

NRL TESTING Catalogue

TGA-Licensed Donor Screening, Reference Testing, and Custom Solutions –

Your Trusted Partner in Quality

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Why NRL Testing?

Accurate patient diagnosis relies on highly specialised reference and confirmatory testing laboratories.

NRL is a **trusted leader** in infectious disease testing, offering expert reference, screening, and contract testing services. Our laboratory supports critical healthcare needs, including blood and tissue donor screening, ensuring the highest standards of diagnostic accuracy.

As a **GMP-accredited** and **TGA-licensed** facility, NRL provides validated testing for HIV, HBV, HCV, HTLV, and Syphilis. We specialise in resolving complex cases where routine screening is inconclusive and offer TGA-licensed testing for cadaveric samples when alternative sample types are not validated for IVD use.

With proven expertise and a commitment to quality, **NRL Testing delivers** reliable results when they matter most.



OUR SERVICE OFFERING

CMVN Testing



1. Cytomegalovirus (CMV) IgG Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Sodium and Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA),

Plasma (Sodium and Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 200ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive < 12.0, Equivocal \geq 12.0 and < 14.0, Reactive \geq 14.0

Units of Measurement: U/mL

2. Cytomegalovirus (CMV) IgM Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Sodium and Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA),

Plasma (Sodium and Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 200ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive < 18.0, Equivocal ≥ 18.0 and < 22.0, Reactive ≥ 22.0

Units of Measurement: U/mL

Hepatitis Testing



Hepatitis B virus Serology – Core Antibody (Total)

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples including specimens collected from post-mortem donors (non-heart beating). Post-mortem specimens must be collected within 24 hours of death.

Specimen Required: Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA),

Plasma (Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 500ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive > 1.1, Equivocal 0.9 ≤ and ≤1.1. Reactive < 0.9

Units of Measurement: Index

2. Hepatitis B virus Serology – Surface Antigen

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples including specimens collected from post-mortem donors (non-heart beating). Post-mortem specimens must be collected within 24 hours of death.

Specimen Required: Blood (ACD), Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate),

Plasma (ACD), Plasma (EDTA), Plasma (Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 500ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive <0.05, Reactive ≥ 0.05

Units of Measurement: IU/mL

3. Hepatitis B virus Serology – Surface Antigen Confirmatory

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (ACD), Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate),

Plasma (ACD), Plasma (EDTA), Plasma (Lithium Heparin), Plasma (Sodium Citrate), Serum **Specimen Volume Min:** 700ul for low reactive samples and 20ul for highly reactive samples

Turnaround Time: 7 Days

Reference Ranges: Non-reactive <0.05, Reactive ≥ 0.05

Units of Measurement: IU/mL

4. Hepatitis B virus Serology – Surface Antibody

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum (from tubes with and without separator gel) and plasma samples

Specimen Required: Blood (K2 EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (K2

EDTA), Plasma (Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 500ul **Turnaround Time:** 5 Days

Reference Ranges: Negative <9.0, Equivocal 9.0 ≤ and <11.0, Positive ≥ 11.0

Units of Measurement: mIU/mL

Hepatitis Testing



5. Hepatitis B virus Serology – Anti-HBe

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Lithium

Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 300ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive \geq 1.1, Equivocal \leq 0.9 and <1.1, Reactive < 0.9

Units of Measurement: Index

6. Hepatitis B virus Serology – HBeAg

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Lithium

Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 300ul **Turnaround Time:** 5 Days

Reference Ranges: Negative <0.09, Equivocal ≥ 0.09 and <0.11, Positive ≥ 0.11

Units of Measurement: PEIU/mL

7. Hepatitis B virus Serology – HBc IgM

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Lithium

Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 250ul Turnaround Time: 5 Days

Reference Ranges: Non-reactive <0.9, Equivocal \geq 0.9 and <1.1, Reactive \geq 1.1

Units of Measurement: Index

8. Hepatitis C virus Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples including specimens collected from post-mortem donors (non-heart beating). Post-mortem specimens must be collected within 24 hours of death.

Specimen Required: Blood (ACD), Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (ACD),

Plasma (EDTA), Plasma (Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 300ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive <1.0, Reactive ≥1.0

Units of Measurement: S/CO

Hepatitis Testing



9. Hepatitis C virus Serology

TEST DETAILS

Assay Name: Bio-Rad Monolisa HCV Ag-Ab ULTRA V2 EIA **Test Method:** Semi-quantitative enzyme immunoassay **Specimen Type:** Human serum and plasma samples

Specimen Required: Blood (ACD), Blood (EDTA), Blood (Gel Tube), Blood (Sodium Citrate), Plasma (ACD), Plasma (EDTA), Plasma

(Sodium Citrate), Serum Specimen Volume Min: 100ul Turnaround Time: 5 Days

Reference Ranges: Negative <1.0, Positive ≥1.0. Units of Measurement: S/Co ratio

10. Hepatitis A Serology - Anti-HAV

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples **Specimen Required:** Serum, Plasma (Sodium Heparin)

Specimen Volume Min: 500ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive ≥ 1.1, Equivocal ≤ 0.9 and <1.1, Reactive <0.9

Units of Measurement: Index

11. Hepatitis A Serology - HAV IgM

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Lithium Heparin), Plasma

(Sodium Citrate), Serum Specimen Volume Min: 300ul Turnaround Time: 5 Days

Reference Ranges: Non-reactive <0.9, Equivocal \geq 0.9 and <1.1, Reactive \geq 1.1

Units of Measurement: Index

12. Hepatitis C virus Serology - Western Blot

TEST DETAILS

Assay name: MP Diagnostics HCV Blot 3.0 WB Test Method: Qualitative enzyme immunoassay Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 50ul

Results Interpretation: Non-reactive: No bands of 1+ or greater reactivity

Reactive: 1+ or greater reactivity to 2 or more HCV antigens OR 2+ or greater reactivity to core band only **Indeterminate:** Any single HCV band of 1+ or greater reactivity but does not meet criteria for positive

Turnaround Time: 7 Days **Reference Ranges:** N/A

Units of Measurement: HCV specific bands

HIV Testing



1. Human immunodeficiency virus Serology Screening (HIV)

TEST DETAILS

Test Method: Antigen/ Antibody CLIA

Specimen Type: Human serum and plasma samples including specimens collected from post-mortem donors (non-heart beating). Post-mortem specimens must be collected within 24 hours of death.

Specimen Required: Blood (ACD), Blood (EDTA), Blood (Gel Tube), Blood (Lithium and Sodium Heparin), Blood (Sodium Citrate), Plasma (ACD), Plasma (EDTA), Plasma (Lithium and Sodium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 400ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive <1.0, Reactive ≥ 1.0

Units of Measurement: S/CO

2. Bio-Rad Geenius HIV 1/2 Confirmatory Rapid Assay

TEST DETAILS

Test Method: Rapid immunochromatographic qualitative assay

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Heparin), Blood (Citrate), Plasma (ACD), Plasma (EDTA), Plasma (Heparin), Plasma (Citrate),

Serum

Specimen Volume Min: 100ul Turnaround Time: 3 Days Reference Ranges: N/A Units of Measurement: N/A

3. MP Diagnostics HIV Blot 2.2 WB

TEST DETAILS

Test Method: Qualitative enzyme immunoassay **Specimen Type:** Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Heparin), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Heparin), Plasma (Sodium Citrate),

Serum

Specimen Volume Min: 50ul

Result Interpretation:

Non-Reactive

- No viral specific bands present: HIV NEGATIVE
- Detection of p17 antibodies only: HIV NEGATIVE

Reactive:

- $\bullet \quad \text{Detection of 2 ENV (gp160/gp41 and gp120) and any of GAG (p17, p24, p55) or POL (p31, p51, p66): HIV-1 POSITIVE}\\$
- Detection of 2 ENV (gp160/gp41 and gp120) and any of GAG (p17, p24, p55) or POL (p31, p51, p66) and HIV-2 specific band is visible: HIV-1 POSITIVE with HIV-2 INDICATED

<u>Indeterminate:</u>

- Any viral specific bands present but pattern does not meet criteria for POSITIVE: INDETERMINATE
- Any viral specific bands present but pattern does not meet criteria for POSITIVE but HIV-2 specific band is visible: INDETERMINATE
 with HIV-2 INDICATED

Turnaround Time: 7 Days

Units of Measurement: HIV specific bands

HTLV Testing



1. Human T lymphotropic viruses I and II Serology (HTLV)

TEST DETAILS

Test Method: Total Antibody CLIA

Specimen Type: Human serum and plasma samples including specimens collected from post-mortem donors (non-heart beating).

Post-mortem specimens must be collected within 24 hours of death.

Specimen Required: Blood (ACD), Blood (EDTA), Blood (Gel Tube), Blood (Lithium Heparin), Blood (Sodium Citrate), Plasma (ACD),

Plasma (EDTA), Plasma (Lithium Heparin), Plasma (Sodium Citrate), Serum

Specimen Volume Min: 500ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive < 1.0, Reactive ≥ 1.0

Units of Measurement: S/CO

2. MP Diagnostics HTLV Blot 2.4 WB

TEST DETAILS

Test Method: Qualitative enzyme immunoassay **Specimen Type:** Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Heparin), Blood (Sodium Citrate), Plasma (EDTA), Plasma (Heparin), Plasma (Sodium Citrate),

Serum

Specimen Volume Min: 50ul

Result Interpretation:

Non-Reactive

• No reactivity to HTLV specific proteins: HTLV Negative

Reactive:

- Reactivity to GAG (p19 with or without p24) and two ENV (GD21 and rgp46-I): HTLV-I Positive
- Reactivity to GAG (p24 with or without p19) and two ENV (GD21 and rgp46-II): HTLV-II Positive
- Reactivity to GAG (p19 and p24) and ENV (GD21):
- (HTLV-I Positive if p19≥ p24): HTLV-I Positive
- (HTLV-II Positive if p19< p24): HTLV-II Positive

Indeterminate:

• HTLV specific bands detected but do not meet criteria for HTLV-I, HTLV-II or HTLV positive: Indeterminate

Turnaround Time: 7 Days **Reference Ranges:** N/A

Units of Measurement: HTLV specific bands

3. HTLV-1 Proviral Load (PVL) Assay

TEST DETAILS

 $\textbf{Test Method:} \ \mathsf{Quantitative} \ \mathsf{Polymerase} \ \mathsf{Chain} \ \mathsf{Reaction} \ (\mathsf{qPCR})$

Intended Use: For monitoring HTLV-1 proviral load in patients where a diagnosis of HTLV-1 has been made by serology

Specimen Type: Peripheral Blood Mononuclear Cells (PBMCs) or Peripheral Blood Leukocytes (PBLs) isolated from whole blood

Specimen Required: Blood (EDTA) transported at ambient (15-25°C) temperature; Blood (BD Vacutainer® CPT" Mononuclear Cell

Preparation Tube - Sodium Citrate) transported on side at 2-21°C following centrifugation. Specimen Volume Min: 4mL

Turnaround Time: 5 Days

Units of Measurement: Blood (EDTA): HTLV-1 copies/10⁵ PBLs, Blood (CPT™ - Sodium Citrate): HTLV-1 copies/10⁵ PBMCs

Multiplex Testing



1. Multiplex HIV/HCV/HBV Nucleic Acid Test- Cobas MPX Test

TEST DETAILS

Test Method: Qualitative multiplex test

Specimen Type: Human serum and plasma samples including specimens collected from living and post-mortem donors (non-heart beating).

Specimen Required:

Living donor blood samples

- Plasma collected in EDTA, CPD, CPDA1, CP2D and 4% Sodium Citrate (apheresis plasma) anticoagulant and serum collected in serum clot tubes
- Blood collected in CPD, CPDA1, CP2D anticoagulant, Becton-Dickinson EDTA Plasma Preparation Tubes (BD PPT") or Greiner Vacuette® K2EDTA Plasma Gel Tubes
- Blood collected in serum clot tubes (without plug or separator)

Plasma and Serum samples must be centrifuged within 72 hours of draw.

Cadaveric blood samples

- Cadaveric blood collected in EDTA anticoagulant
- Cadaveric blood samples collected in serum clot tubes (without plug or separator)

Plasma and Serum samples must be centrifuged within 72 hours of draw.

Note: Specimens collected from cadaver donors must be collected within 24 hours of death.

Specimen Volume Min:

- Living Donor Samples: 1.1ml
- Cadaveric Donor Samples: 400μL

Turnaround Time: 7 Days **Units of Measurement:** Ct values

Please refer to Sample Storage and Transport Requirements for further information: <u>Click here</u>

Rubella Testing



1. Rubella IgG II Serology (Quantitative)

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Heparin), Plasma (EDTA), Plasma (Heparin), Serum

Specimen Volume Min: 200ul **Turnaround Time:** 5 Days

Reference Ranges: Negative < 7.0, Equivocal ≥ 7.0 and < 10.0, Positive ≥ 10.0

Units of Measurement: IU/mL

2. Rubella IgM Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Citrate), Plasma (EDTA), Plasma (Citrate), Serum

Specimen Volume Min: 200ul **Turnaround Time:** 5 Days

Reference Ranges: Non-reactive < 20.0, Equivocal ≥ 20.0 and < 25.0, Reactive ≥ 25.0

Units of Measurement: AU/mL

Syphilis Testing



1. Treponema Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples including specimens collected from post-mortem donors (non-heart beating).

Post-mortem specimens must be collected within 24 hours of death.

Specimen Required: Blood (EDTA), Blood Heparin), Blood (Citrate), Plasma (EDTA), Plasma (Heparin), Plasma (Citrate), Serum

Specimen Volume Min: 300ul **Turnaround Time:** 5 Days

Reference Ranges: Negative <0.9, Equivocal ≤0.9-<1.1, Reactive ≥1.1

Units of Measurement: Index

2. Becton Dickenson BD Macro-Vue Rapid Plasma Reagin (RPR) Card Test (Qualitative and Quantitative)

TEST DETAILS

Test Method: Agglutination

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Heparin), Plasma (EDTA), Plasma (Heparin), Serum

Specimen Volume Min: 100ul Turnaround Time: 3 Days Reference Ranges: N/A Units of Measurement: N/A

Toxoplasma Testing



1. Toxoplasma gondii IgG Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

Specimen Required: Blood (EDTA), Blood (Heparin), Blood (Citrate), Plasma (EDTA), Plasma (Heparin), Plasma (Citrate), Serum

Specimen Volume Min: 200ul **Turnaround Time:** 5 Days

Reference Ranges: Negative <7.2, Equivocal \geq 7.2 and <8.8, Positive \geq 8.8

Units of Measurement: IU/mL

2. Toxoplasma gondii IgM Serology

TEST DETAILS

Test Method: CLIA

Specimen Type: Human serum and plasma samples

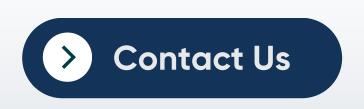
Specimen Required: Blood (EDTA), Blood (Heparin), Blood (Citrate), Plasma (EDTA), Plasma (Heparin), Plasma (Citrate), Serum

Specimen Volume Min: 200ul **Turnaround Time:** 5 Days

Reference Ranges: Negative <6.0, Equivocal ≥ 6.0 and <8.0, Positive ≥ 8.0

Units of Measurement: AU/mL

For more information about our testing services or to discuss your specific requirements, please reach out to us - we are here to help





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