

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

**Prostate Cancer**

Typical Certificate of Analysis | Disease-State Specimens | SKU ID: SPB-TCOA-022

Parameter		Typical / SKU Entry
Product name		Prostate 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	
Total and free PSA	Reported when available / as applicable	
Gleason score	Reported when available / as applicable	
stage	Reported when available / as applicable	
treatment	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.