SpeciBio
by Celltech Discovery Solutions

SPECIBIO

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

Human Plasma - ACD Formula A

Typical Certificate of Analysis | Human Plasma | SKU ID: SPB-TCOA-014

Parameter	Typical / Template Entry	
Product name	Human Plasma - ACD Formula A	
Product category	Human Plasma	
Matrix	Plasma	
Anticoagulant / additive	ACD Formula A	
Donor status	Healthy virally-tested donor	
Format	Single or pooled	
Volume options	0.5, 1, 5, 10 mL	
Intended research use	Red-cell studies; platelet function	
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**	
Donor age/sex	Reported when available / as applicable	
Collection date/time	Reported when available / as applicable	
Processing within 24 h	Reported when available / as applicable	
Freeze-thaw count	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

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