QConnect
Follow the trend

Quality Control Solutions

NRL
Science of Quality

DiaMex GmbH
Highend diagnostic products

CONTENT

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.

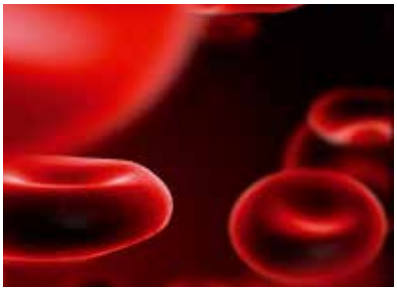
Mission
To promote the quality of tests and testing for infectious diseases globally.

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.

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

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 individual 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 methodology 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*

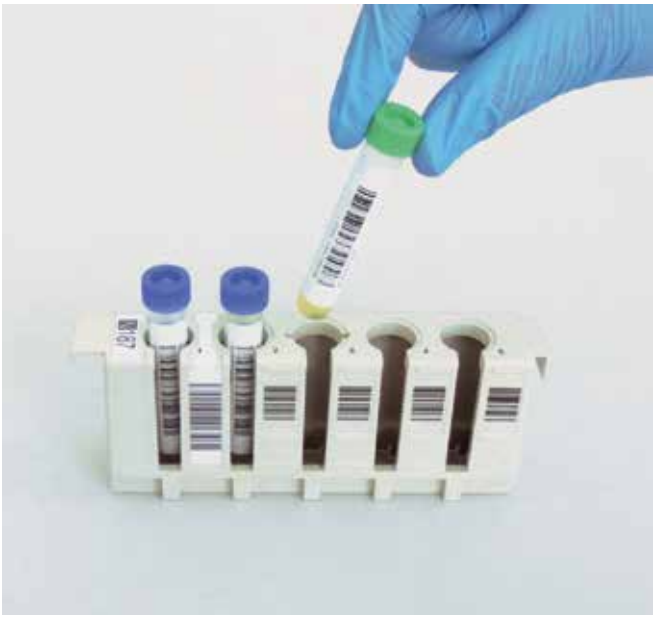
CONTACT MEMBERS

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.

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

OVERVIEW: CONTROL / ASSAY COMBINATIONS

SEROLOGICAL CONTROLS BLOOD SCREENING

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

SEROLOGICAL CONTROLS BLOOD SCREENING

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

SEROLOGICAL CONTROLS HEPATITIS

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

SEROLOGICAL CONTROLS TORCH

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

SEROLOGICAL CONTROLS OTHERS

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

SEROLOGICAL CONTROLS OTHERS

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

SEROLOGICAL CONTROLS TROPICAL DISEASES

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

Optitrol Blue

Storage and Stability

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

Analytes included

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

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol Yellow

Storage and Stability

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

Analytes included

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

System: Abbott PRISM

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

For further information see instructions for use.

* From date of manufacture

Optitrol Purple

Storage and Stability

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

System: Abbott PRISM

Analytes included

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol Green

Storage and Stability

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

System: Bio-Rad

Analytes included

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

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

Optitrol Red

Storage and Stability

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

System: Roche Elecsys, Cobas

Analytes included

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

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

System: Siemens ADVIA Centaur

Analytes included

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

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

Optitrol Grey

Storage and Stability

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

System: Siemens Enzygnost

Analytes included

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol SeroNeg

Storage and Stability

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

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

Negative for

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol HIVp24

Storage and Stability

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

Analytes included

HIV 1 p24 Antigen

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol HIV 2

Storage and Stability

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

Analytes included

Anti-HIV 2 IgG

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol HEPR-1 and HEPR-2

Storage and Stability

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

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

Analytes included

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

CAT. NO.	CONTENT	KIT
SR12045	**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 HEPA-2

Storage and Stability

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

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

Analytes included

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

CAT. NO.	CONTENT	KIT
SR12025	**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 ToRCH M

Storage and Stability

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

System: Abbott ARCHITECT
DiaSorin LIAISON, LIAISON XL

Analytes included

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol ToRCH G

Storage and Stability

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

System: Abbott ARCHITECT
DiaSorin LIAISON, LIAISON XL
Siemens Enzygnost

Analytes included

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol Pediatric G

Storage and Stability

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

Analytes included

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

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

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

For further information see instructions for use.

* From date of manufacture

Optitrol Pediatric M

Storage and Stability

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

Negative for

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

System: DiaSorin LIAISON XL
Siemens Enzygnost
NovaTec, Novagnost

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

For further information see instructions for use.

* From date of manufacture

Optitrol Measles M

Storage and Stability

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

System: DiaSorin LIAISON XL
Siemens Enzygnost

Analytes included

Anti-Measles IgM

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

System: DiaSorin LIAISON XL
NovaTec, Novagnost

Analytes included

Anti-Parvo B19 IgM

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

For further information see instructions for use.

* From date of manufacture

Optitrol Mumps M

Storage and Stability

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

System: DiaSorin LIAISON XL
Siemens Enzygnost

Analytes included

Anti-Mumps IgM

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

System: DiaSorin LIAISON XL
Siemens Enzygnost

Analytes included

Anti-VZV IgM

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 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
Fujirebio
Biokit

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

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

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

System: Trinity Biotech

Analytes included

Anti-*Plasmodium sp.* IgG

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

For further information see instructions for use.

* From date of manufacture

Optitrol Chagas

Storage and Stability

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

System: DiaSorin LIAISON XL
Roche Elecsys
Abbott PRISM

Analytes included

Anti-*Trypanosoma sp.* IgG

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

For further information see instructions for use.

* From date of manufacture

NEW

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

Available soon

Optitrol NAT CTNG

Storage and Stability

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

Analytes included

Chlamydia trachomatis
Neisseria gonorrhoeae

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

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

Optitrol NAT MUT

Storage and Stability

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

Analytes included

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

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

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

Optitrol NAT HSV 1/2

Storage and Stability

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

Analyte included

HSV 1/2

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

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

Available soon

Optitrol NAT VZV

Storage and Stability

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

Analyte included

Varicella zoster virus

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

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

Optitrol NAT CMV

Storage and Stability

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

Analyte included

Cytomegalovirus

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

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

Optitrol NAT BKV-JVC

Storage and Stability

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

Analytes included

BK Virus
JC Virus

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

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

Available soon

Gastroenteritis

Storage and Stability

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

Analytes included

Single control of each analyte, see table below

CONTENT		KIT
Positive control		10 x 1.2 mL
PRODUCT	**CAT. NO.**	**ANALYTE**
Optitrol NAT Campylobacter	NT03011	*Campylobacter spp.*
Optitrol NAT Clostridium	NT03012	*Clostridium difficile A/B*
Optitrol NAT E. coli	NT03013	*Escherichia coli*
Optitrol NAT Salmonella	NT03014	*Salmonella spp.*
Optitrol NAT Shigella	NT03015	*Shigella spp.*
Optitrol NAT Vibrio	NT03016	*Vibrio cholerae*
Optitrol NAT Yersinia	NT03017	*Yersinia enterolytica*
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 *Staphylococcus aureus*
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

Available soon

Blood Borne Viruses and Parasites

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 HBV Screening	NT01011	Hepatitis B virus
Optitrol NAT HBV Viral Load	NT01012	Hepatitis B virus
Optitrol NAT HCV Screening	NT01021	Hepatitis C virus
Optitrol NAT HCV Viral Load	NT01022	Hepatitis C virus
Optitrol NAT HIV Screening	NT01031	Human immunodeficiency virus 1
Optitrol NAT HIV Viral Load	NT01032	Human immunodeficiency virus 1
Optitrol NAT Triplex	NT01041	HBV, HCV, HIV 1
Optitrol NAT NEG	NT01051	Negative for HBV, HCV, HIV 1
Optitrol NAT HAV Parvo	NT01111	Hepatitis A virus
		Parvovirus B 19
Optitrol NAT HEV	NT01121	Hepatitis E virus
Optitrol NAT CHIKV	NT01122	Chikungunya virus
Optitrol NAT Dengue	NT01123	Dengue Virus
Optitrol NAT Malaria	NT01131	*Plasmodium falciparum*
Optitrol NAT Babesia	NT01132	*Babesia spp.*

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

Available soon

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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ESfEQA
European Society for
External Quality Assessment

DAkkS
Deutsche
Akkreditierungsstelle
D-EP-19851-01-00

Quality Assessment Schemes Program

2022

CONTENT - ESFEQA PROGRAMS

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ESfEQA

ABOUT ESfEQA

A high quality standard is essential for every medical laboratory since test results are the basis for medical decisions and have an important impact on the well-being and treatment of patients. There are different approaches to maintain and improve quality in medical laboratories.
ESfEQA – European Society for External Quality Assessment – supports laboratories to assess the quality of their analytical results and ultimately improve their performance by providing well-designed external quality assessment programs. ESfEQA offers a wide range of External Quality Assessment Schemes. ESfEQA was founded in Heidelberg/Germany in 2013 and is accredited according to the international standard ISO 17043:2010 by the German national accreditation body DAkkS. Since its foundation, ESfEQA has expanded its program portfolio and at the same time the number of laboratories participating in ESfEQA's external quality assessment schemes. Currently, ESfEQA offers more than 90 quantitative and qualitative EQA programs worldwide in the areas of biochemistry, immunology, microbiology, molecular diagnostics and hematology.

Registration and Sample Ordering

ESfEQA offers EQA schemes worldwide and cooperates with reliable regional distributors. They are the direct business partners of participants, responsible for the ordering process, invoicing and local shipment of survey samples.
ESfEQA offers programs with 2, 4 or 12 surveys per year. In general, programs should be ordered for an entire calendar year. To ensure a cost-effective shipping process, survey samples are shipped semi-annually as long as this frequency is permitted by sample stability.

Survey Calendar

The dates for begin of result entry and deadline for result entry are published in this catalogue and on the ESfEQA website (www.esfeqa.eu).

Submission of Results, Survey Reports and Certificates

Participants submit their results online via the TEQA web-application. Requests for new method, instrument and reagent codes can be made online. The subscription to any ESfEQA program allows participants to submit up to three results obtained from a single control set using different devices. Reports and certificates are provided online as pdf-files within 3 weeks (within 10 days for monthly programs) after the deadline of result submission. Report files and certificates can be stored electronically, forwarded and printed.

New Programs

Based on the feedback of our participants, ESfEQA extends the EQA portfolio continously. Please contact us for further suggestions on new programs.
Programs that have not been listed on the ESfEQA ISO 17043 accreditation certificate yet are marked in this catalogue as not accredited.

Heidelberg, September 2021

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BIOCHEMISTRY PROGRAMS

BILIRUBIN NEONATAL — BILI-N

New Program

2 lyohilized samples (minimum 0,5 mL) of human serum.
4 surveys per year.

Analytical parameter:

Bilirubin

BLOOD GAS AND ELECTROLYTES — BG

Liquid buffered aqueous solution or serum-based samples (minimum 2 mL). 4 or 12 surveys per year.
One sample per survey in monthly program (BG12), two samples per survey in quarterly program (BG4).

Analytical parameters:

Calcium	pCO_2	Sodium
Chloride	pH	Urea
Glucose	pO_2	
Lactate	Potassium	

CARDIAC MARKER — CM

Lyophilized samples (minimum 1 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (CM12), two samples per survey in quarterly program (CM4).
The samples are based on human serum. Analytical devices that are intended for whole blood only are not suitable for these samples.

Analytical parameters:

BNP	Homocysteine	NT-proBNP
CK-MB (mass)	Myoglobin	Troponin I
CK-MB (activity)		Troponin T

CEREBROSPINAL FLUID — CSF

2 liquid samples (minimum 1 mL) made from human serum and other human and chemical components.
4 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Albumin	IgG	Sodium
Chloride	IgM	Protein
Glucose	Lactate	
IgA	LDH	

CLINICAL CHEMISTRY CC

Lyophilized samples (5 mL) of human sera with added enzymes and proteins of human origin.
2, 4 or 12 surveys per year. One sample per survey in monthly program (CC12), two samples per survey in quarterly and semiannual programs (CC4 and CC2).

Analytical parameters:

Albumin	Cholinesterase	Lithium
ALP Alkaline phosphatase	CK Creatinkinase	Magnesium
ALT/GPT	Creatinine	Phosphate
Amylase	Copper	Potassium
Amylase pancreatic	Gamma GT	Sodium
AST/GOT	Glucose	TIBC Total Iron Binding Capacity
Bilirubin, direct	HDL Cholesterol	Total protein
Bilirubin, total	Iron	Triglycerides
Calcium	Lactate	UIBC Unsaturated Iron Binding Capacity
Calcium (ionized)	LDH Lactate Dehydrogenase	Urea
Chloride	LDL Cholesterol	Uric acid
Cholesterol	Lipase	Zinc

COAGULATION COA

Lyophilized samples (1 mL) of human plasma.
4 or 12 surveys per year. One sample per survey in monthly program (COA12), two samples per survey in quarterly program (COA4).

Analytical parameters:

aPTT (activated Partial Thromboplastin Time)	D-Dimer	Protein C
Antithrombin III	Fibrinogen	Protein S
	PT (prothrombin time)	

CO-OXIMETRY OXI

2 liquid or lypholized samples (minimum 0,5 mL) containing bovine hemoglobin.
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytische Parameter:

Oxyhemoglobin	Carboxyhemoglobin	total Hemoglobin
Desoxyhemoglobin	Methemoglobin	

DRUGS OF ABUSE DAT

2 liquid or lyophilized samples (minimum 1 mL) of filtered human urines with added drugs for qualitative analysis.
4 surveys per year.

Analytical parameters:

Acetylmorphine	Cannabinoids	Metamphetamines
Amphetamines	Cocaine and metabolites	Opiates
Barbiturates	MDMA	Synthetic Cannabinoids (K2/Spice)
Benzodiazepines	Methadone and metabolites	Tricyclic Antidepressants
Buprenorphine		

ETHANOL, AMMONIA AND BICARBONATE — ETH

Liquid samples (minimum 0.5 mL) with added compounds. 4 or 12 surveys per year. One sample per survey in monthly program (ETH12), two samples per survey in quarterly program (ETH4).

Analytical parameters:

Ethanol	Ammonia	Bicarbonate*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010

FECAL OCCULT BLOOD — FOB

2 liquid samples (minimum 0.5 mL) simulating extracted stool samples. 2 surveys per year.

Analytical parameters:

Human Hemoglobin (qualitative and quantitative)

GLYCATED HEMOGLOBIN — GHB

Lyophilized samples (minimum 0.5 mL) of hemolysate of human blood.
4 surveys or 12 per year. One sample per survey in monthly program (GHB12), two samples per survey in quarterly program (GHB4).

Analytical parameters:

HbA1c	Hemoglobin

PROTHROMBIN TIME (INR)-POCT — INR-POCT

2 liquid samples (minimum 0.3 mL) suitable for POCT analyzers, e.g. Roche Coaguchek, Siemens Xprecia Stride, Abbott iStat.
4 surveys per year.

New Program

Analytical parameters:

Prothrombine time (INR)

QUALITATIVE URINE ANALYSIS (URINE STICK) — US

2 liquid samples (min. 2 mL) of urine preparation of human origin with added preservatives and stabilizers.
4 surveys per year.

Analytical parameters:

Bilirubin	Ketone bodies	Specific Gravity
Glucose	Leucocytes	Total Protein
hCG	Nitrite	Urobilinogen
Hemoglobin	pH	

QUALITATIVE URINE ANALYSIS (URINE STICK) USXL

2 liquid samples (min. 10 mL) of urine preparation of human origin with added preservatives and stabilizers.
4 surveys per year.

Analytical parameters:

Bilirubin	Ketone bodies	Specific Gravity
Glucose	Leucocytes	Total Protein
hCG	Nitrite	Urobilinogen
Hemoglobin	pH	

THERAPEUTIC DRUGS TDM

2 liquid samples (minimum 2 mL) with added compounds.
4 surveys per year.

Analytical parameters:

Amikacin	Gentamicin	Procainamide
Carbamazepine	Lidocain	Salicylate
Chinidine	NAPA	Theophylline
Chloramphenicol	Paracetamol	Tobramycin
Digoxin	Phenobarbital	Valproic Acid
Disopyramide	Phenytoin	Vancomycin
Ethosuximide	Primidone	

URINE CHEMISTRY UC

2 lyophilized samples (minimum 5 mL) of urine of human origin with added preservatives and stabilizers.
4 surveys per year.

Analytical parameters:

Albumin / Microalbumin	Glucose	Total protein
Amylase*	Magnesium	Sodium
Calcium	Osmolality	Urea
Chloride	Phosphate	Uric acid
Creatinine	Potassium	

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

URINE SEDIMENTS USED

2 liquid samples (minimum 5 mL) of urine of human origin. 4 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Bacteria qual., semi-quant., quant.	Red cells qual., semi-quant., quant.
Casts qual., semi-quant., quant.	White cells qual., semi-quant., quant.
Crystals qual., semi-quant., quant.	

IMMUNOLOGY PROGRAMS

HCG — HCG

1 lyophilized sample (minimum 1 mL) of human serum with added analytes of human origin.
4 surveys per year.

Analytical parameters:

hCG qualitative

HORMONES — HOR

Liquid or lyophilized samples (minimum 2 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (HOR12), two samples per survey in quarterly program (HOR4).

Analytical parameters:

Aldosterone	hCG	T3, free
AMH	Homocysteine	T3, total
Androstendione	Human Growth Hormone	T4, free
Calcitonin	IgE	T4, total
C-Peptide	Insulin	Testosterone
Cortisol	LH (Luteinizing Hormone)	Thyreoglobulin
DHEA-S	Methylmalonic Acid	TSH
Estradiol	PTH	Vitamin B12
Ferritin	Progesterone	Vitamin D (25-OH)
Folate	Prolactin	17-OH-Progesterone
FSH	SHBG	

PROCALCITONIN — PCT

2 lyophilized samples (minimum 0.5 mL) of human sera with added analyte.
4 surveys per year.

Analytical parameters:

Procalcitonin

SPECIFIC PROTEINS — SP

Liquid (minimum 1 mL) or lyophilized samples (1 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (SP12), two samples per survey in quarterly program (SP4).

Analytical parameters:

Albumin	C4	IgM
Alpha-1-acid glycoprotein	Ceruloplasmin	Kappa light chains, total* and free
Alpha-1-antitrypsin	CRP (C-Reactive Protein)	Lambda light chains, total* and free
Alpha-2-macroglobulin	Haptoglobin	Prealbumin
ASO	IgA	RF
Beta-2-microglobulin	IgE	soluble Transferrin receptor (sTfR)*
C3	IgG	Transferrin

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

THYROID ANTIBODIES — ANTI-THYR

2 samples (minimum 0,5 mL) .
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytische Parameter:

anti-TG	anti-TPO

TUMOR MARKER — TM

Liquid or lyophilized samples (minimum 2 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program (TM12), two samples per survey in quarterly program (TM4).

Analytical parameters:

AFP	CA 125	PSA, total
CEA	CA 15-3	PSA, free
CA 19-9	Ferritin	

TUMOR MARKER & HORMONES — TMH

Lyophilized sample (minimum 3 mL) of human sera with added analytes.
4 or 12 surveys per year. One sample per survey in monthly program (TMH12), two samples per survey in quarterly program (TMH4).

Analytical parameters:

AFP	Ferritin	PSA, total
Aldosterone	Folate	PTH
AMH	FSH	SHBG
Androstendione	hCG	T3, free
CA 125	Homocysteine	T3, total
CA 15-3	Human Growth Hormone	T4, free
CA 19-9	IgE	T4, total
Calcitonin	Insulin	Testosterone
CEA	LH (Luteinizing Hormone)	Thyreoglobulin
Cortisol	Methylmalonic Acid	TSH
C-Peptide	Progesterone	Vitamin B12
DHEA-S	Prolactin	Vitamin D (25-OH)
Estradiol	PSA, free	17-OH-Progesterone

MICROBIOLOGY PROGRAMS

ADENOVIRUS — ADE

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Adenovirus

ASPERGILLUS FUMIGATUS — ASF

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG, IgM and total antibodies against Aspergillus fumigatus

BACTERIOLOGY — BAC-C, BAC-E

4 lyophilized samples (pure strains and/or mixture of bacteria): 2 for identification and 2 for antibiotic susceptibility testing (AST). AST according to EUCAST guidelines (BAC-E) or according to CLSI guidelines (BAC-C)
4 surveys per year. (Simulated) clinical information about the sample type is provided.

Analytical parameters:

Identification (genus and species)
Antibiotic susceptibility testing (according to EUCAST or CLSI guidelines)

BORRELIA — BOR

2 liquid samples (minimum 0.3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Borrelia

BORRELIA IgG-ANTIBODY INDEX (AI) — BOR-G-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

Borrelia IgG-antibody index (AI), qualitative and quantitative

BORRELIA IgM-ANTIBODY INDEX (AI) — BOR-M-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the anti-body index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

Borrelia IgM-antibody index (AI), qualitative and quantitative

BRUCELLA — BRU

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgA, IgG and IgM antibodies against Brucella	agglutinating antibodies against Brucella

CHAGAS — CHA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG antibodies against Trypanosoma cruzi

CHIKUNGUNYA VIRUS — CHIKV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Chikungunya Virus

CHLAMYDOPHILA PNEUMONIAE — CHP

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Chlamydophila pneumoniae

CHLAMYDIA TRACHOMATIS — CHT

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Chlamydia trachomatis

COXSACKIEVIRUS — COX

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Coxsackievirus

DENGUE VIRUS — DENV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Dengue Virus

ECHO-VIRUS — ECH

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against ECHO-Virus

ENTEROVIRUS — ENT

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Enterovirus

EPSTEIN-BARR VIRUS — EBV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-EBV VCA IgG + total	anti-EBV EBNA-1 IgG + total	anti-EBV VCA IgM

HEPATITIS A VIRUS — HAV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HAV IgG + total	anti-HAV IgM

HEPATITIS B VIRUS — HBV

2 liquid samples (minimum 1 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HBs (qual. and quant.*)	anti-HBe	HBeAg
anti-HBc IgG + total	HBsAg (qual. and quant.)	anti-HBc IgM

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

HEPATITIS E VIRUS — HEV

2 liquid samples (minimum 0,3 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-HEV IgG + total	anti-HEV IgM

HIV ANTIBODIES AND ANTIGEN — HIV

2 liquid samples (minimum 0,3 mL) of human plasma.
4 surveys per year.

Analytical parameters:

anti-HIV 1/2 antibodies	HIV p24 Antigen*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

HTLV I/II — HTL

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

anti-HTLV I/II

INFECTIOUS DISEASE COMBINATION CONTROL — INF

2 liquid samples (minimum 0,5 mL) of human plasma. 4 surveys per year (INF4).
4 liquid samples (minimum 0,5 mL) of human plasma. 4 surveys per year (INF4x4).
2 liquid samples (minimum 0,5 mL) of human plasma. 2 surveys per year (INF2).

Analytical parameters:

anti-HIV 1/2 / p24 Ag — anti-HBc — HBsAg
anti-HCV

INFLUENZA A VIRUS — INA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza A Virus

INFLUENZA B VIRUS — INB

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Influenza B Virus

LEPTOSPIRA — LEP

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Leptospira — agglutinating antibodies against Leptospira*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

MALARIA MICROSCOPY — MALM

2 slides of stained smears.
4 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Malaria Parasite Detection	Stage Identification
Species Identification	Quantification of Plasmodium falciparum

MEASLES — MEA

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Measles Virus

PARAINFLUENZA VIRUS — PIN

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA reagents. Other reagents upon request.

Analytical parameters:

IgA, IgG and IgM antibodies against Parainfluenza Virus

PARVOVIRUS B19 — PAR

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Parvovirus B19

RESPIRATORY SYNCYTIAL VIRUS — RSV

2 liquid samples (minimum 0,3 mL) of human plasma.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010. The scheme is intended for Novatec, Virion/Serion, Virotech and Euroimmun ELISA and Euroimmun IFT reagents. Other reagents upon request.

Analytical parameters:

IgG, IgM and IgA antibodies against Respiratory Syncytial Virus (RSV)

SARS-CoV-2 ANTIBODIES — COVID

4 liquid samples (minimum 0,3 mL) of human plasma.
4 surveys per year.

Analytical parameters:

IgA, IgG, IgM and antibodies total against SARS-CoV-2
neutralizing antibodies aganist SARS-CoV-2

SARS-CoV-2 ANTIGEN — COVAG

3 liquid or lyophilized samples (minimum 0,3 mL) simulating swab specimens (e.g. oropharyngeal, nasopharyngeal, nasal etc.).
4 surveys per year. SARS-CoV-2 antigen positive samples contain inactivated whole virus.

Analytical parameters:

SARS-CoV-2 Antigen qualitative and quantitative

SYPHILIS — SYP

2 liquid samples (1 mL) of human plasma. 4 surveys per year (SYP4) in quarterly program, 2 surveys per year (SYP2) in semi-anual program.

Analytical parameters:

anti-Treponema pallidum antibodies (qualitative)
IgG and IgM antibodies against Treponema pallidum (qualitative)*
IgG and IgM, antibodies total against Treponema pallidum (semi-quantitative)*
IgG and IgM, antibodies total against Treponema pallidum (quantitative)*
Non-treponemal Lipoid antibodies (qualitative)
Non-treponemal Lipoid antibodies (semi-quantitative)*

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

TBEV IgG-ANTIBODY INDEX (AI) — TBEV-G-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

TBEV IgG-antibody index (AI)

TBEV IgM-ANTIBODY INDEX (AI) — TBEV-M-AI

One CSF/serum sample pair and (simulated) clinical information on the patient needed to calculate the antibody index is provided to the participant. The sample volume is at least 1.0 mL for the CSF sample and 0.3 mL for the serum sample.
2 surveys per year. This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

New Program

Analytical parameters:

TBEV IgM-antibody index (AI)

ToRCH TORCH

2 liquid samples (minimum 1 mL) of human plasma. 4 surveys per year.

Analytical parameters:

anti-CMV IgG (qual. and quant.*)	anti-HSV 1 IgG	anti-Rubella IgM
anti-CMV IgM	anti-HSV 2 IgG	anti-Toxoplasma gondii IgG (qual. and quant.*)
anti-HSV 1/2 IgG (qual. and quant.*)	anti-HSV 1 IgM	anti-Toxoplasma gondii IgM
anti-HSV 1/2 IgM	anti-HSV 2 IgM	
	anti-Rubella IgG (qual. and quant.*)	

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

VARICELLA ZOSTER VIRUS VZV

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG, IgM, and IgA antibodies against Varicella Zoster Virus (VZV), qual. and quant*

* The quantitative antibody determination is not accredited according to DIN EN ISO/ IEC 17043:2010.

WEST NILE VIRUS WNV

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against West Nile Virus

ZIKA VIRUS ZIKV

2 liquid samples (minimum 0,3 mL) of human plasma. 2 surveys per year.

Analytical parameters:

IgG and IgM antibodies against Zika Virus

HBV MOLECULAR — HBVM

2 lyophilized samples (minimum 1,1 mL) of human serum. Virus positive samples contain the whole genome of inactivated HBV.
4 surveys per year. This program is not accredited according to DIN EN ISO/IEC 17043:2010.
Launch 2nd quarter 2022.

New Program

Analytische Parameter:

HBV-DNA

HCV MOLECULAR — HCVM

2 lyophilized samples (minimum 1,1 mL) of human serum. Virus positive samples contain the whole genome of inactivated HCV.
4 surveys per year. This program is not accredited according to DIN EN ISO/IEC 17043:2010.
Launch 2nd quarter 2022.

New Program

Analytische Parameter:

HCV-RNA

HIV MOLECULAR — HIVM

2 lyophilized samples (minimum 1,1 mL) of human serum. Virus positive samples contain the whole genome of inactivated HIV.
4 surveys per year. This program is not accredited according to DIN EN ISO/IEC 17043:2010.
Launch 2nd quarter 2022.

New Program

Analytische Parameter:

HIV-RNA

SARS-COV-2 MOLECULAR — COVM

3 liquid or lyophilized samples (minimum 1 mL) containing human epithel cells or fibroblasts as control for positive nucleic acid extraction and amplification. Virus-positive samples contain the whole genome of inactivated SARS-CoV-2, thus covering all possible gene targets used in different NAT/PCR assays.
4 surveys per year.

Analytical parameters:

SARS-CoV-2 RNA (qualitative) General detection as well as reporting per gene target	SARS-CoV-2 RNA (quantitative) General indication as well as reporting of quantitative value per gene target

HEMATOLOGY PROGRAMS

BLOOD GROUPING ABO

2 liquid samples (minimum 4 mL) of stabilized human red cells suspended in a buffered fluid and preservative. Erythrocyte suspensions contain a red blood cell concentration of 8% minimum. 4 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

ABO-Typing	Rhesus (D)-Detection

IMMUNOHEMATOLOGY IMHEM

2 erythrocyte suspensions (patient; min. 4 mL), 2 serum samples (patient; min. 4 mL) and 2 erythrocyte suspensions (donor; min. 4 mL). Erythrocyte suspensions contain a red blood cell concentration of 8% minimum. 2 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

ABO-Typing	Kell-Antigen Detection	Cross-matching
A-Subtypes	Direct Coombs test	
Rhesus (D)-Detection	Antibody screening	
Rh-Typing	Antibody identification	

ERYTHROCYTE SEDIMENT. RATE ON ALCOR ISED ANALYZERS ESRAL

2 liquid samples (about 4 mL) of stabilized human red cells suspended in a buffered fluid and preservative. 2 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE ON ALIFAX ANALYZERS ESRAF

3 liquid samples (about 3 mL) for transmittance measurement related to ESR values in human samples presented in Greiner tubes (ESRAF-G) or in Sarstedt tubes (ESRAF-S). 2 surveys per year.
This program is not accredited according to DIN EN ISO/ IEC 17043:2010.

Analytical parameters:

Erythrocyte Sedimentation Rate

ERYTHROCYTE SEDIMENTATION RATE — ESR

2 liquid samples (3 mL) containing erythrocytes in blood collection tubes (75x13mm) with pierceable caps. 4 surveys per year. The samples are not suitable for testing on Alifax and Alcor iSED instruments.

Analytical parameters:

Erythrocyte Sedimentation Rate

HEMOGRAM — HEM

Plasma like fluid samples (minimum 2 mL) that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs. 2, 4 or 12 surveys per year. One sample per survey in monthly program (HEM12), two samples per survey in quarterly and semiannual program (HEM4 and HEM2). This program is suitable for hematology analyzers with and without leucocyte-differentiation.

Analytical parameters:

HCT (hematocrit)
HGB (hemoglobin)
MCH (mean corpuscular hemoglobin)
MCHC (mean cellular hemoglobin concentration)
MCV (mean corpuscular volume)
MPV (mean platelet volume)
PCT (Plateletcrit)
PLT (platelets)
RBC (red blood cells)
RDW (RBC distribution width)
WBC (white blood cells)

HEMOGRAM INCL. 3-PART DIFF. — HEM3D

2 plasma like fluid samples (minimum 1,5 mL) that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs. 4 surveys per year.
This program is dedicated for 3-part WBC/leucocyte differential hematology analyses.

Analytical parameters:

GRAN (granulocytes)
HCT (hematocrit)
HGB (hemoglobin)
LYMPH (lymphocytes)
MCH (mean corpuscular hemoglobin)
MCHC (mean cellular hemoglobin concentration)
MCV (mean corpuscular volume)
MID, MXD (mid-sized leucocytes)
MONO (monocytes)
MPV (mean platelet volume)
NEUT (Neutrophiles)
PCT (Plateletcrit)
PLT (platelets)
RBC (red blood cells)
RDW (RBC distribution width)
WBC (white blood cells)

HEMOGRAM INCL. 5-PART DIFF. — HEM5D

2 plasma like fluid samples (minimum 1,5 mL) that contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs. 4 surveys per year.

Analytical parameters:

BASO (basophiles)*
EO (eosinophiles)*
HCT (hematocrit)
HGB (hemoglobin)
LYMPH (lymphocytes)
MCH (mean corpuscular hemoglobin)
MCHC (mean cellular hemoglobin concentration)
MCV (mean corpuscular volume)
MONO (monocytes)
MPV (mean platelet volume)
NEUT (neutrophiles)
PCT (plateletcrit)
PDW (platelet distribution width)*
PLT (platelets)
RBC (red blood cells)
RDW (RBC distribution width)
RET (reticulocytes)*
WBC (white blood cells)

* This parameter is not accredited according to DIN EN ISO/ IEC 17043:2010.

CASE STUDY PROGRAM CASE

This programme focuses on the interpretation of analytical data and aims to support and strengthen the skills of staff to draw the right conclusions from the analytical results.
Participants receive the case description online and submit their interpretation of the clinical data via the ESFEQA web application.
12 surveys per year.

New Program

Parameters:

Suspected diagnosis	Parameters supporting the suspected diagnosis
Other tests to confirm the diagnosis	Therapy suggestions

ESfEQA INTERNATIONAL EQA SCHEMES SURVEY SAMPLE SCHEDULE 2022
Quarterly Programs and Semi-annual Programs 1

Program (Program Code) Quarterly Programs	Sample	Begin of Result Entry - Closing Date	Program (Program Code) Semi-annual Programs 1	Sample	Begin of Result Entry - Closing Date
ABO - Blood Grouping			ADE - Adenovirus		
ANTI-THYR - Thyroid Antibodies			ASF - Aspergillus fumigatus		
BAC-C, BAC-E - Bacteriology	2022_01_a	14/02/2022 - 07/03/2022	BOR - Borrelia	2022_01_a	25/04/2022 - 16/05/2022
BG4 - Blood Gas & Electrolytes	2022_01_b		BOR-G-AI - Borrelia IgG-Antibody Index	2022_01_b	
BILI-N - Bilirubin Neonatal			BOR-M-AI - Borrelia IgM-Antibody Index		
CC4 - Clinical Chemistry	2022_02_a	11/04/2022 - 02/05/2022	BRU - Brucella		
CM4 - Cardiac Marker	2022_02_b		CHA - Chagas		
COA4 - Coagulation			CHIKV - Chikungunya Virus	2022_02_a	31/10/2022 - 21/11/2022
CSF - Cerebrospinal Fluid			CHP - Chlamydophila Pneumoniae	2022_02_b	
DAT - Drugs of Abuse	2022_03_a	11/07/2022 - 01/08/2022	CHT - Chlamydia Trachomatis		
EBV - Epstein-Barr Virus	2022_03_b		COX - Coxsackievirus		
ESR - Erythrocyte Sedimentation Rate			DENV - Dengue Virus		
ETH4 - Ethanol	2022_04_a	17/10/2022 - 07/11/2022	ECH - Echovirus		
GHB4 - Glycated Hemoglobin	2022_04_b		ENT - Enterovirus		
HAV - Hepatitis A			ESRAF-G, ESRAF-S - ESR on Alifax analyzers		
HBV - Hepatitis B			ESRAL - ESR on Alcor analyzers		
HBVM - HBV Molecular			FOB - Fecal Occult Blood		
HCG - hCG			HTL - HTLV I/II		
HCVM - HCV Molecular			IMHEM - Immunohematology		
HEV - Hepatitis E			INA - Influenza A		
HIV - HIV Antibodies and Antigen			INB - Influenza B		
HIVM - HIV Molecular			LEP - Leptospira		
HOR4 - Hormones			MEA - Measles		
INF4, INF4x4 - Infectious Disease Control			PAR - Parvovirus B19		
INR-POCT - Prothrombine time (POCT)			PIN - Parainfluenza Virus		
MALM - Malaria Microscopy			RSV - Respiratory Syncytial Virus		
PCT - Procalcitonin			TBEV-G-AI - TBEV IgG-Antibody Index		
COVID - SARS-CoV-2 (COVID-19) antibodies			TBEV-M-AI - TBEV IgM-Antibody Index		
COVAg - SARS-CoV-2 (COVID-19) antigen			VZV - Varicella Zoster Virus		
COVM - SARS-CoV-2 (COVID-19) molecular			WNV - West-Nile Virus		
HEM3D - Hemogram including 3-part Differential			ZIKV - Zika Virus		
HEM5D - Hemogram including 5-part Differential					
HEM4 - Hemogram					
OXI - CO-Oximetry					
SP4 - Specific Proteins					
SYP4 - Syphilis					
TDM -Therapeutic Drugs					
TM4 - Tumor Marker					
TMH4 - Tumor Marker/Hormones					
ToRCH - Torch Parameters					
UC - Urine Chemistry					
USED - Urine Sediments					
US, USXL - Qualitative Urine Analysis					

The suffix _a and/or _b of the sample identifcation are subject to change to other letters e.g. _c and/or _d

Place your order at least 2 months prior to the begin of the corresponding testing period (3 months for ABO, ESR, ESRAF, ESRAL, HEM4, HEM12, HEM3D, HEM5D and IMHEM).

ESfEQA INTERNATIONAL EQA SCHEMES SURVEY SAMPLE SCHEDULE 2022
Monthly Programs and Semi-annual Programs 2

Program (Program Code)	Sample	Begin of Result Entry - Closing Date	Program (Program Code)	Sample	Begin of Result Entry - Closing Date
Monthly Programs			Semi-annual Programs 2		
BG12 - Blood Gas and Electrolytes	2022_01_a	31/01/2022 - 14/02/2022	CC2 - Clinical Chemistry	2022_01_a	14/02/2022 - 07/03/2022
CASE - Case Study Program (CASE)	2022_02_a	21/02/2022 - 07/03/2022	HEM2 - Hemogram	2022_01_b	
CC12 - Clinical Chemistry	2022_03_a	21/03/2022 - 04/04/2022	SYP2 - Syphilis		
CM12 - Cardiac Marker	2022_04_a	18/04/2022 - 02/05/2022	INF2 - Infectious Disease Control		
COA12 - Coagulation	2022_05_a	16/05/2022 - 30/05/2022		2022_02_a	11/07/2022 - 01/08/2022
ETH12 - Ethanol	2022_06_a	13/06/2022 - 27/06/2022		2022_02_b	
GHB12 - Glycated Hemoglobin	2022_07_a	18/07/2022 - 01/08/2022			
HEM12 - Hemogram	2022_08_a	15/08/2022 - 29/08/2022			
HOR12 - Hormones	2022_09_a	12/09/2022 - 26/09/2022			
SP12 - Specific Proteins	2022_10_a	17/10/2022 - 07/11/2022			
TM12 - Tumor Marker	2022_11_a	14/11/2022 - 28/11/2022			
TMH12 - Tumor Marker/Hormones	2022_12_a	05/12/2022 - 19/12/2022			

The suffix _a and/or _b of the sample identifcation are subject to change to other letters e.g. _c and/or _d

Place your order at least 2 months prior to the begin of the corresponding testing period (3 months for ABO, ESR, ESRAF, ESRAL, HEM4, HEM12, HEM3D, HEM5D and IMHEM).

GENERAL TERMS FOR THE PARTICIPATION IN EXTERNAL QUALITY ASSESSMENT SURVEYS OF ESFEQA

Status September 2021

1. Participation
The participation in the external quality assessment (EQA) surveys of ESfEQA is open to any¬one who performs laboratory tests in their own practice or in a managed medical laboratory. The follow-ing conditions for participation apply.

2. Consent to conditions of participation
By registering with ESfEQA GmbH, the participant agrees to these general terms and conditions of participation.

3. Assignment of services
Individual parts of EQA schemes (e.g. pretesting of values, packaging and shipping) may be as-signed to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. ESfEQA catalog
The ESfEQA portfolio of offered EQA schemes and the analytes contained in the individual programs are described in the ESfEQA catalog. Depending on the availability of samples and the number of participants ESfEQA reserves the right, not to offer the entire spectrum of analytes for each EQA survey or sample.

5. Schedule
The schedule is published in the catalog and on the ESfEQA website. It contains the deadlines for ordering, the testing period, and the deadline for result submission. After the deadline for ordering there is no entitlement for the acceptance of orders. Results have to be submitted to ESfEQA elec-tronically or by fax-form until the closing date. The calendar date refers to the time zone at the place of business of ESfEQA in Heidelberg, Germany (GMT +1).

6. Cancelation of EQA surveys
ESfEQA reserves the right to cancel or postpone EQA surveys. This information will be provided to participants before the originally planned shipping date of the samples. In this case, ESfEQA tries to offer an alternative date in a timely manner.

7. Registration
For the participation in ESfEQA EQA surveys a registration is required. This can be done online, or the necessary information can be provided to ESfEQA in written form. The following infor¬mation is required: laboratory name, name of the organization/hospital, name of participant, number of analyti-cal devices, and e-mail address.

8. Ordering of samples
The distribution of ESfEQA EQA surveys is usually carried out by international distributors. If there is no distributor available in the participant's region, sales can be carried out directly by ESfEQA. The ordering process between participants and distributors is the responsibility of the parties involved. As a rule, an EQA programme is ordered for a full calendar year. Orders placed during the year gener¬ally include the survey samples up to the end of the current calendar year.

9. Homogeneity and stability of EQA samples
The EQA survey samples selected by ESfEQA were examined and evaluated with regard to homo-geneity and stability.

10. Designation of EQA samples
The EQA samples can be distinguished by their identifier. The identifier consists of the short name of the program, the year of the survey, the survey number and an index, when several samples are pro¬vided in a single survey. Thus, the sample with the labeling CM4_2022_01_a belongs to the quar-terly program Cardiac Marker (CM4) in the year 2022 and is sample “a” of the first survey. Samples with the same designation are not necessarily identical, i. e. different results can be measured de-spite the same designation. ESfEQA makes the correct allocation to the original batch and thus to the target values.

11. Shipping of EQA samples
Shipping of the EQA samples takes place by postal or parcel service. Due to governmental re-strictions, or insufficient stability, sample shipping of individual EQA programs to specific countries may be excluded.

12. Instructions for Use
Instructions for Use are provided to the participants for each EQA survey on the ESfEQA website (www.esfeqa.eu). A printout of the Instructions for Use is usually enclosed with the sample package. The Instructions for Use include instructions for the preparation of the samples, sample stability and the deadline for submission of results.

13. Use of EQA samples
Usually, EQA samples are to be handled like patient samples and measured in the same way as rou-tine samples according to the instructions of the instrument and reagent manufacturers. They may only be used for the purpose of participating in an EQA survey and may not be used in a misappro-priated manner. Generally, the usual precautions in the laboratory for potentially hazardous and po-tentially infectious samples apply to EQA samples.

14. Submission of survey results
Where applicable the submission of the results includes, in addition to the actual measured value, the indication of the method used, the instrument used and the reagent used. The input mask in the evaluation software application TEQA used by ESfEQA predetermines the required information for each EQA program. A list of methods, instruments and reagents is provided in the configuration section.
If the method, instrument or reagent used for the measurement by the participant is not included in this selection list, participants may add their method, instrument or reagent to this list through the in-put mask “coding request”. They can then select their added method, instrument and reagent to complete their configuration prior to entering their test results.
The selection of method, instrument and reagent as well as the submission of results are to be trans¬mitted through the web-application TEQA. Participants receive the login data required for the entry of results from ESfEQA. The password consists of at least 8 characters, of which at least 2 are special characters. Username and password are to be treated confidentially by the participant.
As alternative to the result submission via the web-application TEQA, results can be submitted using forms, that can be sent to ESfEQA either by E-Mail (info@esfeqa.eu) or Fax (+49 6221 894669-90). The corresponding forms that are specific for each EQA program and survey are provided on the ESfEQA website. ESfEQA encourages the participants to submit their results online via the secured TEQA

web application for the sake of data security and convenience.
ESfEQA evaluates all survey results that are submitted by the participants in due time. For loss or late arrival of their data the participant bears the risk. There is no claim for data assessment of test results arrived late.
Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. In general, result should be reported as measured, however, results specified "< test range' (e.g. "< 10") and "> test range" (e.g. ">2000") are not valid. If the analyzer system displays such results, they shall be interpreted as follows: for results below the test range, the lower test range limit should be reported (e.g. "10"). For samples that have analyte concentra-tions above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit (e.g. "2000") can be reported as the result. Several units are usually availa-ble for entering quantitative results. The units are converted into the standard unit used by ESfEQA.
Laboratories are obliged to treat their results confidentially and not to pass them on to third parties until the EQA survey report has been received. If ESfEQA becomes aware of the passing on or falsi¬fication of results or the collusion between participants, ESfEQA reserves the right to exclude those concerned from further participation in EQA surveys conducted by ESfEQA as well as to exclude the issuance of reports.

15. Number of results per participant
For each EQA sample and analyte, up to 3 values per participant can be submitted. The values have to be determined by different analytical devices that are independent from each other.

16. Correction of transmitted results
Once the results have been submitted via the web-application TEQA and the participant realizes any need for changing the results, the participant can submit a change request via the TEQA web appli-cation. This option exists until the deadline of result submission of the particular survey. ESfEQA may change the participant results after checking and accepting the change request. A change re-quest for results submitted by participants via the fax form can be sent to ESfEQA by e-mail or fax until the deadline or result submission. Participants who have submitted their results via the TEQA web application have to use the change request function in TEQA for any change request.

17. Evaluation of EQA results
For each analyte of ESfEQA EQA surveys, the type of target value determination and the ac-ceptance criterion are predefined in advance. For quantitative parameters, the target value is usually the consensus value of the participant results. This value is calculated according to ISO/IEC 13528:2020-09' Statistical methods for use in proficiency testing by interlaboratory comparisons' using robust statistics.
Samples provided for testing of qualitative parameters are thoroughly tested with different analytical systems before being used as control material, thereby setting the target value.
System-specific differences are taken into account where appropriate and possible. The broadest possible distinction is made according to the method, instrument and reagent used (M, I, R group). The minimum number of results of an evaluation group is 5 values. If this number is not reached in the survey, the individual result has to be compared to the robust mean of the next larger group that can be evaluated. Usually, this is the group consisting of participants using the same method (M group) or the general group containing the results of all participants. The definition of the evaluation group is documented in the survey report.
The maximum permissible ranges of the target value of quantitatively determined analytes are defined in advance and can be retrieved from the ESfEQA website. The permissible range for each analyte is derived from its medical relevance as well as the reference interval. In the report display, the upper limit of the permissible range corresponds to a z-value of 3 and the lower limit to a z-value of -3.

18. Survey reports
In general, the participants will be provided with reports electronically via the TEQA web-application within 10 days for monthly programs and within three weeks for quarterly and semi-annual programs after the deadline for submission of the results. The reports include the results submitted by the par-ticipant and their assessment compared to the target values. The data is displayed both in tabular and illustrated form (e. g. Histogram, Shewart chart, Youden plot). The reports are intended for exter¬nal quality assurance of laboratories. They may not be published, passed on or used for purposes other than quality assurance without the written consent of ESfEQA.

19. Fees
The fees for the participation are set and communicated to the participants by the responsible distrib¬utor of ESfEQA programs in their geographical area/country.

20. Certificates
Participants receive a certificate of participation for each EQA program they participate in.
In addition, the participants receive a certificate for the parameters for which they have met the spec¬ified performance criteria in the respective EQA survey. Both certificates are made available to the participants via the TEQA web-application. The certificates are issued simultaneously with the re-ports.

21. Loss and damage of EQA test material
In the event of loss of or damage to the sample material, ESfEQA shall, if possible and to the extent that an immediate complaint has been made, replace the sample material by sending replacement samples without acknowledging any claims. However, the contract is fulfilled on the date of dispatch of the original sample material.

22. Complaints
After receipt of an EQA survey report, a complaint can be made within a period of 4 weeks. After expiry of this period, any claims by the participant on the basis of a complaint are excluded. In the event of a justified complaint, there is a claim for reimbursement of the amount paid for the EQA survey or for the conduction of a substitute EQA survey. It is for ESfEQA to decide on one of these two options. ESfEQA GmbH does not reimburse any costs incurred for reagents, time expenditure etc. unless ESfEQA GmbH is liable in accordance with paragraph 23 of these General Terms and Conditions for Participation.

23. Warranty
ESfEQA shall only be liable for damages of any kind in the case of intent and gross negligence, if the other prerequisites for claims are met. In all other respects, liability for damages of any kind, regard¬less of the basis of the claim, including liability for culpa in contrahendo, is excluded.

24. Confidentiality
Individual EQA data is kept confidential. It is only known to the corresponding participant, their dis-tributor and ESfEQA employees. ESfEQA collects, processes and uses personal data of the partici¬pant only to the extent necessary for the performance of EQA surveys, the preparation of the reports and for the purpose of quality assurance. This includes the forwarding of the data identifiable by sub¬scriber and device number for quality assurance measures to the respective manufacturer of the analytical systems (device and reagent).

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