

Quality Control Solutions

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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

QConnect 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.

QConnect 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.

QConnect 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 QConnect QC sample is available, allowing all QConnect participants using the same assay to compare their QC results.

This QConnect catalogue offers a selection of QC samples for clinical and blood screening laboratories performing serology and/or Nucleic Acid Testing (NAT) 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 QConnect 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 QConnect-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: QConnect 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

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



REFERENCE MATERIALS



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 QConnect and EDCNet users. All data outside the QConnect 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.

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.

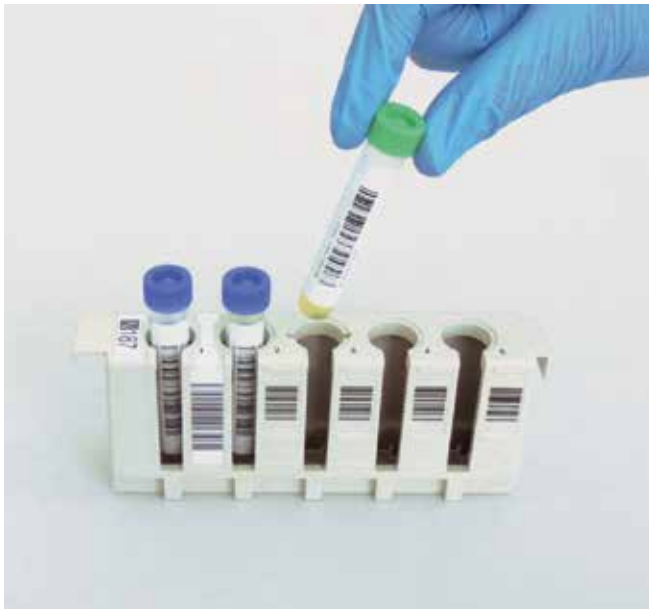
DiaMex offers a portfolio of manufacturer-independent serological quality controls and directs its energy towards the continual development of new products according to the needs of our customers.

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.

THE **READY-TO-USE** CONCEPT



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**

ABOUT NRL

NRL was established in 1985 as part of the Australian Government's HIV/AIDS Strategy, to evaluate HIV tests and adjudicate on the interpretation of HIV test results. Today, NRL remains a not-for-profit scientific organisation that exists for the benefit of the public.

Its overall goal is to support laboratories, in Australia and internationally, that perform testing for the diagnosis and management of human infectious disease. NRL is designated a WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.

Mission

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

Goals

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

- comprehensive and innovative quality assurance services;
- evaluations of tests and test algorithms;
- specialised laboratory testing services;
- training with sustainable outcomes;
- consultation and advice on policy relating to laboratory testing.



ABOUT EXACT DIAGNOSTICS

Quality Policy

By providing quality products and services to laboratories and manufacturers, Exact Diagnostics aims to enhance patient care by ensuring the validity of diagnostic and screening tests results.

Our Quality Management System ensures:

- Our commitments to customer and partner requirements are met.
- Compliance with national and regional laws, regulations, and standards.
- The highest quality of products is created.

Exact Diagnostics is committed to our customers, our people, and our products.

Mission









To meet the exact quality control needs of clinical labs and assay manufacturers.

EXACT DIAGNOSTICS




Exact Diagnostics is a molecular controls and standards company. Exact Diagnostics offers verification panels and daily run controls for ADV, BKV, CMV, EBV, HBV, HCV, HIV 1, Zika, and HPV Genotype Controls as well as numerous Custom Capabilities. Exact Diagnostics' ADV, BKV, CMV, EBV, HBV, HCV, and HIV 1, Zika verification panels have a wide dynamic range. Exact Diagnostics manufactures following cGMP in a FDA registered/ISO 13485 certified facility. Exact Diagnostics is a customer-centric, nimble business focused on the Infectious Disease, Genetics, and Oncology markets.

OVERVIEW: CONTROL / ASSAY COMBINATIONS



SEROLOGY MULTI-MARKER 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	12
	Abbott	Alinity	Alinity s Anti-HBc, Anti-HCV, HBsAg, HIV Ag/Ab Combo	
	DiaSorin	LIAISON LIAISON XL	Anti-HBc CLIA, Treponema Screen CLIA, MUREX HBsAg Quant CLIA, MUREX HCV Ab CLIA, MUREX HIV Ab/Ag CLIA, MUREX recHTLV I/II CLIA	
	Abbott	PRISM	HBcore ChLIA, HBsAg ChLIA, HCV ChLIA, HIV O Plus ChLIA, HTLV I / HTLV II ChLIA	12
	Abbott	PRISM	HBcore ChLIA, HBsAg ChLIA, HCV ChLIA, HIV Ag/Ab Combo ChLIA, HTLV I / HTLV II ChLIA	13
	Bio-Rad		Genscreen Plus HIV Ag-Ab EIA, ULTRA HIV Ag-Ab EIA	13
			Monalisa Anti-HBc Plus EIA, Anti-HCV Plus Version 2 EIA, HBsAg ULTRA EIA, HCV Ag-Ab ULTRA V2 EIA	
			Syphilis EIA II Total Antibody	
	Roche	Elecsys Cobas	Anti-HBc ECLIA, Anti-HCV II ECLIA, Anti-HTLV-I/II ECLIA, HBsAg II ECLIA, HIV combi ECLIA, HIV combi PT ECLIA, Syphilis ECLIA	14
	Siemens	ADVIA Centaur	ADVIA Centaur HBsAgII ChLIA, HCV ChLIA, HIV Ag/Ab Combo (CHIV) ChLIA, HIV1/O/2 Enhanced (EHIV) ChLIA, Syphilis (SYPH) ChLIA	14
	Siemens	Enzygnost	Anti-HCV 4.0, Anti-HIV 1/2 Plus EIA, HBsAg 6.0 EIA, Anti-HBc monoclonal, Syphilis	15
	Abbott	ARCHITECT Alinity, PRISM	All assays for anti-HIV, anti-HCV, anti-HTLV, anti-HBc, anti-Treponema, HBsAg, HIVp24	15
	DiaSorin	LIAISON LIAISON XL		
	Bio-Rad			
	Roche	Elecsys Cobas		
	Siemens	ADVIA Centaur		



SEROLOGY MULTI-MARKER HEPATITIS

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
 HEPR	Abbott	ARCHITECT	Anti-HAV IgG, Anti-HBs, Anti-HBe	16
	DiaSorin	LIAISON LIAISON XL	Anti-HAV, Anti-HBe	
			Anti-HBs II	
	Roche	Elecsys, Cobas	Anti-HAV, Anti-HBs, Anti-HBe	
	Siemens	ADVIA Centaur	Anti-HAV Total, Anti-HBs, Anti-HBe	
	Wantai		HEV-IgG ELISA	
 HEPA-1	DiaSorin	LIAISON LIAISON XL	HAV IgM, HBc IgM, HBeAg	16
	Wantai		HEV-IgM ELISA	
 HEPA-2	Abbott	ARCHITECT	Anti-HAVAb IgM, Anti-HBc IgM, HBeAg	16
	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	





SEROLOGY MULTI-MARKER TORCH

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
 TORCHM	Abbott	ARCHITECT	Toxo IgM, Rubella IgM, CMV IgM, EBV VCA IgM	17
	DiaSorin	LIAISON LIAISON XL	Toxo IgM, Rubella IgM, CMV IgM, EBV VCA IgM, HSV 1/2 IgM	
 TORCHG	Abbott	ARCHITECT	Toxo IgG, Rubella IgG, CMV IgG, EBV VCA IgG, EBNA-1 IgG	17
	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	



SEROLOGY MULTI-MARKER OTHERS

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	DiaSorin	LIAISON LIAISON XL	Measles IgG, Mumps IgG, Parvovirus B19 IgG, VZV IgG	18
	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	
	Siemens, NovaTec	Enzygnost Novagnost		






SEROLOGY SINGLE-MARKER BLOOD SCREENING

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	Abbott	ARCHITECT PRISM	HIV Ab/Ag Combo HIV Combo	19
	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	19
	DiaSorin	LIAISON (XL)	Murex HIV Ab/Ag	
	Roche	Elecsys, Cobas	HIV Combi	
	Siemens	ADVIA Centaur	HIV Ag/Ab Combo Assay	
	Abbott	ARCHITECT PRISM	rHTLV-I/II HTLV-I/HTLV-II	20
	DiaSorin	LIAISON (XL)	recHTLV I/II	
	Newmarket Biomedical		Newbio-PK TPHA	20
	Fujirebio		Serodia Treponema pallidum particle agglutination (TP-PA) test	
	Biokit		RPR reditest	

SEROLOGY SINGLE-MARKER TROPICAL DISEASES

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
	Trinity Biotech		Captia Malaria EIA	21
	DiaSorin	LIAISON (XL)	MUREX Chagas	
	Roche	Elecsys	Chagas	
	Abbott	PRISM	Chagas	

SEROLOGY SINGLE-MARKER OTHERS

QC Sample Name	Assay			Page
	Manufacturer	System	Assay Name	
 MeaslesM	DiaSorin	LIAISON (XL)	Measles IgM	22
	Siemens	Enzygnost	Anti-Measles-Virus/IgM	
 Parvo M	DiaSorin	LIAISON (XL)	Biotrin Parvovirus B19 IgM	22
	NovaTec	Enzygnost	Parvovirus B19 IgM	
 MumpsM	DiaSorin	LIAISON (XL)	Mumps IgM	22
	Siemens	Enzygnost	Anti-Parotitis-Virus/IgM	
 VZV M	DiaSorin	LIAISON (XL)	VZV IgM	23
	Siemens	Enzygnost	Anti-VZV/IgM	
 HSV 2	DiaSorin	LIAISON (XL)	HSV-2 IgG	23

MOLECULAR QUALITY CONTROLS

QC Sample Name	Analytes	Assay / Instrument	Page
QConnect CTNGNAT	C. trachomatis N. gonorrhoeae	All assays that detect <i>Chlamydia trachomatis</i> / <i>Neisseria gonorrhoeae</i>	23
QConnect TriScreen	HIV RNA HBV DNA HCV RNA	Roche cobas TaqScreen MPX Test, v 2.0 (s201) Roche cobas MPX Test (6800/8800)	24
QConnect HIV RNA	HIV RNA	Grifols Ultrio Plus (Tigris)	24
QConnect HCV RNA	HCV RNA	Grifols Ultrio Elite (Panther)	24
QConnect HBV DNA	HBV DNA	Roche TaqScreen MPX Test, v 1.0 (s201)	25
QConnect HIVNAT Low	HIV RNA	All quantitative (viral load) assays including: Abbott M2000sp/rt, Roche COBAS AmpliPrep/TaqMan, Roche cobas 6800/8800	25
QConnect HBVNAT Low	HBV DNA	All quantitative (viral load) assays including: Abbott M2000sp/rt, Roche COBAS AmpliPrep/TaqMan, Roche cobas 6800/8800	25
QConnect HCVNAT Low	HCV RNA	All quantitative (viral load) assays including: Abbott M2000sp/rt, Roche COBAS AmpliPrep/TaqMan, Roche cobas 6800/8800	26
QConnect CMVNAT Low	CMV DNA	All qualitative and viral load CMV DNA assays	26
QConnect NATNEG	Negative	All blood screening and clinical NAT	26
QConnect HPVNEG	Negative	All HPV qualitative assays	27
QConnect HPV16NAT	HPV DNA (ge- notype 16)	All HPV qualitative assays	27
QConnect HPV18NAT	HPV DNA (ge- notype 18)	All HPV qualitative assays	27

SEROLOGY MULTI-MARKER BLOOD SCREENING



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01011	Positive control	4 x 5 mL	
SR01012	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01021	Positive control	4 x 5 mL	
SR01022	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture

SEROLOGY MULTI-MARKER BLOOD SCREENING



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01031	Positive control	4 x 5 mL	
SR01032	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01041	Positive control	4 x 5 mL	
SR01042	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture

SEROLOGY MULTI-MARKER BLOOD SCREENING



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01051	Positive control	4 x 5 mL	
SR01052	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01061	Positive control	4 x 5 mL	
SR01062	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture

SEROLOGY MULTI-MARKER BLOOD SCREENING



QConnect 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

CAT. NO.	CONTENT	KIT	
SR01071	Positive control	4 x 5 mL	
SR01072	Negative control	2 x 5 mL	4 x 5 mL
	Positive control	2 x 5 mL	

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR01000	Negative control	4 x 1 mL

For further information see instructions for use.

* From date of manufacture

SEROLOGY MULTI-MARKER HEPATITIS



QConnect HEPR



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

CAT. NO.	CONTENT	KIT
SR02013	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect HEPA-1



Storage and Stability

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

Analytes included

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

CAT. NO.	CONTENT	KIT
SR02023	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect HEPA-2



Storage and Stability

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

Analytes included

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

CAT. NO.	CONTENT	KIT
SR02033	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT	
SR03023	Positive control	4 x 2.5 mL	
SR03024	Negative control	2 x 2.5 mL	4 x 2.5 mL
	Positive control	2 x 2.5 mL	

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT	
SR03013	Positive control	4 x 2.5 mL	
SR03014	Negative control	2 x 2.5 mL	4 x 2.5 mL
	Positive control	2 x 2.5 mL	

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR05013	Positive control	4 x 2.5 mL
SR05017	Positive control	2 x 2.5 mL
SR05002	Negative control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR05005	Negative control	2 x 2.5 mL
SR05004	Negative control	2 x 1 mL
SR05003	Negative control	1 x 2.5 mL

For further information see instructions for use.

* From date of manufacture

SEROLOGY SINGLE-MARKER BLOOD SCREENING



QConnect 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

CAT. NO.	CONTENT	KIT
SR01101	Positive control	4 x 5 mL
SR01103	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR01113	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture

SEROLOGY SINGLE-MARKER BLOOD SCREENING



QConnect 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

CAT. NO.	CONTENT	KIT
SR01143	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR01137	Positive control	2 x 2.5 mL

For further information see instructions for use.

* From date of manufacture

SEROLOGY SINGLE-MARKER TROPICAL DISEASES



QConnect 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

CAT. NO.	CONTENT	KIT
SR06013	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR06023	Positive control	4 x 2.5 mL

For further information see instructions for use.

* From date of manufacture

SEROLOGY SINGLE-MARKER OTHERS



QConnect 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

CAT. NO.	CONTENT	KIT
SR05047	Positive control	2 x 2.5 mL
SR05048	Positive control	2 x 1 mL
SR05045	Positive control	1 x 1 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR05057	Positive control	2 x 2.5 mL
SR05058	Positive control	2 x 1 mL
SR05055	Positive control	1 x 1 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR05067	Positive control	2 x 2.5 mL
SR05068	Positive control	2 x 1 mL
SR05065	Positive control	1 x 1 mL

For further information see instructions for use.

* From date of manufacture

SEROLOGY SINGLE-MARKER OTHERS



QConnect 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

CAT. NO.	CONTENT	KIT
SR05077	Positive control	2 x 2.5 mL
SR05078	Positive control	2 x 1 mL
SR05075	Positive control	1 x 1 mL

For further information see instructions for use.

* From date of manufacture



QConnect 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

CAT. NO.	CONTENT	KIT
SR03037	Positive control	2 x 2.5 mL

For further information see instructions for use.

* From date of manufacture

MOLECULAR QUALITY CONTROLS



QConnect CTGNAT



Storage and Stability

Sealed:* 18 months at -20°C
After opening: 24 hours at 2 to 8°C

Analytes included

Chlamydia trachomatis
Neisseria gonorrhoeae

CAT. NO.	CONTENT	KIT
NT20101	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX20101>

For further information see instructions for use.

* From date of manufacture

MOLECULAR QUALITY CONTROLS



QConnect TriScreen



Storage and Stability

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

Analytes included

HIV RNA
HBV DNA
HCV RNA

CAT. NO.	CONTENT	KIT
NT10101	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX10101>

For further information see instructions for use.

* From date of manufacture



QConnect HIV RNA



Storage and Stability

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

Analytes included

HIV RNA

CAT. NO.	CONTENT	KIT
NT11001	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX11001>

For further information see instructions for use.

* From date of manufacture



QConnect HCV RNA



Storage and Stability

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

Analytes included

HCV RNA

CAT. NO.	CONTENT	KIT
NT10801	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX10801>

For further information see instructions for use.

* From date of manufacture

MOLECULAR QUALITY CONTROLS



QConnect HBV DNA



Storage and Stability

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

Analytes included

HBV DNA

CAT. NO.	CONTENT	KIT
NT10701	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX10701>

For further information see instructions for use.

* From date of manufacture



QConnect HIV NAT Low



Storage and Stability

Sealed:* 18 months at -20°C
After opening: 24 hours at 2 to 8°C

Analytes included

HIV RNA

CAT. NO.	CONTENT	KIT
NT21001	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX21001>

For further information see instructions for use.

* From date of manufacture



QConnect HBV NAT Low



Storage and Stability

Sealed:* 18 months at -20°C
After opening: 24 hours at 2 to 8°C

Analytes included

HBV DNA

CAT. NO.	CONTENT	KIT
NT20701	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX20701>

For further information see instructions for use.

* From date of manufacture

MOLECULAR QUALITY CONTROLS



QConnect HCVNAT Low



Storage and Stability

Sealed:* 18 months at -20°C
After opening: 24 hours at 2 to 8°C

Analytes included

HCV RNA

CAT. NO.	CONTENT	KIT
NT20801	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX20801>

For further information see instructions for use.

* From date of manufacture



QConnect CMVNAT Low



Storage and Stability

Sealed:* 18 months at -20°C
After opening: 24 hours at 2 to 8°C

Analytes included

CMV DNA

CAT. NO.	CONTENT	KIT
NT20401	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX20401>

For further information see instructions for use.

* From date of manufacture



QConnect NATNEG



Storage and Stability

Sealed:* 18 months at -20°C
After opening: 24 hours at 2 to 8°C

Negative for:

HIV RNA, HCV RNA, HBV DNA and CMV DNA

CAT. NO.	CONTENT	KIT
NT10102	Negative control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX10102>

For further information see instructions for use.

* From date of manufacture

MOLECULAR QUALITY CONTROLS



QConnect HPVNEG



Storage and Stability

Sealed:* 18 months at 2 to 8°C
After opening: Up to 10 days at room temperature

Negative for:

HPV DNA

CAT. NO.	CONTENT	KIT
NT21501	Negative control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX21501>

For further information see instructions for use.

* From date of manufacture



QConnect HPV16NAT



Storage and Stability

Sealed:* 18 months at 2 to 8°C
After opening: Up to 10 days at room temperature

Analytes included

HPV DNA (genotype 16)

CAT. NO.	CONTENT	KIT
NT21502	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX21502>

For further information see instructions for use.

* From date of manufacture



QConnect HPV18NAT



Storage and Stability

Sealed:* 18 months at 2 to 8°C
After opening: Up to 10 days at room temperature

Analytes included

HPV DNA (genotype 18)

CAT. NO.	CONTENT	KIT
NT21503	Positive control	10 x 1.4 mL

E-label product key: <http://qa.e-labeling.eu/EDX21503>

For further information see instructions for use.

* From date of manufacture



4th Floor Healy Building, 41 Victoria Parade
FITZROY VICTORIA 3065, AUSTRALIA
Phone +61 3 9418 1111
Fax +61 3 9418 1155
www.nrlquality.org.au/qconnect



3400 Camp Bowie Blvd. CBH-214
Fort Worth, Texas 76107, USA
Phone: +1 817 989 9262
Fax: +1 817 735 5485
www.exactdiagnostics.com



Highend diagnostic products

Siemensstraße 38
69123 Heidelberg, GERMANY
Phone +49(0) 6221-894669-40
Fax +49(0) 6221-894669-90
www.diamex.com