

# Quality Control Solutions

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## ABOUT DIAMEX

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Based on many years of experience with our associated plasma donation centres in Heidelberg and Munich, the expansion of the range of services from plasma sourcing to the production of in vitro diagnostics was a strategic consequence.

DiaMex offers a portfolio of manufacturer-independent serological and NAT quality controls and directs its energy towards the continual development of new products according to the needs of our customers.

The controls are designed to optimally accommodate the requirements/demands of the modern laboratory.

At the same time, we take care to keep an optimal price-performance ratio along with the highest quality standards. Our actions are also determined through the observance of legal and regulatory requirements as well as continually striving for improvement.

DiaMex is certified according to DIN EN ISO 13485.

Long term cooperation with our partners builds the basis for our growth. We see the further development of the product portfolio together with our partners as a significant factor of success.

## ABOUT NRL

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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 diseases. 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?

QConnect is your completely integrated and simplified QC solution.



## WHY USE QCONNECT?

Because 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.

We've made QC easy.

## QCONNECT FEATURES

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### QC SAMPLES

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Optitrol QC samples have been specifically optimised and validated to match assays commonly used for infectious diseases testing. These QC samples have been designed to react at an appropriate level within the analytical range of various assays.

Optitrol QC samples are registered IVDs, manufactured in an ISO 13485 facility and where applicable, are standardised against the WHO international standards leading to traceability claims, consistent with ISO 17511.

Optitrol QC serology samples are ready-to-use and are bar-coded to ensure traceability. For your convenience, the Serology Multimarker Range of products is easily identifiable by their colour coding. Globally, a

single batch of each Optitrol QC sample is available, allowing all QConnect participants using the same assay to compare their QC results.

This Optitrol catalogue offers a selection of QC samples for clinical and blood screening laboratories performing serology and/or Nucleic Acid Testing (NAT) for a range of infectious diseases. Simply locate the assay currently in use and select the appropriately matched QC.

QC Samples for Europe can be ordered through Dia-Mex ([order@diamex.com](mailto:order@diamex.com)) and for elsewhere, through NRL ([www.nrlquality.org.au/purchasing-qconnect-qcs](http://www.nrlquality.org.au/purchasing-qconnect-qcs)). Establishing standing orders is highly recommended as a way of ensuring that your stock never runs low.

EDCNet is an internet-based software program specifically designed for monitoring both serology and NAT QC results. EDCNet allows for the simple collection, management and analysis of QC data in real-time. **Access to this multilingual software is free** when purchasing Optitrol QC samples and you can log in to EDCNet anywhere around the world, at any time.

Once registered, QConnect members can access EDCNet through logging in with a username and password. The anonymity of all participants is protected by a unique laboratory code. EDCNet has security systems similar to that used for internet banking, is supported by all major internet browsers and requires no software installation.

QConnect members who use EDCNet can share QC data to assess the accuracy and precision of their assays. All Optitrol-labelled products are automatically set up in EDCNet. You can edit or delete data as required. There is no need to back up data in case of loss and EDCNet can be interfaced with your individu-

al Laboratory Information System or instrumentation. EDCNet functionality is designed for all levels of users. Basic users can set up EDCNet and walk away, having automated alerts and reports sent directly to their email address. Power users can take advantage of the advanced in-built QC analysis functions to identify and investigate trends and shifts in QC results. Customised QC reports, providing real-time review of results in a Levey-Jennings or Mean/Scatter graphical or tabular format, can be sent directly to each QConnect member by email or saved as a PDF. EDCNet can be programmed to automatically schedule the email delivery of your customised report on a weekly or monthly basis.

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.

For further information about EDCNet please refer to: [www.nrlquality.org.au/qconnect](http://www.nrlquality.org.au/qconnect)

 **QCONNECT LIMITS**

QConnect Limits take advantage of peer data sharing and provide users robust, pre-determined control limits. QC limits are based on up to 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?**

Traditional QC approaches used to determine QC limits have been derived or modified from clinical chemistry and may not be applicable to serology or NAT. QConnect Limits, developed by NRL, utilise historical data by determining expected upper and lower values of results for each QC sample/assay combination. All QConnect participants using the same assay and the same QC sample submit results to EDCNet. Over time, multiple lots of QC samples have been tested by many laboratories, operators and instruments across

numerous lots of reagents. These results reflect the expected extent of variation for that QC sample/assay combination. These results have been extracted and analysed in collaboration with a biostatistician. The variation of QC results, both within each QC lot and between each QC lot was used to determine an upper and lower limit for each QC sample/ assay combination. These limits allows for the identification of any unexpected QC result, potentially identifying unacceptable variation from a range of sources including reagent lot numbers; 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 validated by an NRL staff member. Participants can overlay the QConnect Limits on Levey-Jennings and other EDCNet charts in conjunction with laboratory-specific and peer group limits. NRL also provides a suggested approach, including a check list, for the investigation and troubleshooting of unexpected results.

Note: Optitrol QC samples are used in addition to the manufacturers' controls and as such, the manufacturers' instructions for validating an assay should be adhered to.

For further information regarding QConnect Limits please refer to:

[www.nrlquality.org.au/qconnect](http://www.nrlquality.org.au/qconnect)



## MU REPORTS

To fulfil regulatory requirements with ease, you can access free annual MU reports specific for your laboratory. NRL has developed a method for estimating and reporting MU for quantitative assays based on a comparison of your laboratory's QC results with those reported by other laboratories using the same QC sample/assay combination (peer group). The metho-

dology for determining MU is published and scientifically validated. The MU estimation accounts for the assay's imprecision (random error) and bias (systematic error).

For more information regarding MU reports please refer to:

[www.nrlquality.org.au/qconnect](http://www.nrlquality.org.au/qconnect)



## QUESTIONS & ANSWERS

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](mailto:qconnect@nrlquality.org.au)



## REFERENCE MATERIALS

We know you don't have time to spend countless hours searching for information. QConnect 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

Please refer to: [www.nrlquality.org.au/qconnect](http://www.nrlquality.org.au/qconnect)



## CONTACT MEMBERS

QConnect is your gateway to a QC community and allows you to access advice from your peers, NRL staff and other experts in the field, wherever you are in the world.

## SUPPORT AT YOUR FINGERTIPS

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

# THE READY-TO-USE CONCEPT

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Our **ready-to-use** concept means that the controls may remain directly in the carrier or robots of the test system. The additional step of refilling of the controls manually from conventional dropper bottles into the vials of the carrier is no longer necessary. Less dead volume is required for multi analyte measurements in a single vial, thus saving the customer valuable control material.

## ADVANTAGES





- ▶ vials developed according to the individual platform (e. g. for ARCHITECT®, LIAISON® and others)
- ▶ high yield
- ▶ ready to use solutions
- ▶ less sources of error
- ▶ better protection against contamination
- ▶ predefined control limits
- ▶ barcode labels are included

▶▶▶ **easy handling and highly efficient**





# OVERVIEW: CONTROL / ASSAY COMBINATIONS





## SEROLOGICAL CONTROLS BLOOD SCREENING

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	Abbott	ARCHITECT	Anti-HBc II CMIA, Anti-HCV CMIA, HBsAg Qualitative II CMIA, HIV Ag/Ab Combo CMIA, rHTLV I/II CMIA, Syphilis TP CMIA	13
	Abbott	Alinity s	Anti-HBc, Anti-HCV, HBsAg, HIV Ag/Ab Combo	
	DiaSorin	LIAISON LIAISON XL	Anti-HBc, Treponema Screen, MUREX HBsAg Quant, MUREX HCV Ab, MUREX HIV Ab/Ag, MUREX recHTLV I/II	
	Abbott	PRISM	HBcore, HBsAg, HCV, HIV O Plus, HTLV I / HTLV II	13
	Abbott	PRISM	HBcore, HBsAg, HCV, HIV Ag/Ab Combo, HTLV I / HTLV II	14
	Bio-Rad		Genscreen Plus HIV Ag-Ab, ULTRA HIV Ag-Ab	14
			Monolisa Anti-HBc Plus, Anti-HCV Plus Version 2, HBsAg ULTRA, HCV Ag-Ab ULTRA V2	
			Syphilis Total Antibody	
	Roche	Elecsys Cobas	Anti-HBc, Anti-HCV II, Anti-HTLV-I/II, HBsAg II, HIV combi, HIV combi PT, Syphilis	15
	Siemens	ADVIA Centaur	ADVIA Centaur HBsAgII, HCV, HIV Ag/Ab Combo (CHIV), HIV1/O/2 Enhanced (EHIV), Syphilis (SYPH)	15
	Siemens	Enzygnost	Anti-HCV 4.0, Anti-HIV 1/2 Plus EIA, HBsAg 6.0 EIA, Anti-HBc monoclonal, Syphilis	16
	Abbott	ARCHITECT Alinity, PRISM	All assays for anti-HIV, anti-HCV, anti-HTLV, anti-HBc, anti-Treponema, HBsAg, HIVp24	16
	DiaSorin	LIAISON LIAISON XL		
	Bio-Rad			
	Roche	Elecsys Cobas		
	Siemens	ADVIA Centaur		



## SEROLOGICAL CONTROLS BLOOD SCREENING

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	Abbott	ARCHITECT PRISM	HIV Ab/Ag Combo HIV Ab/Ag Combo	17
	DiaSorin	LIAISON (XL)	Murex HIV Ab/Ag	
	Roche	Elecsys, Cobas	Elecsys HIV Combi PT	
	Siemens	ADVIA Centaur	HIV Ag/Ab Combo Assay	
	Bio-Rad		Genscreen Ultra HIV Ag-Ab, HIV-1 Ag Assay	
	Abbott	ARCHITECT PRISM	HIV Ag/Ab Combo HIV Ag/Ab Combo	17
	DiaSorin	LIAISON (XL)	Murex HIV Ab/Ag	
	Roche	Elecsys, Cobas	Elecsys HIV Combi PT	
	Siemens	ADVIA Centaur	HIV Ag/Ab Combo Assay	



## SEROLOGICAL CONTROLS HEPATITIS

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	DiaSorin	LIAISON LIAISON XL	Anti-HAV, Anti-HBe	18
			Anti-HBs II	
	Wantai		HEV-IgG ELISA	
	Abbott	ARCHITECT	Anti-HAV IgG, Anti-HBs, Anti-HBe	
	Roche	Elecsys, Cobas	Anti-HAV, Anti-HBs, Anti-HBe	
	Siemens	ADVIA Centaur	Anti-HAV Total, Anti-HBs, Anti-HBe	
	DiaSorin	LIAISON LIAISON XL	HAV IgM, HBc IgM, HBeAg	18
			Wantai	
	Abbott	ARCHITECT	Anti-HAVAb IgM, Anti-HBc IgM, HBeAg	
	Roche	Elecsys, Cobas	Anti-HAV IgM, Anti-HBc IgM, HBeAg	
	Siemens	ADVIA Centaur	Anti-HAV IgM, Anti-HBc IgM, HBeAg	
	Mikrogen	ELISA	recomWell HEV IgM ELISA	







## SEROLOGICAL CONTROLS TORCH

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	Abbott	ARCHITECT	Toxo IgM, Rubella IgM, CMV IgM, EBV VCA IgM	19
	DiaSorin	LIAISON LIAISON XL	Toxo IgM, Rubella IgM, CMV IgM, EBV VCA IgM, HSV 1/2 IgM	
	Abbott	ARCHITECT	Toxo IgG, Rubella IgG, CMV IgG, EBV VCA IgG, EBNA-1 IgG	19
	DiaSorin	LIAISON LIAISON XL	Toxo IgG II, Rubella II IgG, CMV IgG II, VCA IgG, HSV 1/2 IgG, EBNA IgG	
	Siemens	Enzygnost	Toxo/IgG, Anti-Rubella/IgG, Anti-CMV/IgG, Anti-EBV IgG, Anti-EBNA/IgG, HSV-1/2/IgG	



## SEROLOGICAL CONTROLS OTHERS

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	DiaSorin	LIAISON LIAISON XL	Measles IgG, Mumps IgG, Parvovirus B19 IgG, VZV IgG	20
	Siemens, NovaTec	Enzygnost Novagnost	Anti-Measles-Virus/IgG, Anti-Parotitis-Vir./ IgG, Anti-VZV/IgG, Novagnost Parvovirus B19 IgG	
	DiaSorin	LIAISON (XL)	All assays for Anti-measles virus IgM,	20
	Siemens, NovaTec	Enzygnost Novagnost	Anti-mumps virus IgM, Anti-parvovirus B19 IgM, Anti-VZV IgM	

## SEROLOGICAL CONTROLS OTHERS

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
 MeaslesM	DiaSorin	LIAISON (XL)	Measles IgM	21
	Siemens	BEP	Enzygnost Anti-Measles-Virus/IgM	
 Parvo M	DiaSorin	LIAISON (XL)	Biotrin Parvovirus B19 IgM	21
	NovaTec	BEP	Novagnost Parvovirus B19 IgM	
 MumpsM	DiaSorin	LIAISON (XL)	Mumps IgM	22
	Siemens	BEP	Enzygnost Anti-Parotitis-Virus/IgM	
 VZV M	DiaSorin	LIAISON (XL)	VZV IgM	22
	Siemens	BEP	Enzygnost Anti-VZV/IgM	
 HSV 2	DiaSorin	LIAISON (XL)	HSV-2 IgG	23
 SyphilisG	Newmarket Biomedical		Newbio-PK TPHA	23
	Fujirebio		Serodia Treponema pallidum particle agglutination (TP-PA) test	
	Biokit		RPR reditest	

## SEROLOGICAL CONTROLS TROPICAL DISEASES

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
 Malaria	Trinity Biotech		Captia Malaria EIA	24
 Chagas	DiaSorin	LIAISON (XL)	MUREX Chagas	24
	Roche	Elecsys	Chagas	
	Abbott	PRISM	Chagas	

# SEROLOGICAL CONTROLS BLOOD SCREENING



## Optitrol Blue



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
 Anti-HCV IgG  
 HBsAg  
 Anti-HBc IgG  
 Anti-HTLV I IgG  
 Anti-*Treponema* IgG

**System:** Abbott ARCHITECT, Alinity s  
 DiaSorin LIAISON, LIAISON XL

CAT. NO.	CONTENT	KIT
SR11011	Positive control	4 x 5 mL
SR11013	Positive control	2 x 5 mL
SR11019	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Yellow



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
 Anti-HCV IgG  
 HBsAg  
 Anti-HBc IgG  
 Anti-HTLV I IgG  
 Anti-*Treponema* IgG

**System:** Abbott PRISM

CAT. NO.	CONTENT	KIT
SR11021	Positive control	4 x 5 mL
SR11023	Positive control	2 x 5 mL
SR11029	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture

# SEROLOGICAL CONTROLS BLOOD SCREENING



## Optitrol Purple



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
Anti-HCV IgG  
HBsAg  
Anti-HBc IgG  
Anti-HTLV I IgG  
Anti-*Treponema* IgG

**System:** Abbott PRISM

CAT. NO.	CONTENT	KIT
SR11031	Positive control	4 x 5 mL
SR11033	Positive control	2 x 5 mL
SR11039	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Green



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
Anti-HCV IgG  
HBsAg  
Anti-HBc IgG  
Anti-HTLV I IgG  
Anti-*Treponema* IgG

**System:** Bio-Rad

CAT. NO.	CONTENT	KIT
SR11041	Positive control	4 x 5 mL
SR11043	Positive control	2 x 5 mL
SR11049	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture

# SEROLOGICAL CONTROLS BLOOD SCREENING



## Optitrol Red



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
Anti-HCV IgG  
HBsAg  
Anti-HBc IgG  
Anti-HTLV I IgG  
Anti-*Treponema* IgG

**System:** Roche Elecsys, Cobas

CAT. NO.	CONTENT	KIT
SR11051	Positive control	4 x 5 mL
SR11053	Positive control	2 x 5 mL
SR11059	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Orange



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
Anti-HCV IgG  
HBsAg  
Anti-HBc IgG  
Anti-HTLV I IgG  
Anti-*Treponema* IgG

**System:** Siemens ADVIA Centaur

CAT. NO.	CONTENT	KIT
SR11061	Positive control	4 x 5 mL
SR11063	Positive control	2 x 5 mL
SR11069	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture

# SEROLOGICAL CONTROLS BLOOD SCREENING



## Optitrol Grey



### Storage and Stability

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

### Analytes included

Anti-HIV 1 IgG  
 Anti-HCV IgG  
 HBsAg  
 Anti-HBc IgG  
 Anti-*Treponema* IgG

**System:** Siemens Enzygnost

CAT. NO.	CONTENT	KIT
SR11071	Positive control	4 x 5 mL
SR11073	Positive control	2 x 5 mL
SR11079	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol SeroNeg



### Storage and Stability

Sealed:\* 36 months at 2 to 8°C  
 After opening: 90 days at 2 to 8°C

### Negative for

Anti-HIV 1 IgG  
 Anti-HCV IgG  
 HBsAg  
 Anti-HBc IgG  
 Anti-HTLV I IgG  
 Anti-*Treponema* IgG

**System:** Abbott ARCHITECT, Alinity s, PRISM  
 DiaSorin LIAISON, LIAISON XL  
 Roche Elecsys, Cobas; Bio-Rad  
 Siemens ADVIA Centaur

CAT. NO.	CONTENT	KIT
SR11001	Negative control	2 x 1 mL
SR11002	Negative control	2 x 5 mL

For further information see instructions for use.

\* From date of manufacture



# SEROLOGICAL CONTROLS BLOOD SCREENING



## Optitrol HIVp24



### Storage and Stability

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

### Analytes included

HIV 1 p24 Antigen

**System:** Abbott ARCHITECT, PRISM  
 DiaSorin LIAISON XL  
 Roche Elecsys, Cobas; Bio-Rad  
 Siemens ADVIA Centaur

CAT. NO.	CONTENT	KIT
SR11101	Positive control	4 x 5 mL
SR11103	Positive control	4 x 2.5 mL
SR11105	Positive control	1 x 1 mL
SR11107	Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol HIV 2



### Storage and Stability

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

### Analytes included

Anti-HIV 2 IgG

**System:** Abbott ARCHITECT, PRISM  
 DiaSorin LIAISON XL  
 Roche Elecsys, Cobas  
 Siemens ADVIA Centaur

CAT. NO.	CONTENT	KIT
SR11115	Positive control	1 x 1 mL
SR11117	Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol HEPR-1 and HEPR-2



### Storage and Stability

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

**System:** Abbott ARCHITECT  
 DiaSorin LIAISON, LIAISON XL  
 Roche Elecsys, Cobas  
 Siemens ADVIA Centaur; Wantai

### Analytes included

Anti-HBs IgG  
 Anti-HBe IgG  
 Anti-HAV IgG  
 Anti-HEV IgG

CAT. NO.	CONTENT	KIT
SR12045	<b>HEPR-1</b> Positive control	1 x 1 mL
SR12047	<b>HEPR-1</b> Positive control	2 x 2.5 mL
SR12055	<b>HEPR-2</b> Positive control	1 x 1 mL
SR12057	<b>HEPR-2</b> Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol HEPA-1 and HEPA-2



### Storage and Stability

Sealed:\* 12 months at 2 to 8°C  
 After opening: 90 days at 2 to 8°C

**System:** DiaSorin LIAISON, LIAISON XL  
 Roche Elecsys, Cobas; Wantai  
 Abbott ARCHITECT, Mikrogen ELISA  
 Siemens ADVIA Centaur

### Analytes included

HBeAg  
 Anti-HBc IgM  
 Anti-HAV IgM  
 Anti-HEV IgM

CAT. NO.	CONTENT	KIT
SR12025	<b>HEPA-1</b> Positive control	1 x 1 mL
SR12027	<b>HEPA-1</b> Positive control	2 x 2.5 mL
SR12035	<b>HEPA-2</b> Positive control	1 x 1 mL
SR12037	<b>HEPA-2</b> Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture

# SEROLOGICAL CONTROLS TORCH



## Optitrol ToRCH M



### Storage and Stability

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

**System:** Abbott ARCHITECT  
 DiaSorin LIAISON, LIAISON XL

### Analytes included

Anti-Rubella IgM  
 Anti-Toxoplasma IgM  
 Anti-CMV IgM  
 Anti-EBV VCA IgM  
 Anti-HSV 1 IgM

CAT. NO.	CONTENT	KIT
SR13027	Positive control	2 x 2.5 mL
SR13029	Positive control	1 x 1 mL
SR13057	Negative control	2 x 2.5 mL
SR13059	Negative control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol ToRCH G



### Storage and Stability

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

**System:** Abbott ARCHITECT  
 DiaSorin LIAISON, LIAISON XL  
 Siemens Enzygnost

### Analytes included

Anti-Rubella IgG  
 Anti-Toxoplasma IgG  
 Anti-CMV IgG  
 Anti-EBV VCA IgG  
 Anti-EBV EBNA IgG  
 Anti-HSV 1 IgG

CAT. NO.	CONTENT	KIT
SR13017	Positive control	2 x 2.5 mL
SR13019	Positive control	1 x 1 mL
SR13047	Negative control	2 x 2.5 mL
SR13049	Negative control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Pediatric G



### Storage and Stability

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

### Analytes included

Anti-Measles IgG  
 Anti-Mumps IgG  
 Anti-Parvo B19 IgG  
 Anti-VZV IgG

**System:** DiaSorin LIAISON, LIAISON XL  
 Siemens Enzygnost  
 NovaTec, Novagnost

CAT. NO.	CONTENT	KIT
SR15015	Positive control	1 x 1 mL
SR15017	Positive control	2 x 2.5 mL
SR15006	Negative control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Pediatric M



### Storage and Stability

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

### Negative for

Anti-Measles IgM  
 Anti-Mumps IgM  
 Anti-Parvo B19 IgM  
 Anti-VZV IgM

**System:** DiaSorin LIAISON XL  
 Siemens Enzygnost  
 NovaTec, Novagnost

CAT. NO.	CONTENT	KIT
SR15003	Negative control	1 x 1 mL
SR15005	Negative control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture

## SEROLOGICAL CONTROLS OTHERS



### Optitrol Measles M



#### Storage and Stability

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

#### Analytes included

Anti-Measles IgM

**System:** DiaSorin LIAISON XL  
Siemens Enzygnost

CAT. NO.	CONTENT	KIT
SR15047	Positive control	2 x 2.5 mL
SR15048	Positive control	2 x 1 mL
SR15045	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



### Optitrol Parvo M



#### Storage and Stability

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

#### Analytes included

Anti-Parvo B19 IgM

**System:** DiaSorin LIAISON XL  
NovaTec, Novagnost

CAT. NO.	CONTENT	KIT
SR15057	Positive control	2 x 2.5 mL
SR15058	Positive control	2 x 1 mL
SR15055	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Mumps M



### Storage and Stability

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

### Analytes included

Anti-Mumps IgM

**System:** DiaSorin LIAISON XL  
 Siemens Enzygnost

CAT. NO.	CONTENT	KIT
SR15067	Positive control	2 x 2.5 mL
SR15068	Positive control	2 x 1 mL
SR15065	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol VZV M



### Storage and Stability

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

### Analytes included

Anti-VZV IgM

**System:** DiaSorin LIAISON XL  
 Siemens Enzygnost

CAT. NO.	CONTENT	KIT
SR15077	Positive control	2 x 2.5 mL
SR15078	Positive control	2 x 1 mL
SR15075	Positive control	1 x 1 mL

For further information see instructions for use.

\* From date of manufacture

## SEROLOGICAL CONTROLS OTHERS



### Optitrol Syphilis G



#### 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

**System:** Newmarket Biomedical  
Fujirebio  
Biokit

CAT. NO.	CONTENT	KIT
SR11135	Positive control	1 x 1 mL
SR11137	Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



### Optitrol HSV 2



#### Storage and Stability

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

#### Analytes included

Anti-HSV 2 IgG

**System:** DiaSorin LIAISON XL

CAT. NO.	CONTENT	KIT
SR13035	Positive control	1 x 1 mL
SR13037	Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Malaria



### 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

**System:** Trinity Biotech

CAT. NO.	CONTENT	KIT
SR16015	Positive control	1 x 1 mL
SR16017	Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



## Optitrol Chagas



### Storage and Stability

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

### Analytes included

Anti-*Trypanosoma sp.* IgG

**System:** DiaSorin LIAISON XL  
 Roche Elecsys  
 Abbott PRISM

CAT. NO.	CONTENT	KIT
SR16025	Positive control	1 x 1 mL
SR16027	Positive control	2 x 2.5 mL

For further information see instructions for use.

\* From date of manufacture



DiaMEX provides an attractive, universal quality control for both diabetes diagnostics and the management of chronic hyperglycaemia by a newly developed, innovative manufacturing process.

Optitrol HbA1c Low and Optitrol HbA1c High are quality controls based on 100% human blood.



## Optitrol HbA1c Low



### Storage and Stability

Lyophilisate, ready to use by reconstitution with pure water

Sealed:\* 24 months at 2 to 8°C

After opening: 7 days at 2 to 8°C or  
1 day at room temperature

### Analytes included

HbA1c  
Hb

**System:** Common methods for determination of HbA1c (Immunologic-, Enzymatic-, Chromatographic Assays).

CAT. NO.	CONTENT	KIT
DB01011	Control normal scale	4 x 1 mL**
DB01012	Control normal scale	10 x 1 mL**

For further information see instructions for use.

\* From date of manufacture    \*\* Different fillings also available upon request



## Optitrol HbA1c High



### Storage and Stability

Lyophilisate, ready to use by reconstitution with pure water

Sealed:\* 24 months at 2 to 8°C

After opening: 7 days at 2 to 8°C or  
1 day at room temperature

### Analytes included

HbA1c  
Hb

**System:** Common methods for determination of HbA1c (Immunologic-, Enzymatic-, Chromatographic Assays).

CAT. NO.	CONTENT	KIT
DB02011	Control pathological scale	4 x 1 mL**
DB02012	Control pathological scale	10 x 1 mL**

For further information see instructions for use.

\* From date of manufacture    \*\* Different fillings also available upon request



## Optitrol NAT CTNG



### Storage and Stability

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

### Analytes included

*Chlamydia trachomatis*  
*Neisseria gonorrhoeae*

CAT. NO.	CONTENT	KIT
NT02011	Positive control	10 x 1.2 mL

For further information see instructions for use.  
\* From date of manufacture



## Optitrol NAT MUT



### Storage and Stability

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

### Analytes included

*Mycoplasma genitalium*  
*Mycoplasma hominis*  
*Ureaplasma urealyticum*  
*Ureaplasma parvum*  
*Trichomonas vaginalis*  
*Treponema pallidum*

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

For further information see instructions for use.  
\* From date of manufacture



## Optitrol NAT HSV 1/2



### Storage and Stability

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

### Analyte included

HSV 1/2

CAT. NO.	CONTENT	KIT
NT02021	Positive control	10 x 1.2 mL

For further information see instructions for use.  
\* From date of manufacture

Available soon



## Optitrol NAT VZV



### Storage and Stability

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

### Analyte included

Varicella zoster virus

CAT. NO.	CONTENT	KIT
NT02023	Positive control	10 x 1.2 mL

For further information see instructions for use.  
\* From date of manufacture



## Optitrol NAT CMV



### Storage and Stability

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

### Analyte included

Cytomegalovirus

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

For further information see instructions for use.  
\* From date of manufacture



## Optitrol NAT BKV-JVC



### Storage and Stability

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

### Analytes included

BK Virus  
JC Virus

CAT. NO.	CONTENT	KIT
NT05031	Positive control	10 x 1.2 mL

For further information see instructions for use.  
\* From date of manufacture

Available soon



**Gastroenteritis**



**Storage and Stability**

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

**Analytes included**

**Single control** of each analyte, see table below

CONTENT		KIT
Positive control		10 x 1.2 mL
PRODUCT	CAT. NO.	ANALYTE
Optitrol NAT Campylobacter	NT03011	<i>Campylobacter spp.</i>
Optitrol NAT Clostridium	NT03012	<i>Clostridium difficile A/B</i>
Optitrol NAT E. coli	NT03013	<i>Escherichia coli</i>
Optitrol NAT Salmonella	NT03014	<i>Salmonella spp.</i>
Optitrol NAT Shigella	NT03015	<i>Shigella spp.</i>
Optitrol NAT Vibrio	NT03016	<i>Vibrio cholerae</i>
Optitrol NAT Yersinia	NT03017	<i>Yersinia enterocolitica</i>
Optitrol NAT Adenovirus	NT03031	Adenovirus
Optitrol NAT Norovirus	NT03032	Norovirus GI/GII
Optitrol NAT Rotavirus	NT03033	Rotavirus A

For further information see instructions for use.  
\* From date of manufacture



**Miscellaneous**



**Storage and Stability**

Sealed:\* 18 months at -20°C  
After opening: 5 days at 2 to 8°C

**Analytes included**

**Single control** of each analyte, see table below

CONTENT		KIT
Positive control		10 x 1.2 mL
PRODUCT	CAT. NO.	ANALYTE
Optitrol NAT MRSA	NT06011	Methicillin-resistant <i>Staphylococcus aureus</i>
Optitrol NAT EBV	NT06031	Epstein-Barr-virus
Optitrol NAT HPV	NT06032	Human papillomavirus
Optitrol NAT HPV NEG	NT06033	Negative for human papillomavirus

For further information see instructions for use.  
\* From date of manufacture



## Blood Borne Viruses and Parasites



### Storage and Stability

Sealed:\* 18 months at  $-20^{\circ}\text{C}$   
 After opening: 5 days at 2 to  $8^{\circ}\text{C}$

### Analytes included

**Single control** of each analyte, see table below

CONTENT		KIT
Positive control		10 x 1.2 mL
PRODUCT	CAT. NO.	ANALYTE
Optitrol NAT HBV Screening	NT01011	Hepatitis B virus
Optitrol NAT HBV Viral Load	NT01012	Hepatitis B virus
Optitrol NAT HCV Screening	NT01021	Hepatitis C virus
Optitrol NAT HCV Viral Load	NT01022	Hepatitis C virus
Optitrol NAT HIV Screening	NT01031	Human immunodeficiency virus 1
Optitrol NAT HIV Viral Load	NT01032	Human immunodeficiency virus 1
Optitrol NAT Triplex	NT01041	HBV, HCV, HIV 1
Optitrol NAT NEG	NT01051	Negative for HBV, HCV, HIV 1
Optitrol NAT HAV Parvo	NT01111	Hepatitis A virus
		Parvovirus B 19
Optitrol NAT HEV	NT01121	Hepatitis E virus
Optitrol NAT CHIKV	NT01122	Chikungunya virus
Optitrol NAT Dengue	NT01123	Dengue Virus
Optitrol NAT Malaria	NT01131	<i>Plasmodium falciparum</i>
Optitrol NAT Babesia	NT01132	<i>Babesia spp.</i>

For further information see instructions for use.

\* From date of manufacture



## Optitrol NAT Respiratory



### Storage and Stability

Sealed:\* 18 months at -20°C

After opening: 5 days at 2 to 8°C

### Analytes included – Multi control

*Bordetella pertussis*

*Bordetella parapertussis*

*Chlamydia pneumoniae*

*Mycoplasma pneumoniae*

Adenovirus

Coronavirus

Influenza A virus (H1N1)

Influenza A virus (H3N2)

Influenza B virus

Metapneumovirus

Rhinovirus/Enterovirus

Respiratory syncytial virus

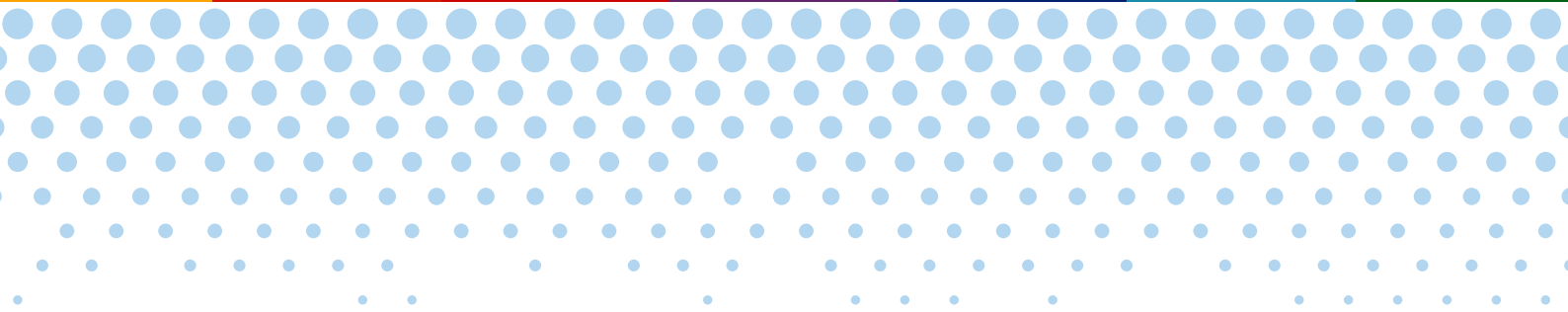
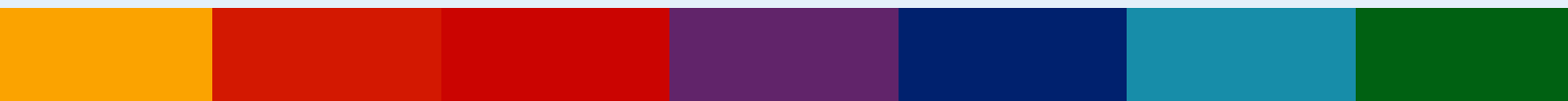
Parainfluenza virus 1

CAT. NO.	CONTENT	KIT
NT04011	Positive control	10 x 1.2 mL

For further information see instructions for use.

\* From date of manufacture





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