

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

Type 1 Diabetes (T1DM)

Typical Certificate of Analysis | Disease-State Specimens | SKU ID: SPB-TCOA-015

Parameter	Typical / Template Entry	
Product name	Type 1 Diabetes (T1DM)	
Product category	Disease-State Specimens	
Matrix	Serum or plasma	
Anticoagulant / additive	As specified on order	
Donor status	Physician-confirmed disease-state donor	
Format	Single or pooled	
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	
HbA1c	Reported when available / as applicable	
Insulin	Reported when available / as applicable	
diagnosis date	Reported when available / as applicable	
medications	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.