NRL PoCT QA

2023 Catalogue

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NRL – About us

The National Serology Reference Laboratory, Australia (NRL) is a not-for-profit, scientific organisation located in Melbourne Australia. We are a World Health Organization (WHO) Collaborating Centre and an authorised WHO Prequalification Evaluation laboratory.

NRL's mission:
To promote the quality of tests and testing for infectious diseases globally.

NRL is accredited to a number of international quality standards, complying with the following:

- ✓ ISO 17043 (Proficiency Testing Scheme Provider)
- ✓ ISO 15189 (Medical Testing Laboratory)
- ✓ ISO 9001 (Quality Management Systems)
- ✓ Current Good Manufacturing Practice (cGMP) (Human Blood and Tissues)

To support its mission, NRL performs the following activities:

- Highly sophisticated quality assurance programs
- Quality control samples and monitoring software
- International proficiency testing programs to 2000+ laboratories in 70+ countries
- Pre- and post-market evaluations of *In-vitro* Diagnostics (IVDs) and associated sample panels
- Specialised and reference testing services, licensed to cGMP
- Biobanking expertise and a significant disease-state plasma bank
- Laboratory capacity and capability building in low- and middle-income countries
- Educational workshops and seminars, mentoring and consultancy
- Global research collaborations

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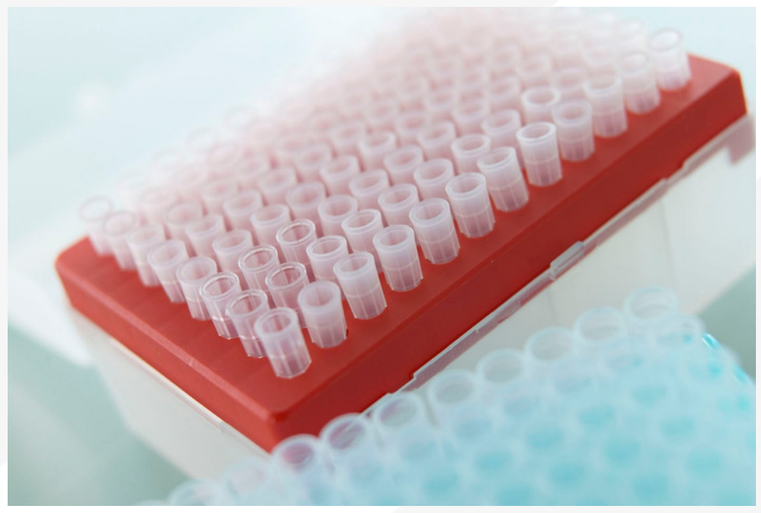
PoCT

Near-patient or Point-of-Care Testing (PoCT) is a way of performing diagnostic testing close to a patient, so that the result can have immediate effect on patient management. Consequently, results from PoCT are used to make critical clinical decisions. The speed at which these results become available also mean that PoCT is used in environments where patient follow-up (i.e. regular monitoring of patients) can be challenging. These challenges are caused by some, or all of the following; geography, conflict, natural disasters, social and cultural issues and economic factors.

The versatility of PoCT has been demonstrated, specifically with rapid diagnostic testing (RDTs) and portable molecular testing technologies (also known as NATs) for infectious diseases such as SARS-CoV-2. RDTs and portable NATs are easy to use and do not require specialist laboratory equipment, unlike laboratory-based testing. This has seen the implementation of PoCT in non-traditional environments, such as schools, airports and workplaces.



All testing which affects patient management is strictly regulated, and includes regular reviews of diagnostic test performance. These checks are rarely performed outside of a laboratory environment, and they can be made more difficult as the people performing the tests are often not laboratory professionals.

All tests can experience failures (1-3). These testing failures can lead to a range of complications including poor patient outcomes, waste of resources, skewed epidemiolocal data, further transmission of infections, unnecessary treatment, loss of confidence in the testing process, and social impact of individuals, especially related to sexually transmitted infections. It is vital that PoCT is monitored by a fit-for-purpose quality assurance (QA) program (4-6).

However, the QA programs currently available are designed for well-resourced laboratory environments, with appropriate infrastructure. Subscribing to these programs is cost prohibitive, owing to the lack of equivalent facilities to store, process, and test samples (7). Therefore, NRL has designed and implemented a QA model for infectious disease testing specifically designed for PoCT environments, including resource-limited settings (NRL PoCT QA).

Looking at the NRL PoCT QA Model-

PoCT QA is comprised of two complementary challenges:

Competency Panels (CP):

The Competency Panels are deigned to assess the competency of the operator, and they consist of a positive and a negative sample. The positive sample is designed to have moderate reactivity on most PoCT. The Competency Panels have been designed to be tested periodically throughout the year, to allow the assessment of ongoing performance (7, 8).

External Quality Assessment Panels (EQA):

The EQAS panels are designed in the same way as NRL's traditional EQA program. The panels consists of 5 vials. Each vial has different reactivity which is unknown to the operator. The operator tests and reports the result of each vial as if it were a true patient specimen. An immediate assessment of the result is then provided at the time of submission.

NRL PoCT QA Program Design:

The NRL PoCT QA program is designed to support PoCT site's quality requirements. A PoCT site should participate in competency assessments regulary, in order to monitor testing performance, in addition to utilising EQAS to access the ability to detect various analytes. The frequency of participation can be defined by the Implementing Partner, however, NRL suggests the following frequency's for each site, as seen on the right.

Following frequency for each site:

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

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Features of NRL PoCT QA

NRL PoCT QA Management

The NRL PoCT QA model is designed to be provided by Implementing Partners, and is not available directly to individual test sites. NRL provides the NRL PoCT QA program to Implementing Partners overseeing a network of test sites, such as the World Health Organization (WHO), ministries of health and IVD manufacturers. Major procurement organisations such as the Global Fund and the Clinton Foundation, as well as FIND or regulatory authorities which review the performance of testing of IVDs, may also be considered as Implementation Partners.

Logistics

The Implementation Partner orders sufficient Quantity of PoCT QA Panels for 6-12 months, to supply their network of testing sites. The panels are shipped ambient, and do not require UN3373. Many countries will not require importation permits, however, local regulations must be followed. The panels are stored at a centralised warehouse in conditions instructed by NRL until they are distributed to the test sites. Then, they can be stored at 2-8°C, as well as room temperature.

Samples

The NRL PoCT competency and EQAS panel samples contain non-infectious materials that are validated for most PoCT devices. All samples are well-characterised, clinical or biological materials, such as whole virus/bacteria rather than extracted nucleic acids or recombinant materials (7, 8).

Storage

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

Software

Building on EDCNet™, NRL designed informatics for the result entry and data analysis of NRL PoCT QA results, through quick response (QR) mobile phone technology. PoCT sites do not always have ready access to computer-based internet, but most individuals have access to smartphone technology. This has led NRL to develop a unique process to facilitate PoCT sites participation in QA, without the restrictions of time limitations.

Result Analysis

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

Logistics

Samples

Storage

Software

Result Analysis

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EDCNet™

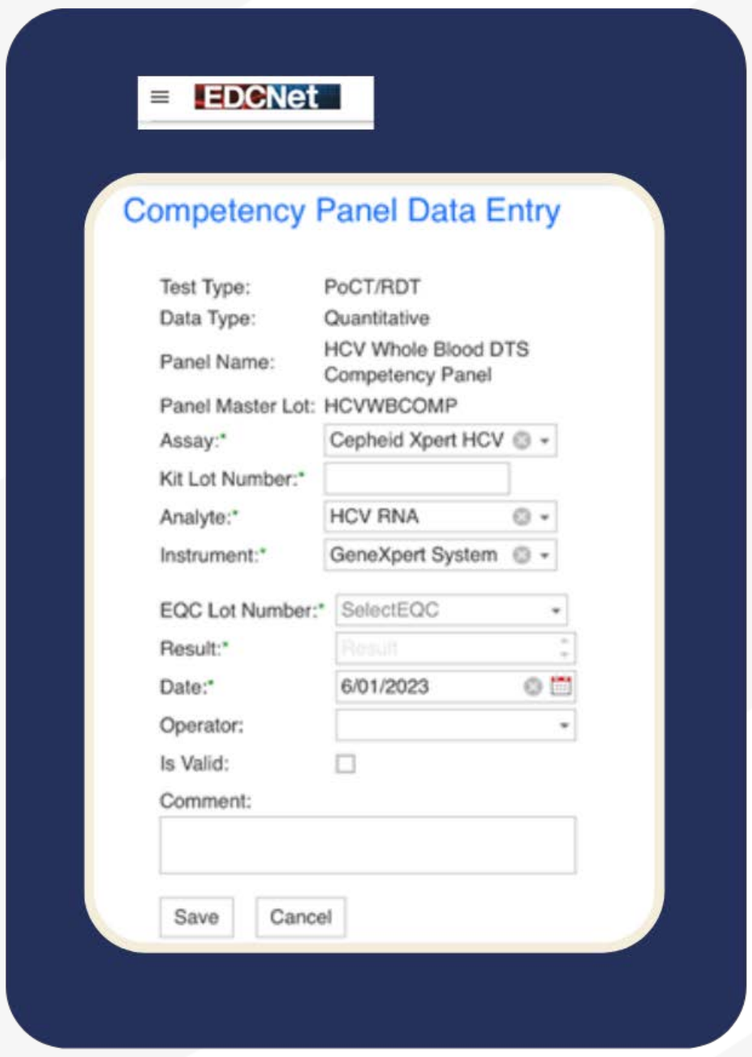
NRL developed EDCNet™in 2001, and has been provided in conjunction with an international quality control program ever since (9). NRL is a world-leader in the monitoring of infectious disease testing, and has developed novel approaches to quality control which is more fit-for-purpose than traditional methods (10). NRL has brought this expertise to PoCT, upgrading EDCNet™ to monitor both qualitative and quantitative data from PoCT.

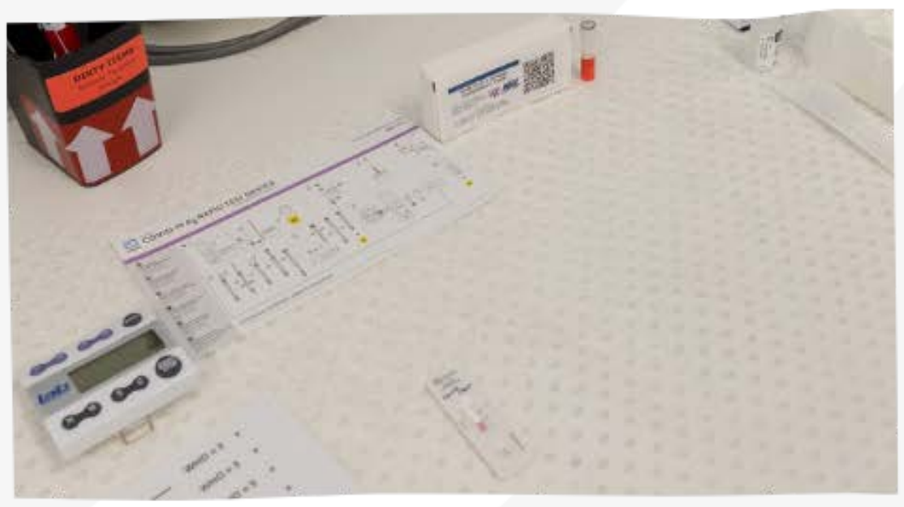
EDCNet™ is a virtual database accessible anywhere internet is available. No software downloads are required, just enrolment into the system. The database is secure and complies with GDPR requirements outlined in the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.

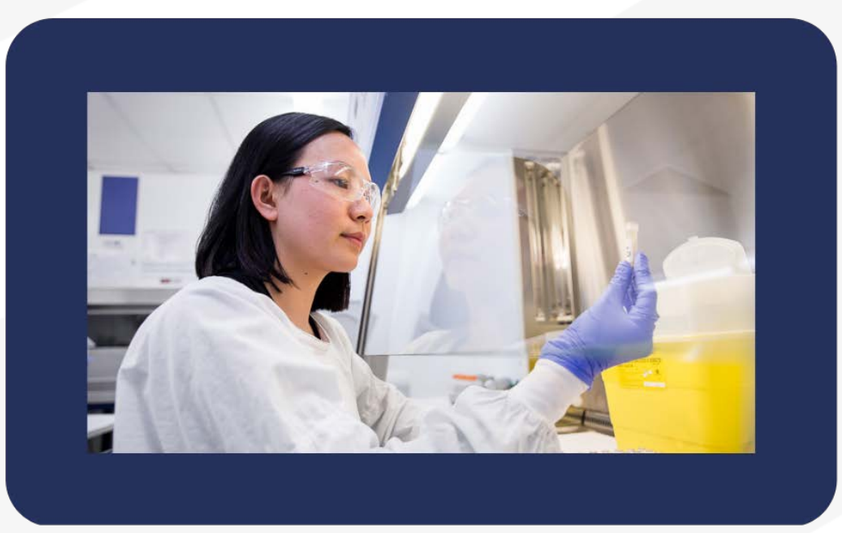
Test sites are enrolled in EDCNet™ and all users are assigned a unique login and password. The test kits and any instrumentation used by the test site are added to EDCNet™ during this setup. On receipt of Competency or EQAS Panels, the user scans a QR code on the box. This QR code will automatically log the user into the EDCNet™ data entry page, and open the data entry screen, auto-populating fields such as test kits, Competency Panel names and instrument details. Where multiple options are available, a drop-down selector is presented. The operator selects the sample being tested, and basic information such as reagent lot number, operator name and date of testing. On submission of results, the data will be analysed, and a response is immediately generated.

The data are stored in a central database and are analysed by NRL staff. Any unusual test results will be investigated by NRL staff and a report provided to the test site, the Implementing Partner and/or the IVD manufacturer, depending on the findings.

EDCNet can also be accessed by clicking this link: *https://edcnet.nrlquality.org.au*







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NRL PoCT QA Programs

NRL PoCT QA 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.

HCV Whole Blood Molecular PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HCVWBCPL	HCVWBEQA
ANALYTE(S)	HCV RNA	
SAMPLE TYPE	Dried whole blood sample	
COMPATIBLE WITH	HCV molecular tests that use fingerstick whole blood	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 2 x 250µL reconstitution buffers	5 x test vials; 5 x 250µL reconstitution buffers
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.	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.

SARS-CoV-2 Antigen Rapid Diagnostic Tests

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	2COVGCPL	2COVGEQA
ANALYTE(S)	SARS-CoV-2 Antigen	
SAMPLE TYPE	Nasal swab	
COMPATIBLE WITH	Most COVID-19 Ag Rapid Diagnostic Tests (contact NRL for more details)	
PANEL FORMAT	1 x positive vial; 1 x negative vial	5 x test vials
DESCRIPTION	The positive vial consists of inactivated SARS-CoV-2 virus suspended in a transport medium. The negative vial contains uninoculated transport medium.	Each vial contains either uninoculated transport medium or inactivated SARS-CoV-2 virus variants of concern at different concentrations.

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Dried Plasma HCV Viral Load PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HCVSPCPL	HCVSPEQA
ANALYTE(S)	HCV RNA	
SAMPLE TYPE	Dried serum/plasma sample	
COMPATIBLE WITH	HCV molecular tests that use serum or plasma	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 2 x 1.2mL reconstitution buffers	5 x test vials; 5 x 1.2mL reconstitution buffers
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.	Each vial consists of dried human serum or plasma, either uninfected or infected with HCV RNA of various HCV genotypes and at various concentrations. The reconstitution buffer is phosphate buffered saline.

Dried Plasma HIV Viral Load PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HIVSPCPL	HIVSPEQA
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	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 2 x 1.2mL reconstitution buffers	5 x test vials; 5 x 1.2mL reconstitution buffers
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.	Each vial consists of dried human serum or plasma either uninfected or infected with HIV RNA or DNA of various genotypes and concentrations. The reconstitution buffer is phosphate buffered saline.

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Dried Plasma HBV Viral Load PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HBVSPCPL	HBVSPEQA
ANALYTE(S)	HBV DNA	
SAMPLE TYPE	Dried serum/plasma sample.	
COMPATIBLE WITH	HBV molecular tests that use serum or plasma	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 2 x 1.2mL reconstitution buffers	5 x test vials; 5 x 1.2mL reconstitution buffers
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.	Each vial consists of dried human serum or plasma either uninfected or infected with HBV DNA or DNA of various genotypes and concentrations. The reconstitution buffer is phosphate buffered saline.

C. trachomatic and *N. gonorrhoea* Molecular PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	CTNGCPL	CTNGEQA
ANALYTE(S)	*C. trachomatis* and *N. gonorrhoea*	
SAMPLE TYPE	Clinical swab	
COMPATIBLE WITH	CTNG molecular tests	
PANEL FORMAT	1 x swab positive for *C. trachomatis*; 1 x swab positive for *N. gonorrhoea*	5 x swabs of various reactives for *C. trachomatis* and/or *N. gonorrhoea*
DESCRIPTION	Two dried swabs, one positive for *C. trachomatis* and the other positive for *N. gonorrhoea,* each being the negative control for the other analyte.	Each swab contains different concentrations of clinical materials known to be positive for a combination of *C. trachomatis* or *N. gonorrhoea.* Various swabs may be infected with other serovars of *Chlamydia* or *Neisseria spp.* These may include antibiotic resistant strains.

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SARS-CoV-2 virus Molecular PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	2COVNCPL	2COVNEQA
ANALYTE(S)	SARS-CoV-2 virus	
SAMPLE TYPE	Clinical liquid sample	
COMPATIBLE WITH	Most COVID-19 near-patient PCR (contact NRL for more details)	
PANEL FORMAT	1 x positive vial; 1 x negative vial, 0.5mL each	5 x test vials at 1.2mL
DESCRIPTION	The positive vial consists of inactivated SARS-CoV-2 virus suspended in a transport medium. The negative vial contains uninoculated transport medium.	Each vial contains either uninoculated transport medium or inactivated SARS-CoV-2 virus variants of concern at different concentrations.

Mycobacterium tuberculosis Molecular PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	MTBCPL	MTBEQA
ANALYTE(S)	*M. tuberculosis* Complex Bacteria	*M. tuberculosis* and drug resistant strains
SAMPLE TYPE	Clinical liquid sample	
COMPATIBLE WITH	Most TB near-patient PCR (contact NRL for more details)	
PANEL FORMAT	1 x positive vial; 1 x negative vial	5 x test vials at 1.2mL
DESCRIPTION	The positive vial consists of inactivated *M. tuberculosis* bacteria suspended in a buffer. The negative vial contains uninoculated buffer.	Each vial contains either uninoculated buffer or inactivated *M. tuberculosis* bacteria at different concentrations.

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HIV Serology PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HIVLFCPL	HIVLFEQA
ANALYTE(S)	anti-HIV & HIV p24	
SAMPLE TYPE	synthetic whole blood-like sample	
COMPATIBLE WITH	HIV lateral flow devices testing serum, plasma or capillary whole blood	
PANEL FORMAT	1 x positive vial; 1 x negative vial, 0.5mL each	5 x 0.5 mL test vials
DESCRIPTION	The positive vial consists of human whole blood-like sample known to be positive for anti-HIV and/or HIV p24 at a known reactivity. The negative sample is uninfected human whole blood-like sample.	Each vial consists of a whole blood-like sample, uninfected or infected with HIV of various genotypes and concentrations.

HCV Serology PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HCVLFCPL	HCVLFEQA
ANALYTE(S)	anti-HCV	
SAMPLE TYPE	Synthetic whole blood-like sample	
COMPATIBLE WITH	HCV lateral flow devices testing serum, plasma or capillary whole blood	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 0.5mL each	5 x 0.5mL test vials
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.	Each vial consists of serum/plasma whole blood-like sample, uninfected or infected with HCV of various genotypes and concentrations.

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HBV Serology PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	HBVLFCPL	HBVLFEQA
ANALYTE(S)	anti-HBs, HBsAg	
SAMPLE TYPE	synthetic whole blood-like sample	
COMPATIBLE WITH	HBV lateral flow devices testing serum, plasma or capillary whole blood	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 0.5mL each	5 x 0.5mL test vials
DESCRIPTION	The positive vial consists of human whole blood-like sample known to be positive for anti-HBs and/or HBsAg at a known reactivity. The negative sample is uninfected human whole blood-like sample.	Each vial consists of serum/plasma whole blood-like sample, uninfected or infected with HBV of various genotypes and concentrations.

Syphilis Serology PoCT QA

	COMPETENCY PANEL	EQAS PANEL
PROGRAM CODE	SYPLFCPL	SYPLFEQA
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	
PANEL FORMAT	1 x positive vial; 1 x negative vial; 0.5mL each	5 x 0.5mL test vials
DESCRIPTION	The positive vial consists of 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.	Each vial consists of serum/plasma whole blood-like sample, uninfected or infected with Syphilis of various concentrations.

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