

Optitrol



Quality Control Solutions



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ABOUT DIAMEX

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

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

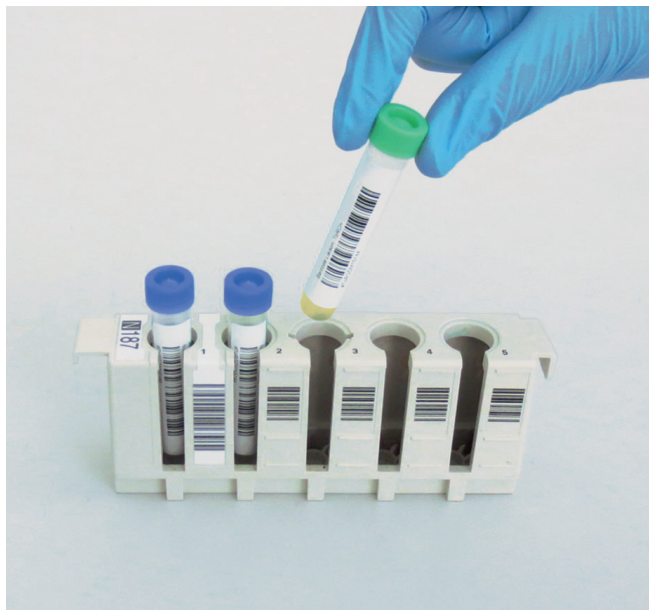
To promote the quality of tests and testing for infectious diseases globally.

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.

THE OPTITROL **READY-TO-USE** CONCEPT



Our Optitrol **ready-to-use** concept means that the controls may fit and remain directly in the carriers or robots of the test systems. 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.

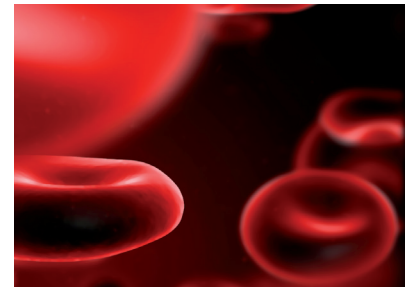
ADVANTAGES

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

▶▶ **easy handling and highly efficient**

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



QC SAMPLES

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 Diamex (order@diamex.com) and for elsewhere, through NRL (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



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



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



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/qconnect



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



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.

OVERVIEW: CONTROL / ASSAY COMBINATIONS





SEROLOGICAL CONTROLS BLOOD SCREENING

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
 Blue	Abbott	ARCHITECT	Anti-HBc II, Anti-HCV, HBsAg Qualitative II, HIV Ag/Ab Combo, rHTLV I/II, Syphilis TP	13
	Abbott	Alinity i Alinity s	Anti-HBc II, Anti-HCV, HBsAg Qualitative II, HIV Ag/Ab Combo, rHTLV I/II, Syphilis TP	
	DiaSorin	LIAISON LIAISON XL	Anti-HBc, Treponema Screen, MUREX HBsAg Quant, MUREX HCV Ab, MUREX HIV Ab/Ag, MUREX recHTLV I/II	
 Green	Bio-Rad		Genscreen Plus HIV Ag-Ab, ULTRA HIV Ag-Ab	13
			Monolisa Anti-HBc Plus, Anti-HCV Plus Version 2, HBsAg ULTRA, HCV Ag-Ab ULTRA V2	
			Syphilis Total Antibody	
 Red	Roche	Elecsys Cobas	Anti-HBc, Anti-HCV II, Anti-HTLV-I/II, HBsAg II, HIV combi, HIV combi PT, Syphilis	14
 Orange	Siemens	ADVIA Centaur	ADVIA Centaur HBsAgII, HCV, HIV Ag/Ab Combo (CHIV), HIV1/O/2 Enhanced (EHIV), Syphilis (SYPH)	14
 SeroNeg	Abbott	ARCHITECT Alinity	All assays for anti-HIV, HIVp24, anti-HCV, anti-HTLV, anti-HBc, HBsAg, anti- <i>Treponema pallidum</i> , anti-HAV, anti-HEV, anti-HBs, anti-HBe, HBeAg	15
	DiaSorin	LIAISON LIAISON XL		
	Bio-Rad			
	Roche	Elecsys Cobas		
	Siemens	ADVIA Centaur		



SEROLOGICAL CONTROLS BLOOD SCREENING

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 HIVp24	Abbott	ARCHITECT PRISM	HIV Ab/Ag Combo HIV Ab/Ag Combo	15
	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	
 HIV2	Abbott	ARCHITECT	HIV Ag/Ab Combo HIV Ag/Ab Combo	16
	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	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 HEPR-1	DiaSorin	LIAISON LIAISON XL	Anti-HAV, Anti-HBe	16
			Anti-HBs II	
	Wantai		HEV-IgG ELISA	
 HEPR-2	Abbott	ARCHITECT	Anti-HAV IgG, Anti-HBs, Anti-HBe	17
	Roche	Elecsys, Cobas	Anti-HAV, Anti-HBs, Anti-HBe	
	Siemens	ADVIA Centaur	Anti-HAV Total, Anti-HBs, Anti-HBe	
 HEPA-1	DiaSorin	LIAISON LIAISON XL	HAV IgM, HBc IgM, HBeAg	17
	Wantai		HEV-IgM ELISA	
 HEPA-2	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	Optimized for assays and platforms including ...			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	18
	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 COVID-19

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
	Abbott	ARCHITECT	SARS-CoV-2 IgG	17
	DiaSorin	LIAISON (XL)	SARS-CoV-2 S1/S2 IgG	
	Roche	Elecsys, Cobas	Anti-SARS-CoV-2	
	YHLO	iFlash	SARS-CoV-2 IgG	
	YHLO	iFlash	SARS-CoV-2 IgM	18




SEROLOGICAL CONTROLS OTHERS

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
	DiaSorin	LIAISON LIAISON XL	Measles IgG, Mumps IgG, Parvovirus B19 IgG, VZV IgG	19
	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, Anti-mumps virus IgM, Anti-parvovirus B19 IgM, Anti-VZV IgM	22
	Siemens, NovaTec	Enzygnost Novagnost		

SEROLOGICAL CONTROLS OTHERS

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 MeaslesM	DiaSorin	LIAISON (XL)	Measles IgM	20
	Siemens	BEP	Enzygnost Anti-Measles-Virus/IgM	
 Parvo M	DiaSorin	LIAISON (XL)	Biotrin Parvovirus B19 IgM	20
	NovaTec	BEP	Novagnost Parvovirus B19 IgM	
 MumpsM	DiaSorin	LIAISON (XL)	Mumps IgM	21
	Siemens	BEP	Enzygnost Anti-Parotitis-Virus/IgM	
 VZV M	DiaSorin	LIAISON (XL)	VZV IgM	21
	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	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 Malaria	Trinity Biotech		Captia Malaria EIA	24
 Chagas-1	DiaSorin	LIAISON (XL)	MUREX Chagas	24
	Abbott	ARCHITECT	Chagas	
	Abbott	Alinity	Chagas	
 Chagas-2	Roche	Elecsys, Cobas	Chagas	24

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 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 SeroNeg



Storage and Stability

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

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

Negative for

Anti-HIV, Anti-HCV
HBsAg, HBeAg
Anti-HBc, Anti-HBs
Anti-HBe
Anti-HAV, Anti-HEV
Anti-HTLV
Anti-*Treponema*

CAT. NO.	CONTENT	KIT
SR11000	Negative control	4 x 1 mL
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



Optitrol HIVp24



Storage and Stability

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

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

Analytes included

HIV 1 p24 Antigen

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

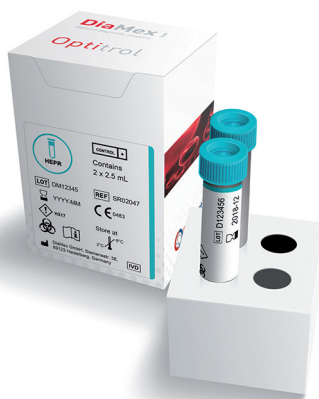
CAT. NO.	CONTENT	KIT
SR11115	Positive control	1 x 1 mL
SR11117	Positive control	2 x 2.5 mL

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

Analytes included

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

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

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

For further information see instructions for use.

* From date of manufacture



Optitrol HEPA-1 and Optitrol HEPA-2



Storage and Stability

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

System:

HEPA-1

DiaSorin LIAISON
Wantai and others

HEPA-2

Abbott ARCHITECT
Roche Elecsys, Cobas
Siemens ADVIA Centaur
Mikrogen and others

Analytes included

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

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

For further information see instructions for use.

* From date of manufacture



Optitrol COVID-19 G



Storage and Stability

Sealed:* 12 months at 2 to 8 °C
After opening: 60 days at 2 to 8 °C

System:

Abbott ARCHITECT
DiaSorin LIAISON XL
Roche Elecsys, Cobas
YHLO iFlash
and others

Analytes included

Anti-SARS-CoV-2 IgG

CAT. NO.	CONTENT	KIT
SR14033	Positive control	4 x 2.5 mL
SR14037	Positive control	2 x 2.5 mL
SR14039	Positive control	1 x 1 mL

For further information see instructions for use.

* From date of manufacture



Optitrol COVID-19 M



Storage and Stability

Sealed:* 12 months at 2 to 8 °C
After opening: 60 days at 2 to 8 °C

System: YHLO iFlash
and others

Analytes included

Anti-SARS-CoV-2 IgM

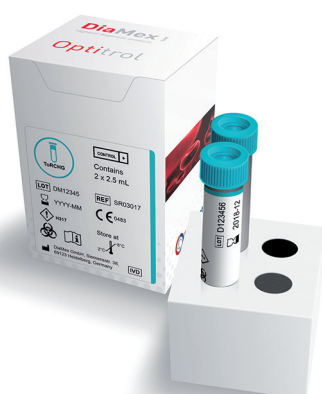
CAT. NO.	CONTENT	KIT
SR14043	Positive control	4 x 2.5 mL
SR14047	Positive control	2 x 2.5 mL
SR14049	Positive control	1 x 1 mL

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

SEROLOGICAL CONTROLS TORCH / OTHERS



Optitrol ToRCH M



Storage and Stability

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

Analytes included

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

System: Abbott ARCHITECT
DiaSorin LIAISON, LIAISON XL

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 Paediatric 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 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

SEROLOGICAL CONTROLS OTHERS



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



Optitrol Paediatric M (negative control)



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 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

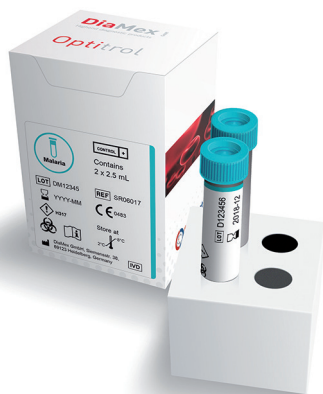
CAT. NO.	CONTENT	KIT
SR13035	Positive control	1 x 1 mL
SR13037	Positive control	2 x 2.5 mL

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-1 and Optitrol Chagas-2



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:

Chagas-1

Abbott ARCHITECT
Abbott Alinity
DiaSorin LIAISON

Chagas-2

Roche Elecsys, Cobas

CAT. NO.	CONTENT	KIT
SR16025	Chagas-1 Positive control	1 x 1 mL
SR16027	Chagas-1 Positive control	2 x 2.5 mL
SR16035	Chagas-2 Positive control	1 x 1 mL
SR16037	Chagas-2 Positive control	2 x 2.5 mL

For further information see instructions for use.

* From date of manufacture

DIABETES QUALITY CONTROLS

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



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



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</i> spp.
Optitrol NAT Clostridium	NT03012	<i>Clostridium difficile</i> A/B
Optitrol NAT E. coli	NT03013	<i>Escherichia coli</i>
Optitrol NAT Salmonella	NT03014	<i>Salmonella</i> spp.
Optitrol NAT Shigella	NT03015	<i>Shigella</i> spp.
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



Storage and Stability

Sealed:* 24 months at -20 °C
After opening: 1 day at 2 to 8 °C

Analytes included

Single control of each analyte, see table below

CONTENT

Positive control
(except Optitrol NAT NEG)

PRODUCT	CAT. NO.	ANALYTE / KIT
Optitrol NAT HBV Screening	NT01011	Hepatitis B virus / 5 x 1.2 mL
	NT01012	Hepatitis B virus / 10 x 1.2 mL
Optitrol NAT HBV Viral Load	NT01013	Hepatitis B virus / 5 x 1.2 mL
	NT01014	Hepatitis B virus / 10 x 1.2 mL
Optitrol NAT HCV Screening	NT01021	Hepatitis C virus / 5 x 1.2 mL
	NT01022	Hepatitis C virus / 10 x 1.2 mL
Optitrol NAT HCV Viral Load	NT01023	Hepatitis C virus / 5 x 1.2 mL
	NT01024	Hepatitis C virus / 10 x 1.2 mL
Optitrol NAT HIV Screening	NT01031	HIV 1 / 5 x 1.2 mL
	NT01032	HIV 1 / 10 x 1.2 mL
Optitrol NAT HIV Viral Load	NT01033	HIV 1 / 5 x 1.2 mL
	NT01034	HIV 1 / 10 x 1.2 mL
Optitrol NAT Triplex	NT01041	HBV, HCV, HIV 1 / 5 x 1.2 mL
	NT01042	HBV, HCV, HIV 1 / 10 x 1.2 mL
Optitrol NAT NEG	NT01051	Negative for HBV, HCV, HIV 1 / 5 x 1.2 mL
	NT01052	Negative for HBV, HCV, HIV 1 / 10 x 1.2 mL

For further information see instructions for use.

* From date of manufacture



Optitrol NAT SARS-CoV-2



Storage and Stability

Sealed:* 12 months at -20 °C
After opening: 5 days at 2 to 8 °C

Analyte included

SARS-CoV-2

CAT. NO.	CONTENT	KIT
NT04031	Positive control	5 x 0.6 mL
NT04032	Positive control	10 x 0.6 mL

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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