

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

Breast Cancer

Typical Certificate of Analysis | Disease-State Specimens | SKU ID: SPB-TCOA-019

Parameter		Typical / Template Entry	
Product name	Breast Cancer		
Product category	Disease-State Specimens		
Matrix	Serum or plasma		
Anticoagulant / additive	As specified on order		
Donor status	Physician-confirmed disease-state donor		
Format	Single donor		
Volume options	Typical 0.5-5 mL; order-specific		
Intended research use	IVD assay validation, biomarker discovery, regulatory studies		
Storage / shipping	-80 C; ship on dry ice		
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	
Total protein	Biuret / equivalent	Typical 6.0-8.5 g/dL; lot-specific	
Appearance	Visual	Clear to slightly opalescent; non-hemolyzed	
Metadata Field	Typical Reporting Status		
AJCC stage	Reported when available / as applicable		
ER/PR/HER2	Reported when available / as applicable		
CA 15-3	Reported when available / as applicable		
treatment status	Reported when available / as applicable		
IRB/consent statement	Reported when available / as applicable		
Diagnosis confirmation	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.