

Quality
Control
Solutions
Catalogue

20
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ABOUT NRL

NRL was established in 1985 as part of the Australian Government's HIV/AIDS Strategy, to evaluate HIV tests and adjudicate on the interpretation of HIV test results. Today, NRL remains a not-for-profit scientific organisation that exists for the benefit of the public. Its overall goal is to support laboratories, in Australia and internationally, that perform testing for the diagnosis and management of human infectious disease. NRL is designated a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.



MISSION

To promote the quality of tests and testing for infectious diseases globally.

GOALS

NRL seeks to ensure that laboratory results for infectious diseases are of high quality by providing:

- Comprehensive and innovative quality assurance services
- Evaluations of tests and test algorithms
- Specialised laboratory testing services
- Training with sustainable outcomes
- Consultation and advice on policy relating to laboratory testing

WHAT IS QCONNECT?

A READY-TO-USE CONCEPT

Ready-to-use concept means that the controls may remain directly in the carrier or robots of the test system. The manual filling step is no longer necessary. Less dead volume is required for multi analyte measurements in a single vial, thus saving customers valuable control material.

ADVANTAGES

- Products developed according to individual platforms (e. g. for ARCHITECT®, LIAISON® and others).
- High yield.
- Ready to use.
- Less sources of error.
- Better protection against contamination.
- Predefined control limits.
- Barcoded labels.
- Easy handling and highly efficient.

1 WHAT IS QCONNECT AND WHY USE IT?

QConnect is a completely integrated and simplified QC solution. Everything connected to QC – ordering of customised QC samples, results management and reporting, control limits, Uncertainty of Measurement (MU) reports, troubleshooting and the ability to liaise with other users and experts - are all streamlined into a single portal.



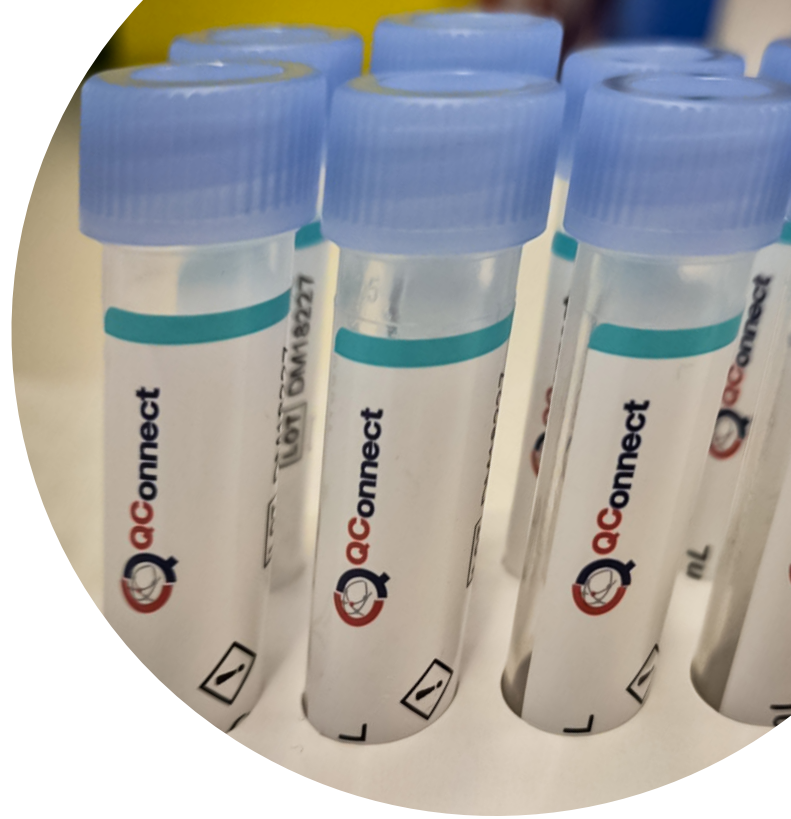
2 QCONNECT FEATURES

- QConnect QC samples have been specifically optimised and validated to match assays commonly used for infectious disease testing. These QC samples have been designed to react at an appropriate level within the analytical range of various assays.
- QConnect QC samples are registered IVDs, manufactured in an ISO 13485 facility and where applicable, are standardised against WHO international standards leading to traceability claims, consistent with ISO 17511.
- QConnect QC samples are ready-to-use and are barcoded to ensure traceability. For your convenience, the Serology Multimarker Range of products is easily identifiable by their colour coding.

3 QC SAMPLES

- A single batch of each QConnect QC sample is available, allowing all QConnect participants using the same assay to compare their QC results.
- This QConnect catalogue offers a selection of QC samples for clinical and blood screening laboratories performing serology and/or Nucleic Acid Testing (NAT). Simply locate the manufacturer and system currently in use, and select the appropriately matched QC.

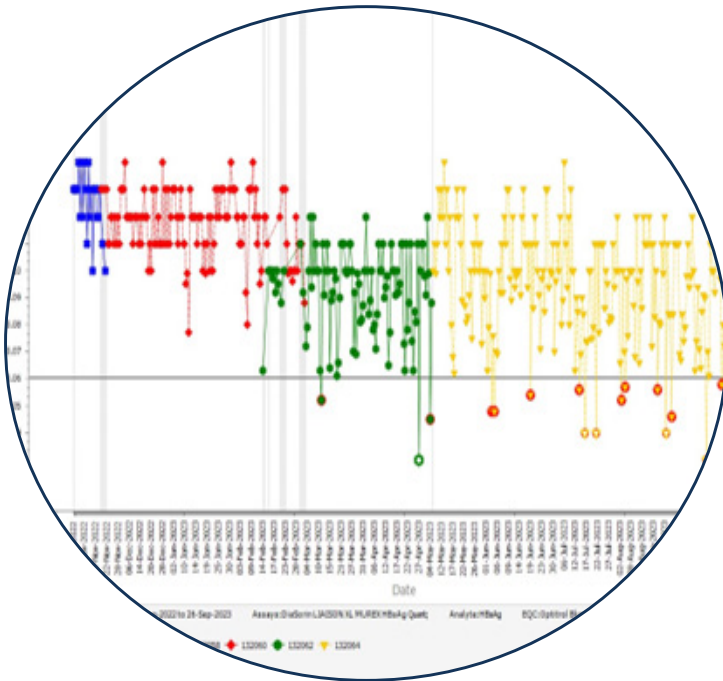
Establishing standing orders are highly recommended as a way of ensuring that your stock never runs low.



4 EDCNET

EDCNet is an internet-based multilingual software free with the purchase of Optitrol QConnect products, specifically designed for monitoring both serology and NAT QC results. EDCNet allows for the simple collection, management and analysis of QC data with ongoing real time support from the NRL QC Services team. Once registered, QConnect members can access EDCNet through logging in with your unique username and password. The anonymity of all participants is protected by a unique laboratory code and latest IT security systems.

QConnect members who use EDCNet can share QC data to assess the accuracy and precision of their assays. All QConnect-labelled products are automatically set up in EDCNet, and the functionality is designed for all levels of users. Customised QC reports, providing real-time review of results in a Levey-Jennings, Mean/Scatter, graphical or tabular format, can be sent directly to each QConnect member by email or saved as a PDF. EDCNet also has a "network" option that allows a group of laboratories to track trends and compare QC test results across all laboratories within that network.



5 INTERFACING

EDCNet interfacing is a move towards automated data entry and subsequent analysis of QConnect testing data, available to all QConnect users. This has been developed to remove the cumbersome and time-consuming manual data entry process and will improve the overall experience of EDCNet data entry. Interfacing has currently been implemented for 5 different instruments from 4 major diagnostic device manufacturers, with more in the pipeline.

EDCNet can now be interfaced with multiple instruments for automated upload of QConnect QC and related Kit Control data. For interfacing to work, bridging software has been developed that links the user system to the EDCNet server, accepting multiple file formats containing testing data. For QConnect users to implement the EDCNet interfacing in their system, a subscription fee will be charged per instrument.

For more information regarding EDCNet interfacing, and related technical details, get in touch with our customer relations team: customerengagement@nrlquality.org.au

6 QCONNECT LIMITS

QConnect Limits take advantage of peer data sharing and provides users robust, predetermined control limits. QConnect Limits are based on more than 10 years of QC data and are available for commonly used QC sample/assay combinations. These statistically validated QC limits give you the confidence to know immediately when your system is not running to specification.

What are QConnect Limits?

- QConnect Limits, developed by NRL, utilise historical data determining expected upper and lower values of results for each EQC sample/assay combination. This method is an improvement on traditional QC approaches used to determine QC limits which have been derived from clinical chemistry and may not be applicable to serology or NAT assays.
- Over time, multiple lots of QC samples have been tested by many laboratories, operators and instruments across numerous reagent lots. Data extracted from EDCNet reflects the expected extent of variation for that QC sample/assay combination.
- QConnect Limits allow for the identification of any unexpected QC result, potentially identifying unacceptable variation from a range of sources including reagent lots; instruments or equipment calibration and maintenance; operator errors; assay and QC sample storage and transport or environmental conditions.

How to use QConnect Limits?

- When entering data into EDCNet, results outside the QConnect Limits for that QC sample/assay combination are flagged in red, indicating further investigation is required. All results outside the QConnect Limits are held in quarantine until they are reviewed by an NRL Quality services staff member.
- Participants can overlay QConnect Limits on Levey-Jennings and other EDCNet charts in conjunction with laboratory-specific and other statistical overlay options. NRL also provides a suggested approach, including a check list, for the investigation and troubleshooting of unexpected results.

7 MU REPORTS

To fulfil regulatory requirements with ease, you can subscribe to annual MU reports specific for your laboratory. NRL has developed a method for estimating and reporting MU for assays based on a comparison of your laboratory's QC results, with those reported by other laboratories (peer group). The methodology for determining MU is published and scientifically validated. The MU estimation accounts for the assay's imprecision (random error) and bias (systematic error).

8 NEWS & INVESTIGATIONS

We know you don't have time to spend countless hours searching for information. NRL also supplies a list of relevant literature about QC for infectious diseases testing including:

- Journal Publications
- Presentations
- Investigations and Case Studies
- Laboratory Standards and Requirements

9 Q&A'S

The QConnect portal provides you with a repository of information including frequently asked questions about the usage, storage, testing or troubleshooting of results obtained from your QC sample.

If you can't find the answers there, additional questions can always be directed to:

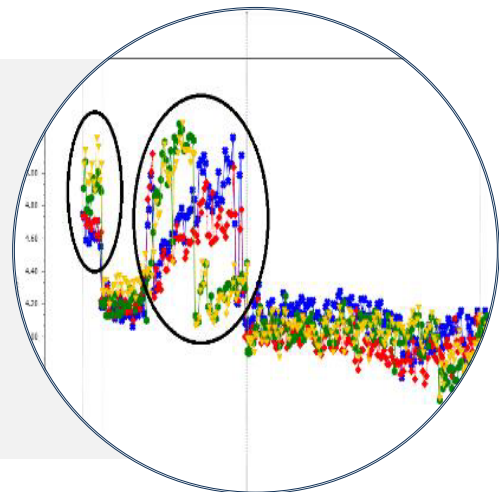
qconnect@nrlquality.org.au

10 SUPPORT

NRL provides scientific and technical support to all QConnect and EDCNet users. All data outside QConnect Limits are reviewed on a daily basis by NRL Quality Assurance Team (QA). As part of the personalised QConnect service, NRL QA Team are available to perform detailed investigations into unusual QC results, liaise with assay manufacturers and issue written reports.



The NRL QConnect approach is the only scientifically validated way to monitor infectious disease testing QC results.



SEROLOGY MULTI-MARKER Blood Screening

Optitrol Blue



Manufacturer	System	Storage and Stability	Analytes included
Abbott →	ARCHITECT Alinity i / s	Sealed:* 24 months at 2 to 8°C	Anti-HBc IgG Anti-HCV IgG Anti-HIV-1 IgG Anti-HTLV-I IgG Anti-Treponema IgG HBsAg
DiaSorin →	LIAISON LIAISON XL	After opening: 90 days at 2 to 8°C	

CAT NO.	CONTENT	KIT
SR11011	Positive control	4 x 5.0 mL

Optitrol Red



Manufacturer	System	Storage and Stability	Analytes included
Roche →	Elecsys cobas	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HBc IgG Anti-HCV IgG Anti-HIV-1 IgG Anti-HTLV-I IgG Anti-Treponema IgG HBsAg

CAT NO.	CONTENT	KIT
SR11051	Positive control	4 x 5.0 mL

Optitrol Green



Manufacturer	System	Storage and Stability	Analytes included
Bio-Rad →	EVOLIS	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HBc IgG Anti-HCV IgG Anti-HIV-1 IgG Anti-HTLV-I IgG Anti-Treponema IgG HBsAg

CAT NO.	CONTENT	KIT
SR11043	Positive control	2 x 5.0 mL

Optitrol Orange



Manufacturer	System	Storage and Stability	Analytes included
Siemens →	ADVIA Centaur Atellica	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HBc IgG Anti-HCV IgG Anti-HIV-1 IgG Anti-HTLV-I IgG Anti-Treponema IgG HBsAg

CAT NO.	CONTENT	KIT
SR11061	Positive control	4 x 5.0 mL

Optitrol SeroNeg



Manufacturer	System	Storage and Stability	Negative for
Abbott →	ARCHITECT Alinity i / s	Sealed:* 36 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HAV
Bio-Rad →	EVOLIS		Anti-HBc
DiaSorin →	LIAISON LIAISON XL		Anti-HBe
Roche →	Elecsys cobas		Anti-HBs
Siemens →	ADVIA Centaur Atellica		Anti-HCV
			Anti-HEV
			Anti-HIV-1
			Anti-HTLV-I
			Anti-Treponema
			HBeAg
			HBsAg
			HIVp24 Ag

CAT NO.	CONTENT	KIT
SR11002	Positive control	2 x 5.0 mL

SEROLOGY MULTI-MARKER Hepatitis

Optitrol HEPA-1



Manufacturer	System	Storage and Stability	Analytes included
bioMérieux →	VIDAS	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HAV IgM
DiaSorin →	LIAISON LIAISON XL		Anti-HBc IgM
Wantai →	ELISA		Anti-HEV IgM
			HBeAg

CAT NO.	CONTENT	KIT
SR12027	Positive control	2 x 2.5 mL

Optitrol HEPA-2



Manufacturer	System	Storage and Stability	Analytes included
Abbott →	ARCHITECT Alinity i	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HAV IgM
Mikrogen →	ELISA		Anti-HBc IgM
Roche →	Elecsys cobas		Anti-HEV IgM
Siemens →	ADVIA Centaur Atellica		HBeAg

CAT NO.	CONTENT	KIT
SR12037	Positive control	2 x 2.5 mL

*From date of manufacture.

Optitrol HEPR-1



Manufacturer	System	Storage and Stability	Analytes included
DiaSorin →	LIAISON LIAISON XL	Sealed:* 18 months at 2 to 8°C	Anti-HAV IgG Anti-HBe IgG
Wantai →	ELISA	After opening: 90 days at 2 to 8°C	Anti-HBs IgG Anti-HEV IgG

CAT NO.	CONTENT	KIT
SR12047	Positive control	2 x 2.5 mL

Optitrol HEPR-2



Manufacturer	System	Storage and Stability	Analytes included
Abbott →	ARCHITECT Alinity i	Sealed:* 18 months at 2 to 8°C	Anti-HAV IgG Anti-HBe IgG
Mikrogen →	ELISA	After opening: 90 days at 2 to 8°C	Anti-HBs IgG Anti-HEV IgG
Roche →	Elecsys cobas		
Siemens →	ADVIA Centaur Atellica		

CAT NO.	CONTENT	KIT
SR12057	Positive control	2 x 2.5 mL

SEROLOGY MULTI-MARKER ToRCH

Optitrol ToRCH G



Manufacturer	System	Storage and Stability	Analytes included
Abbott →	ARCHITECT Alinity i	Sealed:* 24 months at 2 to 8°C	Anti-CMV IgG Anti-EBV EBNA IgG
bioMérieux →	VIDAS	After opening: 90 days at 2 to 8°C	Anti-EBV VCA IgG Anti-HSV 1 IgG
DiaSorin →	LIAISON LIAISON XL		Anti-Rubella IgG Anti-Toxoplasma IgG

CAT NO.	CONTENT	KIT
SR13017	Positive control	2 x 2.5 mL

Optitrol ToRCH M



Manufacturer	System	Storage and Stability	Analytes included
Abbott →	ARCHITECT Alinity i	Sealed:* 24 months at 2 to 8°C	Anti-CMV IgM
bioMérieux →	VIDAS	After opening: 90 days at 2 to 8°C	Anti-EBV VCA IgM
DiaSorin →	LIAISON LIAISON XL		Anti-HSV-1 IgM
			Anti-Rubella IgM
			Anti- <i>Toxoplasma</i> IgM

CAT NO.	CONTENT	KIT
SR13027	Positive control	2 x 2.5 mL

SEROLOGY MULTI-MARKER Others

Optitrol Paediatric G



Manufacturer	System	Storage and Stability	Analytes included
DiaSorin →	LIAISON LIAISON XL	Sealed:* 24 months at 2 to 8°C	Anti-Measles IgG
		After opening: 90 days at 2 to 8°C	Anti-Mumps IgG
			Anti-Parvo B19 IgG
			Anti-VZV IgG

CAT NO.	CONTENT	KIT
SR15017	Positive control	2 x 2.5 mL

Optitrol Paediatric G-2



Manufacturer	System	Storage and Stability	Analytes included
bioMérieux →	VIDAS	Sealed:* 24 months at 2 to 8°C	Anti-Measles IgG
		After opening: 90 days at 2 to 8°C	Anti-Mumps IgG
			Anti-Parvo B19 IgG
			Anti-VZV IgG

CAT NO.	CONTENT	KIT
SR15027	Positive control	2 x 2.5 mL

*From date of manufacture.

SEROLOGY SINGLE-MARKER

Blood Screening

Optitrol HIV p24



Manufacturer	System	Storage and Stability	Analytes included
Abbott	→ ARCHITECT Alinity i / s	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	HIV-1 p24 Antigen
Bio-Rad	→ VIDAS		
bioMérieux	→ VIDAS		
DiaSorin	→ LIAISON LIAISON XL		
Roche	→ Elecsys cobas		
Siemens	→ ADVIA Centaur Atellica		

CAT NO.	CONTENT	KIT
SR11103	Positive control	4 x 2.5 mL

Optitrol HIV 2



Manufacturer	System	Storage and Stability	Analytes included
Abbott	→ ARCHITECT Alinity i / s	Sealed:* 36 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-HIV-2-IgG
DiaSorin	→ LIAISON LIAISON XL		
Roche	→ Elecsys cobas		
Siemens	→ ADVIA Centaur Atellica		

CAT NO.	CONTENT	KIT
SR11117	Positive control	2 x 2.5 mL

Optitrol Syphilis G



Manufacturer

Biokit
Bio-Rad
Fujirebio
Newmarket Biomedical
Trinity Biotech

Storage and Stability

Sealed:*
24 months at 2 to 8°C
After opening:
90 days at 2 to 8°C

Analytes included

Anti-*Treponema pallidum* IgG

CAT NO.	CONTENT	KIT
SR11137	Positive control	2 x 2.5 mL

SEROLOGY SINGLE-MARKER Tropical Diseases

Optitrol Malaria



Manufacturer

Trinity Biotech →

System

ELISA

Storage and Stability

Sealed:*
24 months at 2 to 8°C
After opening:
90 days at 2 to 8°C

Analytes included

Anti-*Plasmodium* sp. IgG

CAT NO.	CONTENT	KIT
SR16017	Positive control	2 x 2.5 mL

*From date of manufacture.

SEROLOGY SINGLE-MARKER

Others

Optitrol COVID-19 G



Manufacturer	System	Storage and Stability	Analytes included
Abbott	→ ARCHITECT Alinity i	Sealed:* 24 months at 2 to 8°C	Anti-SARS-CoV-2 IgG
AESKU	→ AESKULISA	After opening: 60 days at 2 to 8°C	
bioMérieux	→ VIDAS		
DiaSorin	→ LIAISON LIAISON XL		
EUROIMMUN	→ ELISA		
NovaTec	→ NovaLisa		
Roche	→ Elecsys cobas		
YHLO	→ iFlash		

CAT NO.	CONTENT	KIT
SR14037	Positive control	2 x 2.5 mL

Optitrol HSV 2



Manufacturer	System	Storage and Stability	Analytes included
DiaSorin	→ LIAISON LIAISON XL	Sealed:* 24 months at 2 to 8°C	Anti-HSV-2 IgG
		After opening: 90 days at 2 to 8°C	

CAT NO.	CONTENT	KIT
SR13037	Positive control	2 x 2.5 mL

Optitrol Parvo M



Manufacturer	System	Storage and Stability	Analytes included
DiaSorin	→ LIAISON LIAISON XL	Sealed:* 24 months at 2 to 8°C	Anti-Parvo B19 IgM
		After opening: 90 days at 2 to 8°C	

CAT NO.	CONTENT	KIT
SR15057	Positive control	2 x 2.5 mL

Optitrol Mumps M



Manufacturer	System	Storage and Stability	Analytes included
DiaSorin →	LIAISON LIAISON XL	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-Mumps IgM

CAT NO.	CONTENT	KIT
SR15067	Positive control	2 x 2.5 mL

Optitrol VZV M



Manufacturer	System	Storage and Stability	Analytes included
DiaSorin →	LIAISON LIAISON XL	Sealed:* 24 months at 2 to 8°C After opening: 90 days at 2 to 8°C	Anti-VZV IgM

CAT NO.	CONTENT	KIT
SR15077	Positive control	2 x 2.5 mL

*From date of manufacture.

MOLECULAR QUALITY CONTROLS

Blood Borne Viruses

Optitrol NAT HBV Viral Load



Assay/Instrument

All HBV viral load assays

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

HBV DNA

CAT NO.	CONTENT	KIT
NT01014	Positive control	10 x 1.2 mL

Optitrol NAT HCV Viral Load



Assay/Instrument

All HCV viral load assays

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

HCV RNA

CAT NO.	CONTENT	KIT
NT01024	Positive control	10 x 1.2 mL

Optitrol NAT HIV Viral Load



Assay/Instrument

All HIV viral load assays

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

HIV-1 RNA

CAT NO.	CONTENT	KIT
NT01034	Positive control	10 x 1.2 mL

Optitrol NAT HIV-2



Assay/Instrument

All HIV viral load assays

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

HIV-2 RNA

CAT NO.	CONTENT	KIT
NT01036	Positive control	10 x 1.2 mL

Optitrol NAT NEG



Assay/Instrument

Negative for HBV,
HCV, HIV-1/-2 a.o.

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Negative for

HBV DNA
HCV RNA
HIV-1/-2 a.o. RNA

CAT NO.	CONTENT	KIT
NT01051	Negative control	10 x 1.2 mL

Optitrol NAT Triplex



Assay/Instrument

Roche cobas MPX

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

HBV DNA
HCV RNA
HIV-1 RNA

CAT NO.	CONTENT	KIT
NT01042	Positive control	10 x 1.2 mL

*From date of manufacture.

MOLECULAR QUALITY CONTROLS

Other

Optitrol NAT CMV



Assay/Instrument

All qualitative and viral load CMV DNA assays

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

CMV DNA

CAT NO.	CONTENT	KIT
NT02022	Positive control	10 x 1.2 mL

Optitrol NAT CT/NG



Assay/Instrument

All assays that detect *Chlamydia trachomatis* / *Neisseria gonorrhoeae*

Storage and Stability

Sealed:*
24 months at -20 to -40 °C,
5 days at 2 to 8 °C
After opening:
24 hours at 2 to 8 °C

Analytes included

Chlamydia trachomatis
Neisseria gonorrhoeae

CAT NO.	CONTENT	KIT
NT02012	Positive control	10 x 1.2 mL

Optitrol NAT HPV



Assay/Instrument

All HPV qualitative assays

Storage and Stability

Sealed:*
24 months at 2 to 8 °C
After opening:
5 days at 2 to 8 °C

Analytes included

HPV DNA (Genotype 16, 18 & 51)

CAT NO.	CONTENT	KIT
NT06012	Positive control	10 x 1.2 mL

Optitrol NAT HPV NEG



Assay/Instrument

All HPV qualitative assays

Storage and Stability

Sealed:*

24 months at 2 to 8 °C

After opening:

5 days at 2 to 8 °C

Negative for

HPV DNA

CAT NO.	CONTENT	KIT
NT06014	Negative control	10 x 1.2 mL

Optitrol NAT SARS-CoV-2



Assay/Instrument

All assays that detect SARS-CoV-2 RNA

Storage and Stability

Sealed:*

24 months at -20 to -40 °C,

5 days at 2 to 8 °C

After opening:

24 hours at 2 to 8 °C

Analytes included

SARS-CoV-2 RNA

CAT NO.	CONTENT	KIT
NT04032	Positive control	10 x 0.6 mL

*From date of manufacture.