

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

Colorectal Cancer

Typical Certificate of Analysis | Disease-State Specimens | SKU ID: SPB-TCOA-021

| Parameter | Typical / Template Entry | |
|-------------------------------|---|---|
| Product name | Colorectal 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 | |
| CEA | Reported when available / as applicable | |
| stage | Reported when available / as applicable | |
| MSI/KRAS status | Reported when available / as applicable | |
| surgical 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.