

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

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 ≥ 12.0 and < 14.0 , Reactive ≥ 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

1. 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 $0.9 \leq$ 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 $9.0 \leq$ and < 11.0, Positive ≥ 11.0

Units of Measurement: mIU/mL

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 ≥ 1.1 , Equivocal ≤ 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 ≥ 0.9 and < 1.1 , Reactive ≥ 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

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 \geq 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 \geq 1.1, Equivocal \leq 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

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:

- 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

Indeterminate:

- 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

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

NEW

TEST DETAILS

Test Method: Quantitative Polymerase Chain Reaction (qPCR)

Intended Use: The NRL In-House HTLV-1 proviral load (PVL) Assay is an in-vitro nucleic acid amplification test for quantification of Human T lymphotropic type 1 (HTLV-1) viral DNA integrated within genomic DNA (gDNA) obtained from cells of blood from patients already established to have been exposed to virus by HTLV-1 serology. The assay incorporates the quantitative assessment of both an HTLV-1 target sequence as well as an internal human control sequence by qPCR.

This assay is not intended for use as an aid in diagnosis or confirmatory assay for HTLV-1 and is developed as a Class 3 IVD for monitoring HTLV-1 proviral load in patients where a diagnosis of HTLV-1 has been made by serology.

Specimen Type and Minimum Volume Requirements:

1. Whole Blood (EDTA):

- Minimum of 4mL of whole blood collected in a non-separator EDTA tube (e.g., Greiner VACUETTE® EDTA and/or BD Vacutainer® EDTA)
- Samples should be transported at ambient temperature (15 – 25°C).
- Samples must be received at NRL within 10 days from collection.

2. Whole Blood (CPT with Sodium Citrate):

- Minimum of 4mL whole blood collected in BD Vacutainer® CPT with sodium citrate.
- Centrifuge samples according to the tube manufacturer's instructions.
- Following centrifugation, tubes must be stored and transported chilled (2 – 8°C) in a horizontal orientation (on their sides).
- Samples must be received at NRL within 10 days from collection.

3. Buffy Coat / PBMCs:

- Minimum of 400 µL of buffy coat or PBMCs resuspended in 100 µL of PBS per 1 mL of whole blood processed.

4. Dried Blood Spots (DBS), Formalin-Fixed Paraffin-Embedded (FFPE) specimens, Cerebrospinal fluid (CSF) and Bronchoalveolar Lavage (BAL) samples (Research use only)

- Contact NRL clinical and research services for minimum specimen volume and sample storage/transport requirements for these specimens (rd@nrlquality.org.au).

Turnaround Time: 5 working days upon specimen receipt.

Reference Ranges:

- Limit of Detection of Assay: 5.8 copies/reaction
- Limit of Quantification of Assay: 12.5 copies/reaction

Units of Measurement:

- HTLV-1 copies/10⁵ cells
- Blood (EDTA): HTLV-1 copies/10⁵ Peripheral Blood Leukocytes (PBLs)
- Blood (CPT™ - Sodium Citrate): HTLV-1 copies/10⁵ Peripheral Blood Mononuclear Cells (PBMCs)

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: [Click here](#)

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

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

3. Newmarket Biomedical (NewBio) TPHA

TEST DETAILS

Test Method: TPHA

Specimen Type: Human serum, EDTA Plasma

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

Specimen Volume Min: 150uL

Turnaround Time: 5 working days upon specimen receipt.

Reference Ranges: Non-reactive, Equivocal or Reactive

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 ≥ 7.2 and <8.8, Positive ≥ 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**



Contact Us



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