

CERTIFICATE OF ANALYSIS - TYPICAL / ILLUSTRATIVE TEMPLATE

**Normal Human Serum - Type O Rh+**

Typical Certificate of Analysis | Human Serum | SKU ID: SPB-TCOA-046

| Parameter                          | Typical / Template Entry                              |   |
|------------------------------------|---|---|
| Product name                       | Normal Human Serum - Type O Rh+                       |   |
| Product category                   | Human Serum   |   |
| Matrix                             | Serum   |   |
| Anticoagulant / additive           | None - off the clot                                   |   |
| Donor status                       | Healthy screened donor                                |   |
| Format                             | Single or pooled                                      |   |
| Volume options                     | 0.5, 1, 5, 10 mL                                      |   |
| Intended research use              | Immunoassay matrix, controls, assay development       |   |
| 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 |
| Sterility                          | Culture / validated method                            | No growth                                   |
| Metadata Field                     | Typical Reporting Status                              |   |
| Blood group/profile                | Reported when available / as applicable               |   |
| Donor age/sex                      | Reported when available / as applicable               |   |
| Clotting and centrifugation record | 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                              |

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.