

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

Human Whole Blood - Disease State

Typical Certificate of Analysis | Human Whole Blood | SKU ID: SPB-TCOA-005

Parameter	Typical / Template Entry	
Product name	Human Whole Blood - Disease State	
Product category	Human Whole Blood	
Matrix	Whole blood	
Anticoagulant / additive	K2EDTA / Li-Heparin / Citrate	
Donor status	Disease-state donor	
Format	Single donor	
Volume options	1, 5 mL	
Intended research use	Confirmed disease-state studies; clinical metadata included	
Storage / shipping	-80 C frozen or 2-8 C fresh; ship as specified	
Lot number	To be assigned by QA	
Manufacture / collection date	Lot-specific	
Expiry / retest date	Lot-specific, based on validated stability	
Appearance	Lot-specific; acceptable as per product specification	
Test / Attribute	Method	Typical Acceptance / Reporting
HBsAg	ECLIA	Non-reactive
Anti-HCV	ECLIA / ELISA	Non-reactive
HIV-1 Ag/Ab, 4th gen	ECLIA	Non-reactive
HIV-2 Ab	ELISA	Non-reactive
HIV-1 NAT	PCR	Not detected
HCV NAT	PCR	Not detected
HBV NAT	PCR	Not detected
HTLV-I/II Ab	ELISA	Non-reactive
Syphilis	RPR / TPPA	Non-reactive
West Nile Virus NAT	PCR	Not detected
ALT	Kinetic UV assay	Within normal range
CBC parameters	Automated hematology analyzer	Lot-specific report attached
Hemolysis inspection	Visual	Acceptable / no gross hemolysis
Metadata Field	Typical Reporting Status	
Confirmed diagnosis	Reported when available / as applicable	
Medication summary	Reported when available / as applicable	
Relevant clinical biomarkers	Reported when available / as applicable	
Collection date/time	Reported when available / as applicable	

Notes

- Human material must be handled as potentially infectious using universal precautions, even when screened negative.
- Actual COA must include controlled lot-specific results, reviewer approval, and authorized QA signature.

QA Release Field	Entry
Prepared by	SpeciBio QA / Authorized personnel
Reviewed by	QA reviewer - lot-specific
Disposition	Typical: Acceptable when all specifications are met
Signature / date	Required on actual COA

This is a typical COA template for marketing / specification review only. It is not a lot-release COA.

Actual values, lot number, expiry, donor metadata, and authorized signatures must be issued from controlled QA records.