

QUALITY FOR YOUR CONTROLS CONTROLS FOR YOUR QUALITY

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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

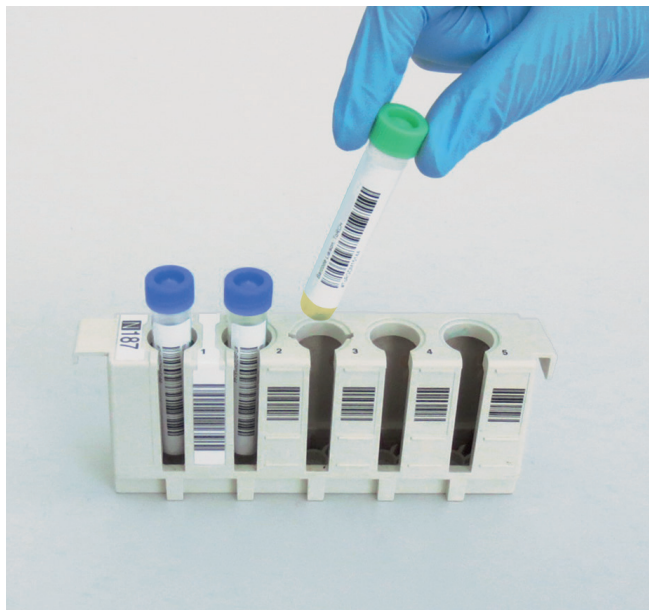
To promote the quality of tests and testing for infectious diseases globally.

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 serological 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.

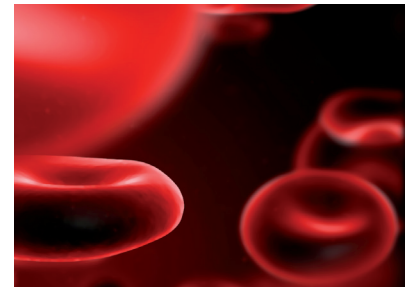
ADVANTAGES

- ▶ 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 allow 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	14
		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	
 Yellow	Abbott	Alinity s	Anti-HCV II, HIV Ag/Ab Combo, HTLV I/II, Syphilis, HBsAg, Anti-HBc	14
 Green	Bio-Rad	EVOLIS	Genscreen Plus HIV Ag-Ab, ULTRA HIV Ag-Ab	15
			Monolisa Anti-HBc Plus, Anti-HCV Plus Version 2, HBsAg ULTRA, HCV Ag-Ab ULTRA V2, MUREX recHTLV I/II	
			Syphilis Total Antibody	
 Red	Roche	cobas	Anti-HBc II, Anti-HCV II, HTLV-I/II, HBsAg II, HIV combi, HIV combi PT, Syphilis	15
 Orange	Siemens	ADVIA Centaur	HBsAgII, HCV, HIV Ag/Ab Combo, HIV1/O/2 Enhanced, Syphilis	16
		Atellica	HBsAgII, HCV, anti-HIV, anti-HBc, Syphilis	
 SeroNeg	Abbott	ARCHITECT	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	16
		Alinity i / s		
	DiaSorin	LIAISON (XL)		
	Bio-Rad	EVOLIS		
	Roche	cobas		
	Siemens	ADVIA Centaur		
		Atellica		

SEROLOGICAL CONTROLS BLOOD SCREENING

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 HIVp24	Abbott	ARCHITECT	HIV Ab/Ag Combo	17
		Alinity i	HIV Ab/Ag Combo	
	DiaSorin	LIAISON (XL)	Murex HIV Ab/Ag	
	Roche	cobas	Elecsys HIV Combi PT	
	Siemens	ADVIA Centaur	HIV Ag/Ab Combo Assay	
		Atellica	HIV Ag/Ab	
	bioMérieux	VIDAS	HIV P24 II	
 HIV 2	Abbott	ARCHITECT	HIV Ag/Ab Combo	17
		Alinity i	HIV Ag/Ab Combo	
	DiaSorin	LIAISON (XL)	Murex HIV Ab/Ag	
	Roche	cobas	Elecsys HIV Combi PT	
	Siemens	ADVIA Centaur	HIV Ag/Ab Combo Assay	
 HTLV II	Abbott	ARCHITECT	rHTLV I/II	18
		Alinity i	rHTLV I/II	
	DiaSorin	LIAISON (XL)	MUREX recHTLV I/II	

SEROLOGICAL CONTROLS HEPATITIS

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 HEPR-1	DiaSorin	LIAISON (XL)	Anti-HAV, Anti-HBe, Murex Anti-HBs, Murex Anti-HEV IgG	18
	Wantai	ELISA	HEV-IgG ELISA	
 HEPR-2	Abbott	ARCHITECT	Anti-HAV IgG, Anti-HBs, Anti-HBe	18
		Alinity i	HAVAb IgG, Anti-HBs, Anti-HBe	
	Roche	cobas	Anti-HAV, Anti-HBs, Anti-HBe	
	Siemens	ADVIA Centaur	HAV Total, Anti-HBs, Anti-HBe	
		Atellica	HAV Total, Anti-HBs, Anti-HBe	
	Mikrogen	ELISA	recomWell HEV IgG	
 HEPA-1	DiaSorin	LIAISON (XL)	HAV IgM, HBc IgM, HBeAg, HEVigM	19
	bioMérieux	VIDAS	HAV IgM, HBc IgM II, HBe/Anti HBe	
	Wantai	ELISA	HEV-IgM ELISA	
 HEPA-2	Abbott	ARCHITECT	Anti-HAVAb IgM, Anti-HBc IgM, HBeAg	19
		Alinity i	HAVAb IgG, Anti-HBc, Anti-HBe	
	Roche	cobas	Anti-HAV IgM, Anti-HBs IgM, HBeAg	
	Siemens	ADVIA Centaur	Anti-HAV IgM, Anti-HBc IgM, HBeAg	
	Mikrogen	ELISA	recomWell HEV IgM	

SEROLOGICAL CONTROLS TORCH

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 ToRCH M	Abbott	ARCHITECT	Toxo IgM, Rubella IgM, CMV IgM, EBV VCA IgM	21
		Alinity i	Toxo IgM, Rubella IgM, CMV IgM, EBV VCA IgM	
	DiaSorin	LIAISON (XL)	Toxo IgM, Rubella IgM, CMV IgM, HSV 1/2 IgM EBV/VCA IgM	
	bioMérieux	VIDAS	TOXO IgM, RUB IgM, CMV IgM, EBV VCA IgM	
 ToRCH G	Abbott	ARCHITECT	Toxo IgG, Rubella IgG, CMV IgG, EBV VCA IgG, EBV EBNA-1 IgG	20
		Alinity i	Toxo IgG, CMV IgG, EBV VCA IgG, EBV EBNA-1 IgG	
	DiaSorin	LIAISON (XL)	Toxo IgG II, Rubella II IgG, CMV IgG II, HSV 1/2 IgG, EBV VCA IgG, EBV EBNA IgG	
	bioMérieux	VIDAS	Toxo IgG II, RUB IgG II, CMV IgG, EBV VCA/EA IgG	
 HSV 2	DiaSorin	LIAISON (XL)	HSV-2 IgG	21

SEROLOGICAL CONTROLS COVID-19

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 COVID-19 G	Abbott	ARCHITECT	SARS-CoV-2 IgG	19
	DiaSorin	LIAISON (XL)	SARS-CoV-2 S1/S2 IgG	
	Roche	cobas	Anti-SARS-CoV-2	
	YHLO	iFlash	SARS-CoV-2 IgG	
	EUROIMMUN	ELISA	Anti-SARS CoV2-ELISA IgG	
	NovaTec	NovaLisa	SARS-CoV-2 IgG	
	bioMérieux	VIDAS	SARS-COV-2 IgG II	
	AESKU	AESKULISA	SARS-CoV-2 NP IgG	
 COVID-19 M	YHLO	iFlash	SARS-CoV-2 IgM	20

SEROLOGICAL CONTROLS OTHERS

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 Measles M	DiaSorin	LIAISON (XL)	Measles IgM	22
 Parvo M	DiaSorin	LIAISON (XL)	Biotrin Parvovirus B19 IgM	22
 Mumps M	DiaSorin	LIAISON (XL)	Mumps IgM	23
 VZV M	DiaSorin	LIAISON (XL)	VZV IgM	23
 Paediatric M	DiaSorin	LIASON (XL)	Negative control for: Measles IgM, Mumps IgM, Biotrin Parvovirus B19 IgM, VZV IgM	24
 Paediatric G	DiaSorin	LIAISON (XL)	Positive or negative control for: Measles IgG, Mumps IgG, Parvovirus B19 IgG, VZV IgG	24
 Paediatric G-2	bioMérieux	VIDAS	Measles IgG, Mumps IgG, Varicella-Zoster IgG	
 Syphilis G	Newmarket Biomedical		Newbio-PK TPHA	25
	Bio-Rad		RPR	
 Lyme/TBE G	Euroimmun	ELISA	Anti-Borrelia-plus-VlsE-ELISA IgG, Anti-FSME-Viren ELISA IgG	25
	Virotech	ELISA	Borrelia+VlsE IgG ELISA, FSME/TBE IgG/IgM ELISA	
	VirionSerion	ELISA	Borrelia Burgdorferi IgG, FSME/TBE Virus IgG	
	DiaSorin	LIASON (XL)	Borrelia IgG	
	bioMérieux	VIDAS	Lyme IgG	
 Lyme/TBE M	Euroimmun	ELISA	Anti-Borrelia-ELISA IgM, Anti-FSME-Viren ELISA IgM	25
	Virotech	ELISA	Borrelia IgM ELISA, FSME/TBE IgG/IgM ELISA	
	VirionSerion	ELISA	Borrelia Burgdorferi IgM, FSME/TBE Virus IgM	
	DiaSorin	LIASON (XL)	Borrelia IgM Quant.	
	bioMérieux	VIDAS	Lyme IgM	

SEROLOGICAL CONTROLS TROPICAL DISEASES

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 Malaria	Trinity Biotech	ELISA	Captia Malaria EIA	27
 Chagas-1	DiaSorin	LIAISON (XL)	MUREX Chagas	27
	Abbott	ARCHITECT	Chagas	
 Chagas-2	Roche	Elecsys, Cobas	Chagas	27

SEROLOGICAL CONTROLS MULTIALLERGY

QC Sample Name	Optimized for assays and platforms including ...			Page
	Manufacturer	System	Assay Name	
 Food	MEDIWISS		AlleisaScreen	26
	Thermo-Fisher		ImmunoCAP	
 Inhale	MEDIWISS		AlleisaScreen	26
	Thermo-Fisher		ImmunoCAP	

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 i (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

CE marked control

* From date of manufacture

** For further information and applicable analyte-/assay-combination see instructions for use



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 Alinity s

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

CE marked control

For further information see instructions for use.

* From date of manufacture

SEROLOGICAL CONTROLS BLOOD SCREENING



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 EVOLIS

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

CE marked control
For further information see instructions for use.
* From date of manufacture



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
HTLV I IgG
Anti-*Treponema* IgG

System: Roche 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

CE marked control
For further information see instructions for use.
* From date of manufacture

SEROLOGICAL CONTROLS BLOOD SCREENING



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
Siemens Atellica

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

CE marked control
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, Anti-HCV
HBsAg, HBeAg
Anti-HBc, Anti-HBs
Anti-HBe
Anti-HAV, Anti-HEV
Anti-HTLV
Anti-*Treponema pallidum*

System: Abbott ARCHITECT, Alinity i/s
DiaSorin LIAISON, LIAISON XL
Siemens ADVIA Centaur Atellica
Roche cobas; Bio-Rad

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

CE marked control
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, Alinity i
DiaSorin LIAISON (XL)
Roche cobas; Bio-Rad; bioMérieux VIDAS
Siemens ADVIA Centaur, Atellica

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

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol HIV 2



Storage and Stability

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

Analytes included

Anti-HIV 2 IgG

System:

Abbott ARCHITECT, Alinity i
DiaSorin LIAISON (XL)
Roche cobas
Siemens ADVIA Centaur

CAT. NO.	CONTENT	KIT
SR11113	Positive control	4 x 2.5 mL
SR11115	Positive control	1 x 1 mL
SR11117	Positive control	2 x 2.5 mL

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol HTLV II



Storage and Stability

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

Analytes included

Anti-HTLV II IgG

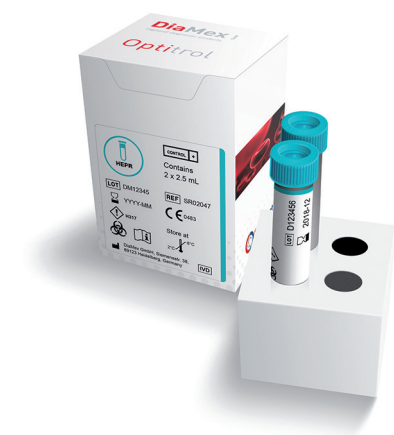
System: Abbott ARCHITECT,
Alinity i
DiaSorin LIASON, LIASON XL

CAT. NO.	CONTENT	KIT
SR11143	Positive control	4 x 2.5 mL
SR11145	Positive control	1 x 1 mL

CE marked control
For further information see instructions for use.
* From date of manufacture



Optitrol HEP-1 and Optitrol HEP-2



Storage and Stability

Sealed:* 18 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:

HEPR-1
DiaSorin LIAISON (XL)
Wantai

HEPR-2
Abbott ARCHITECT, Alinity i
Roche cobas
Siemens ADVIA Centaur, Atellica
Mikrogen

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

CE marked control
For further information see instructions for use.
* From date of manufacture



Optitrol HEPA-1 and Optitrol HEPA-2



Storage and Stability

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

System:

HEPA-1

DiaSorin LIAISON
bioMérieux VIDAS
Wantai

HEPA-2

Abbott ARCHITECT, Alinity i
Roche cobas
Siemens ADVIA Centaur
Mikrogen

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

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol COVID-19 G



Storage and Stability

Sealed:* 24 months at 2 to 8 °C
After opening: 60 days at 2 to 8 °C

System:

Abbott ARCHITECT
DiaSorin LIAISON XL
Roche 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

CE marked control

For further information see instructions for use.

* From date of manufacture

SEROLOGICAL CONTROLS COVID-19 / TORCH



Optitrol COVID-19 M



Storage and Stability

Sealed:* 24 months at 2 to 8 °C
After opening: 60 days at 2 to 8 °C

Analytes included

Anti-SARS-CoV-2
IgM

System: YHLO iFlash
and others

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

CE marked control
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

Analytes included

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

System: Abbott ARCHITECT, Alinity i
DiaSorin LIAISON, LIAISON XL
bioMérieux VIDAS

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

CE marked control
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
bioMérieux VIDAS

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

CE marked control

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

System: DiaSorin LIAISON (XL)

Analytes included

Anti-HSV 2 IgG

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

CE marked control

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)

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

CE marked control

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)

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

CE marked control

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)

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

CE marked control

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)

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

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol Paediatric M (negative control)



Storage and Stability

Sealed:* 36 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)

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

CE marked control
For further information see instructions for use.

* From date of manufacture

CE marked control
For further information see instructions for use.

* From date of manufacture



Optitrol Paediatric G and Optitrol Paediatric G-2



Storage and Stability

Sealed:* 24 months at 2 to 8 °C
After opening: 90 days at 2 to 8 °C
(36 months: neg. control)

Analytes included

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

System:

Paediatric G

DiaSorin LIAISON (XL)

Paediatric G-2

bioMérieux VIDAS

CAT. NO.	CONTENT	KIT
SR15015	Positive control (Paed.G)	1 x 1 mL
SR15017	Positive control (Paed.G)	2 x 2.5 mL
SR15025	Positive control (Paed.G-2)	1 x 1 mL
SR15027	Positive control (Paed.G-2)	2 x 2.5 mL
SR15006	Negative control	2 x 2.5 mL

CE marked control
For further information see instructions for use.

* From date of manufacture

SEROLOGICAL CONTROLS OTHERS



Optitrol Lyme/TBE G and Optitrol Lyme/TBE M



Storage and Stability

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

System: Euroimmun
Virotech
VirionSerion
DiaSorin LIASON (XL)
bioMérieux VIDAS

Analytes included

Optitrol Lyme/TBE G:
Anti-*Borrelia burgdorferi* IgG
Anti-TBEV/FSME IgG
Optitrol Lyme/TBE M:
Anti-*Borrelia burgdorferi* IgM
Anti-TBEV/FSME IgM

CAT. NO.	CONTENT	KIT
SR17015	Positive control (Lyme/TBE G)	1 x 1 mL
SR17017	Positive control (Lyme/TBE G)	2 x 2.5 mL
SR17018	Positive control (Lyme/TBE G)	2 x 1 mL
SR17025	Positive control (Lyme/TBE M)	1 x 1 mL
SR17027	Positive control (Lyme/TBE M)	2 x 2.5 mL
SR17028	Positive control (Lyme/TBE M)	2 x 1 mL

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol Syphilis G



Storage and Stability

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

System: Newmarket Biomedical
Bio-Rad

Analytes included

Anti-*Treponema pallidum* IgG

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

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol Multiallergy Food

and Optitrol Multiallergy Inhale



Storage and Stability

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

Analytes included

Different Anti-IgE
(food allergenes,
aeroallergenes)

System: MEDIWISS Alleisa Screen
ThermoFisher ImmunoCAP

CAT. NO.	CONTENT		KIT
AL0103	Positive control	(Food)	1 x 1 mL
AL0104	Positive control	(Food)	2 x 2.5 mL
AL0105	Positive control	(Food)	4 x 2.5 mL
AL0106	Positive control	(Inhale)	1 x 1 mL
AL0107	Positive control	(Inhale)	2 x 2.5 mL
AL0108	Positive control	(Inhale)	4 x 2.5 mL

CE marked control
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

CE marked control
For further information see instructions for use.
* From date of manufacture



Optitrol Chagas-1 and Optitrol Chagas-2



Storage and Stability

Sealed:* 36 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 (XL)

Chagas-2

Roche 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

CE marked control
For further information see instructions for use.
* From date of manufacture

NAT CONTROLS, BLOOD BORNE VIRUSES / SARS-COV-2



Blood Borne Viruses



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

See table below

CONTENT

Positive controls (except Optitrol NAT NEG)

PRODUCT	CAT. NO.	ANALYTE / KIT
Optitrol NAT HBV Screening	NT01011 NT01012	Hepatitis B virus / 5 x 1.2 mL Hepatitis B virus / 10 x 1.2 mL
Optitrol NAT HBV Viral Load	NT01013 NT01014	Hepatitis B virus / 5 x 1.2 mL Hepatitis B virus / 10 x 1.2 mL
Optitrol NAT HCV Screening	NT01021 NT01022	Hepatitis C virus / 5 x 1.2 mL Hepatitis C virus / 10 x 1.2 mL
Optitrol NAT HCV Viral Load	NT01023 NT01024	Hepatitis C virus / 5 x 1.2 mL Hepatitis C virus / 10 x 1.2 mL
Optitrol NAT HIV Screening	NT01031 NT01032	HIV-1 / 5 x 1.2 mL HIV-1 / 10 x 1.2 mL
Optitrol NAT HIV Viral Load	NT01033 NT01034	HIV-1 / 5 x 1.2 mL HIV-1 / 10 x 1.2 mL
Optitrol NAT Triplex	NT01041 NT01042	HBV, HCV, HIV-1 / 5 x 1.2 mL HBV, HCV, HIV-1 / 10 x 1.2 mL
Optitrol NAT HIV-2	NT01035 NT01036	HIV-2 / 5 x 1.2 mL HIV-2 / 10 x 1.2 mL
Optitrol NAT NEG	NT01051 NT01052	Negative for HBV, HCV, HIV-1/-2 a.o. 5 x 1.2 mL 10 x 1.2 mL

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol NAT SARS-CoV-2



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

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

CE marked control

For further information see instructions for use.

* From date of manufacture

NAT CONTROLS, SEXUAL TRANSMITTED DISEASES



Optitrol NAT CT/NG



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
NT02011	Positive control	5 x 1.2 mL
NT02012	Positive control	10 x 1.2 mL

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol NAT CMV



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

Analyte included

Cytomegalovirus

CAT. NO.	CONTENT	KIT
NT02021	Positive control	5 x 1.2 mL
NT02022	Positive control	10 x 1.2 mL

CE marked control

For further information see instructions for use.

* From date of manufacture



Optitrol NAT HPV and Optitrol NAT HPV NEG



Attention: Controls are not CE marked
Currently available for Australia and New Zealand.

Storage and Stability

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

Analytes included

Human papillomavirus 16, 18, 51

CAT. NO.	CONTENT	KIT
NT06011	Positive control	5 x 1.2 mL
NT06012	Positive control	10 x 1.2 mL
NT06013	Negative control	5 x 1.2 mL
NT06014	Negative control	10 x 1.2 mL

Control is not CE marked
For further information see instructions for use.
* From date of manufacture

Third Party Controls

Right where you need them



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