **De-Identified** *(Specimens/material for which the Receiver and/or the study investigator cannot link private information to the individual from whom the material was obtained)*

Ethical Status [Select from: Exempt from Title 45, Title 21 and HIPAA IRB/consent requirements; Collected under IRB/IEC approved protocol; Consented donor samples collected at FDA Licensed/Registered facilities following GMP]

Donor Consent Status

☐ Exempt from Donor Consent
☐ Individual Informed Donor Consent Obtained/Available

IRB/IEC Reference Code [Insert Code or Not Applicable]

ETHICS STATEMENT

The accompanying human specimens/materials have been obtained in accordance with the applicable country-specific regulatory requirements. The records are held by BBI Solutions Kent and/or the relevant collection sites and can be made available for review by the Receiver or its designee, the FDA, or other regulatory agencies. The records include documentation for collection, handling, labelling and storage of the specimens/materials. Where donor consent is obtained, the scope of the consent also applies to the use of donated samples in research and development applications.

INTENDED USE STATEMENT

The Specimens/material must only be used for studies aligned with the intended use statement as stated below:

Specimens/material may be used for Research & Development, production of *in vitro* diagnostics, control and validation of assays.

Name:		**Position:**	
Signed:		**Date:**	