RapidQ

Quality, Simplified

Product Catalogue

2025

NRL

Science of Quality

Table of Contents

RapidQ ensures reliable results, **anytime, anywhere**

What is Point-of-Care Testing?

Point-of-Care Testing (PoCT) enables diagnostic testing close to the patient, providing immediate results that directly impact clinical decisions. This rapid result availability is crucial in settings where follow-up care is difficult due to geographic, social, economic, or environmental challenges.

PoCT's versatility is evident in its use of rapid diagnostic tests (RDTs) and portable molecular testing (NATs) for infectious diseases like SARS-CoV-2. These technologies are easy to use and don't require specialised laboratory equipment, making PoCT ideal for non-traditional settings such as schools, airports, and workplaces.

However, PoCT, like all diagnostic testing, is regulated and requires regular performance reviews. These checks are often harder to conduct in non-laboratory environments, especially when tests are performed by non-laboratory professionals. Testing failures can result in poor patient outcomes, resource waste, inaccurate epidemiological data, and the spread of infections, underscoring the need for robust quality assurance (QA) programs.

Current QA programs are tailored for well-resourced laboratories and are often cost-prohibitive for resource-limited settings. To address this gap, **NRL has developed a specialised QA model for infectious disease PoCT, designed specifically for these environments.**

RapidQ Model

The RapidQ program is comprised of two key components:

Competency Panels (CP):

Competency Panels evaluate operator proficiency through known positive and negative samples. The positive sample exhibits moderate reactivity across most PoCT methods. These panels are tested periodically to assess assay performance and user competence.

External Quality Assessment Panels (EQA):

EQA panels follow the same structure as NRL traditional programs, consisting of four or five vials with varying reactivity, unknown to the operator. The operator tests and reports results as if from real patient samples, with immediate feedback provided upon submission.

RapidQ Program Design:

The RapidQ program supports PoCT sites in meeting quality standards. Sites should regularly participate in competency assessments and use EQA to confirm the detection of various analytes. While participation frequency is flexible, NRL recommends specific intervals for each site, as outlined *below.*

Minimum quality testing for sites	Optimal quality testing for sites
CP testing **once** per month	CP testing **once** per week
EQAS testing **twice** per year	EQAS testing **three** times per year

RapidQ Programs are designed for analyte specific testing. Please contact NRL to determine availability in your region or if you would like to partner with us to develop other PoCT QA programs.

Our Features

RapidQ Management

The RapidQ model is delivered through Implementing Partners, not directly to individual test sites. NRL partners with organisations like the World Health Organization (WHO), ministries of health, IVD manufacturers, and major procurement bodies (e.g., the Global Fund, the Clinton Foundation, FIND) to manage networks of test sites. Regulatory authorities reviewing IVD performance may also act as Implementation Partners.

Logistics

Implementing Partners order RapidQ panels for 6-12 months to supply their test site networks. The panels are shipped ambient, requiring no UN3373 compliance. Local regulations must be followed, though importation permits may not be necessary. The panels are stored at a centralised warehouse under NRL's specified conditions before being distributed to test sites, where they can be stored at 2-8°C or room temperature.

Samples

The RapidQ competency and EQAS panels contain non-infectious, well-characterised clinical or biological materials, such as whole viruses or bacteria. These samples are validated for most PoCT devices and are not extracted nucleic acids or recombinant materials.

Storage

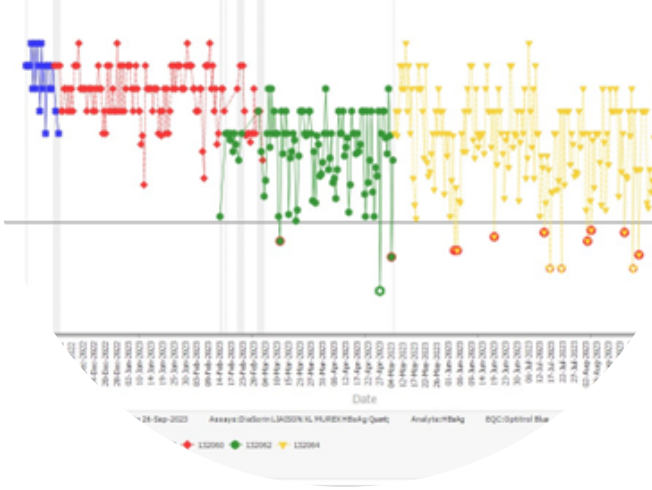
RapidQ panel samples are stable for 24 months when frozen, 6-8 months at 2-8°C, and 3 months at room temperature.

Software

NRL has developed an informatics system, built on EDCNet™, for result entry and data analysis via QR code mobile technology. This system supports PoCT sites that lack regular computer-based internet access, as most individuals have smartphones. This innovative approach facilitates participation in QA without time and software restrictions.

Result Analysis

All data are stored in a central database and analysed periodically. Any unusual variations in test performance are reported to the test site, Implementing Partner, and IVD manufacturer. Critical issues are escalated to the WHO and regulatory authorities



EDCNet™

First developed by NRL in 2001, EDCNet™ has been a cornerstone of our international quality control programs for over two decades. As a global leader in infectious disease testing monitoring, NRL has consistently advanced quality control practices beyond traditional methods. Now, this expertise is powering RapidQ, with EDCNet™ enhanced to support both qualitative and quantitative data monitoring.

What is EDCNet?

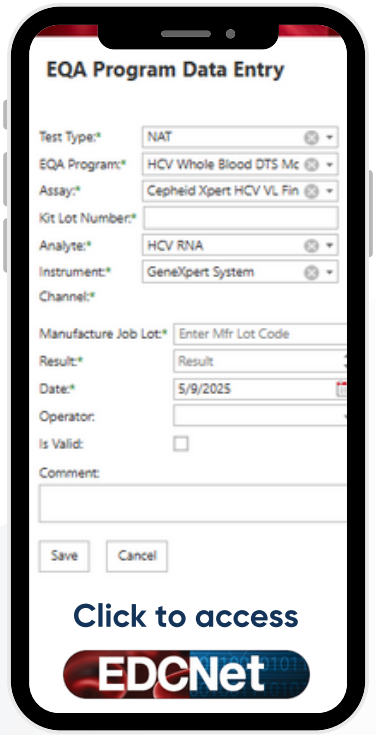
- A virtual, cloud-based database- accessible from anywhere with internet access.
- No software installation required- just enrol and log in.
- Fully GDPR compliant (EU 2016/679).
- Six languages - English, French, German, Italian, Spanish and Polish

How it Works

1. **Enrolment:** Each test site joins EDCNet™ and is issued unique user logins.
2. **Registration:** Sites register their test kits and instrumentation in the system.
3. **Panel Access:** When Competency or EQAS panels are received, users simply scan the QR code on the box.
4. **Auto-Fill:** The system pre-fills key fields (e.g., test kits, panel names, instrument details).
5. **Data Entry:** Users select the sample, reagent lot number, operator name, and testing date.
6. **Instant Feedback:** Once submitted, the results are analysed and immediate performance feedback is provided.

What Happens to the Data?

- All results are securely stored in a central database.
- Data are analysed by NRL staff in real time.
- Unusual or unexpected results are investigated, ensuring accuracy and reliability.
- Reports are generated and shared with the test site, Implementing Partner, and/or IVD manufacturer, depending on the context.



READY-TO-ORDER PRODUCTS

HBV

1. HBV Serology RDT Competency (SC11058)

PROGRAM DETAILS

Program Code: SC11058
Analyte(s): HBsAg
Sample Type: Synthetic whole blood-like sample
Compatible With: HBV lateral flow devices testing serum, plasma or capillary whole blood
Panel Format: 2 vial; 0.5mL each
Description: The positive vial consists of human whole blood-like sample known to be positive for HBsAg at a known reactivity. The negative sample is uninfected human whole blood-like sample

2. HBV Serology RDT PoC EQA (HBSR4)

PROGRAM DETAILS

Program Code: HBSR4
Analyte(s): HBsAg
Sample Type: Synthetic whole blood-like sample
Compatible With: HBV lateral flow devices testing serum, plasma or capillary whole blood
Panel Format: 4 vial; 0.5mL each
Description: Each vial consists of human whole blood-like sample, uninfected or infected with various hepatitis B profiles

3. HBV Dried Plasma Molecular Competency (MC11058)

PROGRAM DETAILS

Program Code: MC11058
Analyte(s): HBV DNA
Sample Type: Dried serum/plasma sample
Compatible With: HBV molecular tests that use serum or plasma
Component: 4 vial: 2 vials dry, 2 vials 1.2mL each reconstitution buffer
Description: The positive vial consists of dried human serum or plasma known to be infected with HBV DNA at a specified concentration in IU/mL. The negative sample is dried uninfected human serum or plasma. The reconstitution buffer is phosphate buffered saline

4. HBV Dried Plasma Molecular PoC EQA (DPBR4)

PROGRAM DETAILS

Program Code: DPBR4
Analyte(s): HBV DNA
Sample Type: Dried serum/plasma sample
Compatible With: HBV molecular tests that use serum or plasma
Component: 8 vial: 4 vials dry, 4 vials 1.2mL each reconstitution buffer
Description: Each vial consists of dried human serum of plasma either uninfected or infected with HBV DNA of various genotypes and concentrations. The reconstruction buffer is phosphate buffered saline

HCV

1. HCV Whole Blood Molecular Competency (MC20028)

PROGRAM DETAILS

Program Code: MC20028
Analyte(s): HCV RNA
Sample Type: Dried Whole Blood Sample
Compatible With: HCV Molecular tests that use fingerstick whole blood
Panel Format: 4 vial: 2 vials dry, 2 vials 0.25mL each PBS
Description: The positive vial consists of dried human whole blood known to be infected with HCV RNA at a specified concentration in IU/mL. The negative sample is dried uninfected human whole blood. The reconstitution buffer is phosphate buffered saline

2. HCV Whole Blood Molecular PoC EQA (DBCR4)

PROGRAM DETAILS

Program Code: DBCR4
Analyte(s): HCV RNA
Sample Type: Dried Whole Blood Sample
Compatible With: HCV Molecular tests that use fingerstick whole blood
Component: 8 vial: 4 vials dry, 4 vials 0.25mL each PBS
Description: Each vial consists of dried human whole blood either uninfected or infected with HCV RNA of various HCV genotypes and concentrations. The reconstitution buffer is phosphate buffered saline

3. HCV Serology RDT Competency (SC11028)

PROGRAM DETAILS

Program Code: SC11028
Analyte(s): anti-HCV
Sample Type: Synthetic whole blood-like sample
Compatible With: HCV Molecular tests that use fingerstick whole blood
Component: 2 vial; 0.5mL each
Description: The positive vial consists of human whole blood-like sample known to be positive for anti-HCV at a known reactivity. The negative sample is uninfected human whole blood-like sample

4. HCV Serology RDT PoC EQA (HCSR4)

PROGRAM DETAILS

Program Code: HCSR4
Analyte(s): anti-HCV
Sample Type: Synthetic whole blood-like sample
Compatible With: HCV Molecular tests that use fingerstick whole blood
Component: 4 vial; 0.5mL each
Description: Each vial consists of human whole blood-like sample, uninfected or infected with anti-HCV of various genotypes and concentrations

5. HCV Dried Plasma Molecular Competency (MC11028)

PROGRAM DETAILS

Program Code: MC11028
Analyte(s): HCV RNA
Sample Type: Dried serum/plasma sample
Compatible With: HCV molecular tests that use serum or plasma
Component: 4 vial: 2 vials dry, 2 vials 1.2mL each
Description: The positive vial consists of dried human serum or plasma known to be infected with HCV RNA at a specified concentration in IU/mL. The negative sample is dried uninfected human serum or plasma. The reconstitution buffer is phosphate buffered saline

6 HCV Dried Plasma Molecular PoC EQA (DPCR4)

PROGRAM DETAILS

Program Code: DPCR4
Analyte(s): HCV RNA
Sample Type: Dried serum/plasma sample
Compatible With: HCV molecular tests that use serum or plasma
Component: 8 vial: 4 vials dry, 4 vials 1.2mL each reconstitution buffer
Description: Each vial consists of dried human serum of plasma either uninfected or infected with HCV RNA of various concentrations. The reconstitution buffer is phosphate buffered saline

HIV

1. HIV Serology RDT Competency (SC11038)

PROGRAM DETAILS

Program Code: SC11038
Analyte(s): anti-HIV
Sample Type: Synthetic whole blood-like sample
Compatible With: HIV Lateral flow devices testing serum, plasma or capillary whole blood
Component: 2 vial; 0.5mL each
Description: The positive vial consists of a human whole blood-like sample known to be positive for anti-HIV at a known reactivity. The negative sample is uninfected human whole blood-like sample

2. HIV Serology RDT PoC EQA (HISR4)

PROGRAM DETAILS

Program Code: HISR4
Analyte(s): anti-HIV and/or HIV p24 Ag, *only for the HISR program*
Sample Type: Synthetic whole blood-like sample
Compatible With: HIV Lateral flow devices testing serum, plasma or capillary whole blood
Component: 4 vial; 0.5mL each
Description: Each vial consists of whole blood-like sample, uninfected or infected with anti-HIV and/or HIV p24 Ag of various genotypes and concentrations

3. HIV Dried Plasma Molecular Competency (MC11037)

PROGRAM DETAILS

Program Code: MC11037
Analyte(s): HIV RNA & DNA
Sample Type: Dried serum/plasma sample
Compatible With: HIV molecular tests that use serum, plasma and whole blood, and assays used in molecular early infection diagnostics
Component: 4 vial: 2 vials dry, 2 vials 1.2mL each reconstitution buffer
Description: The positive vial consists of dried human serum or plasma known to be infected with HIV RNA and/or DNA at a specified concentration in both IU/mL and copies/mL. The negative sample is dried uninfected human serum or plasma. The reconstitution buffer is phosphate buffered saline

4. HIV Dried Plasma Molecular PoC EQA (DPIR4)

PROGRAM DETAILS

Program Code: DPIR4
Analyte(s): HIV RNA & DNA
Sample Type: Dried serum/plasma sample
Compatible With: HIV molecular tests that use serum, plasma and whole blood, and assays used in molecular early infection diagnostics
Component: 8 vial: 4 vials dry, 4 vials 1.2mL each reconstitution buffer
Description: Each vial consists of dried human serum or plasma either uninfected or infected with HIV RNA and/or DNA of various genotypes or concentrations. The reconstitution buffer is phosphate buffered saline

SARS-CoV-2

1. SARS-CoV-2 Antigen RDT Competency (MC18088)

PROGRAM DETAILS

Program Code: MC18088
Analyte(s): SARS-CoV-2 Antigen
Sample Type: Clinical liquid sample
Compatible With: Most COVID-19 Ag Rapid Diagnostic Tests (Contact NRL for more details)
Component: 1 x Positive, 1 x Negative
Description: The positive vial consists of inactivated SARS-CoV-2 virus suspended in a transport medium. The negative vial contains uninoculated transport medium

2. SARS-CoV-2 Antigen RDT PoC EQA (SCVR4)

PROGRAM DETAILS

Program Code: SCVR4
Analyte(s): SARS-CoV-2 Antigen
Sample Type: Clinical liquid sample
Compatible With: Most COVID-19 Ag Rapid Diagnostic Tests (Contact NRL for more details)
Component: 4 x Test Vials
Description: Each vial contains either uninoculated transport medium or inactivated SARS-CoV-2 virus variants of concern at different concentrations

Serology Multi-Marker

1. Multi-Marker Serology RDT Competency (SC11018)

PROGRAM DETAILS

Program Code: SC11018
Analyte(s): HBsAg, anti-HCV, anti-HIV, anti-*Treponema pallidum*
Sample Type: Synthetic whole blood-like sample
Compatible With: Lateral flow devices testing serum, plasma or capillary whole blood for the target analyte(s)
Component: 2 vial; 0.5mL each
Description: The positive vial consists of a human whole blood-like sample known to be positive for HBsAg, anti-HCV, anti-HIV and/or anti-*Treponema pallidum* at a known reactivity. The negative sample is uninfected human whole blood-like sample

2. Multi-Marker Serology RDT PoC EQA (MMSR4)

PROGRAM DETAILS

Program Code: MMSR4
Analyte(s): HBsAg, anti-HCV, anti-HIV and anti-*Treponema pallidum*
Sample Type: Synthetic whole blood-like sample
Compatible With: Lateral flow devices testing serum, plasma or capillary whole blood for the target analyte(s)
Component: 4 vial; 0.5mL each
Description: Each vial consists of human whole blood-like sample, uninfected or infected with HBsAg, anti-HIV, anti-HCV and/or Syphilis of various concentrations

C. trachomatis, N. gonorrhoeae

1. C. trachomatis & N. gonorrhoeae Swab Molecular Competency (MC17096)

PROGRAM DETAILS

Program Code: MC17096
Analyte(s): C. *trachomatis* and N. *gonorrhoeae*
Sample Type: Clinical swab
Compatible With: Molecular tests
Component: 2 dry swabs
Description: Two dried swabs, one positive for C. *trachomatis* and the other positive for N. *gonorrhoeae*, each being the negative control for the other analyte

2. C. trachomatis & N. gonorrhoeae Swab Molecular PoC EQA (CNTR4)

PROGRAM DETAILS

Program Code: CNTR4
Analyte(s): C. *trachomatis* and N. *gonorrhoeae*
Sample Type: Clinical swab
Compatible With: Molecular tests
Component: 4 dry swabs
Description: Each swab contains different concentrations of clinical materials known to be positive for *C. trachomatis* and/or *N. gonorrhoeae*. Various swabs may be infected with other serovars of Chlamydia or Neisseria spp

Syphilis

1. Syphilis Serology RDT Competency (SC17068)

PROGRAM DETAILS

Program Code: SC17068
Analyte(s): anti-*Treponema pallidum*
Sample Type: Synthetic whole blood-like sample
Compatible With: Syphilis lateral flow devices testing serum, plasma or capillary whole blood
Component: 2 vial; 0.5mL each
Description: The positive vial consists of a human whole blood-like sample known to be positive for *anti-T. pallidum* at a known reactivity. The negative sample is uninfected human whole blood-like sample

2. Syphilis Serology RDT PoC EQA (TPSR4)

PROGRAM DETAILS

Program Code: TPSR4
Analyte(s): anti-*Treponema pallidum*
Sample Type: Synthetic whole blood-like sample
Compatible With: Syphilis lateral flow devices testing serum, plasma or capillary whole blood
Component: 4 vial; 0.5mL each
Description: Each vial consists of human whole blood-like sample, uninfected or infected with Syphilis of various concentrations

Tuberculosis

1. Tuberculosis Molecular Competency (MC17118)

PROGRAM DETAILS

Program Code: MC17118
Analyte(s): *M. tuberculosis* Complex bacteria
Sample Type: Clinical liquid sample
Compatible With: Most TB near-patient PCR (contact NRL for more details)
Component: 2 vial; 1.2mL each
Description: The positive vial consists of inactivated *M. tuberculosis* bacteria suspended in a buffer. The negative vial contains uninoculated buffer

2. Tuberculosis Molecular POC EQA (MTBR4)

PROGRAM DETAILS

Program Code: MTBR4
Analyte(s): *M. tuberculosis* and drug resistant strains
Sample Type: Clinical liquid sample
Compatible With: Most TB near-patient PCR (contact NRL for more details)
Component: 4 vial; 1.2mL each
Description: Each vial contains either uninoculated buffer or inactivated *M. tuberculosis* bacteria at different concentrations

IN-DEVELOPMENT

HPV & Group A Strep

The following programs are currently in-development and not yet available for enrolment:

1. **HPV Molecular Competency (MC17108)**
2. **HPV Molecular POC EQA (HPVR4)**
3. **Group A Strep Molecular**

If you are interested in any of these upcoming programs or would like to discuss your laboratory's needs, please get in touch today.

+61 3 9418 1111

info@nrlquality.org.au

nrlquality.org.au