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Biologicals Quality Control B.V. De Droogmakerij 31h 1851 LX Heiloo the Netherlands

#### **Communication**

t: +31 72 20 20 730 e: info@bioqcontrol.com w: bioqcontrol.com

#### **Company details**

**Chamber of commerce:** 27257176

**VAT number:** NL8120.52.845.B.01 **IBAN:** NL89 RABO 0321 5806 13

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# **COMPANY**

#### **Mission**

Our mission is to provide consistent reference standards for validation and quality control of assays for detection of blood borne pathogens. Our ambition is to provide a post-market performance follow-up system for in vitro diagnostic devices (IVDs) intended for viral safety testing of blood products.

This can be achieved by external quality control

ensuring sufficient analytical sensitivity of blood screening tests. In understanding residual viral transmission risk by blood transfusion it is important that standards for validating NAT assays are calibrated in nucleic acid copies or virion numbers. The figure explains the foundations of our system for monitoring blood safety testing.

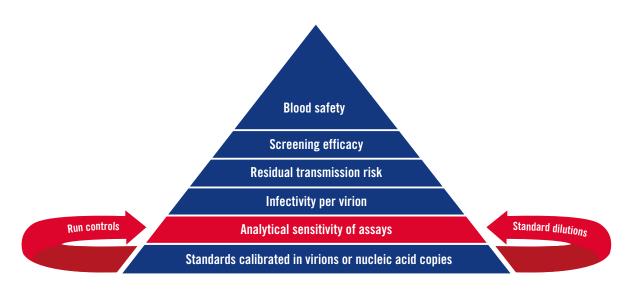


Figure. Standards for reference panels and run controls: foundations for monitoring blood safety

#### History

As head of the Viral Diagnostic Department of the Central Laboratory of the Netherlands Red Cross Blood Transfusion Service (CLB, Amsterdam) Nico Lelie organised the first international proficiency study for NAT methods in collaboration with the Eurohep Pathobiology Group (Lancet 1993 1993:441:722-724).

A manufacturing system was developed in the Viral Quality Control (VQC) unit of CLB (nowadays Sanquin) that proved feasibility of preparing equivalent standard dilutions over time. These standard dilutions were made commercially available by Sanquin as VQC proficiency panels, PeliCheck reference panels and PeliSpy run controls. These reagents were instrumental for standardisation, validation and quality control in the early days of NAT.

In the late 1990s Nico Lelie collaborated with NIBSC (Potters Bar, UK) for preparation and characterization of the first WHO International Standards for viral NAT and serology. From 2000 to 2004 the VQC business unit operated independently in a vacated blood bank in Alkmaar, the Netherlands. In that period the external quality control and assessment programs were further expanded in collaboration with the Dutch Quality Assessment Foundation (MCA, Winterswijk), NRL (Fitzroy, Australia) and DDL (Rijswijk, Netherlands).

In 2004, when Nico Lelie left VQC-Sanquin (to become Scientific Affairs Director of Chiron/ Novartis) the VQC business unit was acquired by a US based company (Acrometrix, Benicia, CA). To maintain the original Sanquin/DDL standards (calibrated in copies and IUs) Harry van Drimmelen and Wim Quint continued the VQC program and founded Biologicals Quality Control (BQC), a company that operated from the DDL facilities (Rijswijk, the Netherlands).

In 2010, after leaving Novartis Diagnostics, Nico Lelie started his own consultancy firm and joined BioQControl as minority shareholder. Following a management buyout in 2017 Nico Lelie and Harry van Drimmelen became the only shareholders and moved the company to a larger facility (Heiloo, the Netherlands). Significant investments in this new laboratory facility have allowed further growth of the scale of manufacturing and guaranteed more secure storage of viral standard dilutions and products at either -80 °C or -30 °C.

#### **Management Team**

The management team has a long history in evaluation of new IVDs, organization of proficiency studies and development of external run controls. Since the inception of the VQC program in 1992 Nico and Harry were involved in the design, validation and manufacturing of quality control products.



Nico Lelie CEO & Scientific Director



Harry van Drimmelen General Manager



## **MANUFACTURING**

Since organising the first international proficiency study of viral NAT methods in the early 1990s (Lancet 1993:441:722-724) our deep frozen viral plasma standards in liquid nitrogen have shown to be stable at -80°C. A fully traceable manufacturing system of gravimetrically recorded dilutions allows for reproducible production of batches of reference samples of known viral concentration.

The batch release control process ensures consistent reactivity of product comparable to the first manufactured reference batch. Our reference standards for viral serologic assays and NAT methods are diluted in the same serum or plasma matrix as clinical samples. The viral safety of run controls is guaranteed by inactivation methods of proven efficacy in the plasma and vaccine industry.

Our ISO 13485 certified manufacturing facility is secured for long term storage of standard dilutions at -80 °C or -30 °C (depending on the stability of the analyte). At regular intervals the facility is audited by the Notified Body (MDC) for ISO 13485:2016 certification. The figure gives an overview of the different types of reference panels and run controls that are manufactured for NAT assays. A series of run controls for viral serology and NAT have been CE marked by the Notified Body (MDC), while others are under review.

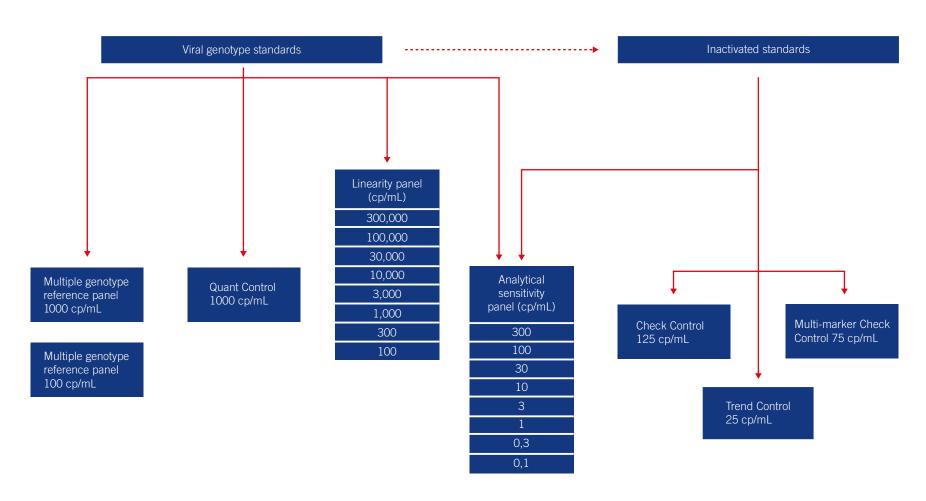


Figure. Schematic overview of preparation of reference panels and run controls from native and inactivated viral standards



## PRODUCT CATALOGUE

#### **Preface**

This catalogue is divided up in different product groups for validation or quality control of infectious disease tests. The products have been primarily designed for blood screening laboratories but they are also suitable for diagnostic laboratories. Over the years our products have been used by blood centers, plasma fractionators, IVD manufacturers and hospital laboratories.

# Thirty years standards and controls for viral serology and NAT

Since the early 1990s we have proven to produce consistent batches of reference panels and run controls from deep frozen viral standards. In the beginning our standard dilution panels were used in proficiency studies for viral serology and NAT. Later PeliCheck reference panels and PeliSpy run controls (prepared from the same standards) were widely used for validation and external quality control of IVDs. The reactivity on the first PeliSpy Controls produced in the mid1990s by VQC-Sanquin is still the same as on the currently produced BioQ Controls. No wonder, the same standards are still the foundation under these products.

Thirty years of data on our native and inactivated viral standards show the evolution of evermore sensitive NAT assays. Our viral standards for NAT have been extensively calibrated in IU/mL against the first WHO International Standards and were also carefully quantified in copies/mL using reference methods.

For understanding blood safety we even compared our viral standards with chimpanzee plasma's of known infectivity. An abundant amount of data on our standard dilution panels allowed for designing ViraQ run controls at close distance to the detection limits of the NAT methods.

The right positioning of run controls is key to being alerted when the analytical sensitivity of blood screening assays is significantly reduced. This functionality of BioQ Controls can be guaranteed because the long term stability of our standards has been firmly established. Stability of reference samples is a first requisite of NAT standardisation.



#### PRODUCT GROUPS

SeraQ Controls for viral serology assays

Multi-Marker HBsAg, anti-HCV, anti-HIV-1 Controls

Multi-Marker HBsAg, anti-HBc, anti-HCV, anti-HIV-1, anti-HTLV-I Controls

SeraQ Controls for Syphilis assays
Anti-Treponema pallidum (Syphilis) Controls

ViraQ Check and Trend Controls for HBV/HCV/HIV NAT assays HBV-DNA Controls HCV-RNA Controls HIV-1 RNA Controls Multi-Marker HBV-DNA, HCV-RNA, HIV-1 RNA Controls HIV-2 RNA Control

ViraQ Check Controls for non-enveloped virus NAT assays
Dual Marker parvo B19V DNA, HAV-RNA Control
HEV-RNA Control

ViraQ Check Controls for Arbovirus NAT assays WNV-RNA Control

Analytical sensitivity panels for HBV-DNA assays HBV-DNA genotype reference panels

Analytical sensitivity panels for HCV-RNA assays HCV-RNA genotype reference panels

Analytical sensitivity panels for HIV-RNA assays HIV-RNA subtype reference panels

Non-enveloped virus standard dilution panels Parvo B19V DNA reference panels HAV-RNA reference panels HEV-RNA reference panels

Arbovirus standard dilution panels WNV-RNA reference panels

Respiratory virus standard dilution panels SARS-CoV-2 RNA reference panels

Multiple viral genotype reference panels
HBV-DNA multiple genotype reference panels
HCV-RNA multiple genotype reference panels
HIV-RNA multiple subtype reference panels
HAV-RNA multiple genotype reference panels

ViraQ Quant Controls for viral load assays HBV-DNA, HCV-RNA, HIV-1 RNA, CMV-DNA, HSV-1 and 2 DNA assays

Linearity Panels for viral load assays HBV-DNA, HCV-RNA, HIV-1 RNA, HIV-2 RNA, and CMV-DNA linearity panels

# SERAQ CONTROLS FOR VIRAL SEROLOGY ASSAYS

SeraQ Multi-Marker Controls are composed of inactivated standards diluted in a defibrinated plasma (serum) matrix. A series of SeraQ Multi-Marker Controls have been designed to generate weakly reactive results (between 2 to 4 times the cutoff signal) in viral serology test systems of different IVD manufacturers.

The product names in the catalogue refer to the targeted test system or manufacturer.



P0374/01 SeraQ Alinity V3, 60 x 2.3 mL (60 tubes in rack/box)



Serum matrix



P0386/02 SeraQ Alinity V4, 10 x 3.0 mL (10 tubes in box)

# SeraQ Controls for ensuring sufficient analytical sensitivity of viral serology assays

Cat. No	SeraQ Control	Quantity	Regul. Status	Storage Temp.	List Price	Kit Insert	
Multi-Marker	· HBsAg, anti-HCV, anti-HIV-1 Controls						
P0078/01	P0078 SeraQ ARCHITECT	60 x 2 mL	DEO	- 20°C	€ 3670	KI407E	
P0078/02	P0078 SeraQ ARCHITECT	10 x 2 mL	PEO	≤ 20°C	€ 670	KI4075	
P0179/01	P0179 SeraQ Elecsys	60 x 2 mL	PEO	≤ 20°C	€ 3670	KI4179	
P0179/02	P0179 SeraQ Elecsys	10 x 2 mL	FEU	≤ 20 €	€ 670	NI4179	
P0180/01	P0180 SeraQ LIAISON	60 x 2 mL	PEO	≤ 20°C	€ 3670	KI4180	
P0180/02	P0180 SeraQ LIAISON	10 x 2 mL	PEU	≤ 20 €	€ 670	NI4100	
P0259/01	P0259 SeraQ Murex	60 x 2 mL	PEO	≤ 20°C	€ 3670	KI4260	
P0259/02	P0259 SeraQ Murex	10 x 2 mL	FEU	≤ 20 €	€ 670	N1420U	
P0309/01	P0309 SeraQ BIO-RAD	60 x 2 mL	PEO	≤ 20°C	€ 3670	KI4277	
P0309/02	P0309 SeraQ BIO-RAD	10 x 2 mL	FEU	≤ 20 €	€ 670	NI42//	
P0374/01	P0374 SeraQ Alinity V3	60 x 2.3 mL	PEO	≤ 20°C	€ 3995	KI4280	
P0374/02	P0374 SeraQ Alinity V3	10 x 2.3 mL	PEU	≤ 20 €	€ 730	N1428U	
Multi-Marker	HBsAg, anti-HBc, anti-HCV, anti-HIV-1, anti-HTLV-I Controls						
P0220/01	P0220 SeraQ Vitros	60 x 2 mL	DEO	* 00°0	€ 4125	1/14204	
P0220/02	P0220 SeraQ Vitros	10 x 2 mL	PEO	≤ 20°C	€ 750	KI4304	
P0320/01	P0320 SeraQ Alinity V2	60 x 3 mL	DEO	< 2000	€ 5525	KI4294	
P0320/02	P0320 SeraQ Alinity V2	10 x 3 mL	PEO	≤ 20°C	€ 1010	NI4294	
P0386/01	P0386 SeraQ Alinity V4	60 x 3 mL	DEO	< 2000	€ 5525	KIAOOG	
P0386/02	P0386 SeraQ Alinity V4	10 x 3 mL	PEO	≤ 20°C	€ 1010	KI4286	

PEO = for performance evaluation only, limited supply to predefined customers CE = CE registered product, market authorization for the European Union

# **SERAQ CONTROLS FOR SYPHILIS ASSAYS**

SeraQ Controls for Syphilis assays are composed of standards diluted in a defibrinated plasma (serum) matrix. A series of SeraQ Anti-Treponemal Controls have been designed to generate weakly reactive results (between 2 to 4 times the cutoff signal) in Syphilis test systems of different IVD manufacturers. The product names in the catalogue refer to the targeted test system or manufacturer.



P0317/01 SeraQ Alinity Syphilis 60 x 2 mL (60 tubes in rack/box)



Serum matrix



P0218/02 SeraQ ARCHITECT Syphilis 10 x 2.0 mL (10 tubes in box)

# SeraQ Controls for ensuring sufficient analytical sensitivity of Syphilis assays

Cat. No	SeraQ Control	Quantity	Regul. Status	Storage Temp.	List Price	Kit Insert	
Anti-Trepone	ma pallidum (Syphilis) Controls						
P0267/01	P0267 SeraQ TPHA Syphilis V2	60 x 2 mL	DEO	* 00°0	€ 2030	VI4066	
P0267/02	P0267 SeraQ TPHA Syphilis V2	10 x 2 mL	PEO	≤ 20°C	€ 375	KI4266	
P0218/01	P0218 SeraQ ARCHITECT Syphilis	60 x 2 mL	OF.	* 00°0	€ 2030	1/14010	
P0218/02	P0218 SeraQ ARCHITECT Syphilis	10 x 2 mL	CE	≤ 20°C	€ 375	KI4218	
P0219/01	P0219 SeraQ Vitros Syphilis	60 x 2 mL	CE	≤ 20°C	€ 2030	KI4305	
P0219/02	P0219 SeraQ Vitros Syphilis	10 x 2 mL	CE	≤ 20 C	€ 375	NI4305	
P0237/01	P0237 SeraQ LIAISON Syphilis	60 x 2 mL	CE	< 20°C	€ 2030	KI4237	
P0237/02	P0237 SeraQ LIAISON Syphilis	10 x 2 mL	CE	≤ 20°C	€ 375	NI4237	
P0260/01	P0260 SeraQ Murex Syphilis	60 x 2 mL	DEO	< 20°C	€ 2030	VIA061	
P0260/02	P0260 SeraQ Murex Syphilis	10 x 2 mL	PEO	≤ 20°C	€ 375	KI4261	
P0312/01	P0312 SeraQ Elecsys Syphilis	60 x 2 mL	DEO	< 2000	€ 2030	1/14070	
P0312/02	P0312 SeraQ Elecsys Syphilis	10 x 2 mL	PEO	≤ 20°C	€ 375	KI4278	
P0313/01	P0313 SeraQ BIO-RAD Syphilis	60 x 2 mL	DEO	< 2000	€ 2030	1/14070	
P0313/02	P0313 SeraQ BIO-RAD Syphilis	10 x 2 mL	PEO	≤ 20°C	€ 375	KI4279	
P0317/01	P0317 SeraQ Alinity Syphilis	60 x 2 mL	DEO	< 2000	€ 2030	1/14001	
P0317/02	P0317 SeraQ Alinity Syphilis	10 x 2 mL	PEO	≤ 20°C	€ 375	KI4281	

PEO = for performance evaluation only, limited supply to predefined customers CE = CE registered product, market authorization for the European Union



# VIRAQ CHECK AND TREND CONTROLS FOR HBV/HCV/HIV NAT ASSAYS

ViraQ Controls are composed of inactivated viral standards in an EDTA plasma matrix. The ViraQ Check 125 Controls for HBV, HCV and HIV detection containing 125 copies/mL are suitable for the Procleix Ultrio Elite and UltrioPlex E assay versions (Grifols). The ViraQ Check Multi-Marker control contains 75 copies/mL of the viral standards and is suitable for the cobas MPX assay (Roche).

The ViraQ Trend Controls containing 25 copies/mL are designed for monitoring the analytical sensitivity of Ultrio Elite and UltrioPlex E reagent batches and performance of individual Panther instruments. An HIV-2 control prepared from an inactivated standard is available for performance evaluation studies. More details about the expected reactivity and positioning of the run controls in relation to the NAT detection limits can be found in the package inserts.



P0063/01 ViraQ HCV Check 125, 60 x 1.5 mL (60 tubes in rack/box)



P0063/02 ViraQ HCV Check 125, 10 x 1.5 mL (10 tubes in zip bag)

#### ViraQ Check and Trend Controls for ensuring sufficient analytical sensitivity of HBV/HCV/HIV NAT assays

Cat. No^	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
HBV-DNA Contro	ols							
P0065/01	P0065 ViraQ HBV Check 125	60 x 1.5 mL	105	02.5	05	* 20°0	€ 1330	1/14061
P0065/02	P0065 ViraQ HBV Check 125	10 x 1.5 mL	125	23.5	CE	≤ 30°C	€ 245	KI4061
P0154/01	P0154 ViraQ HBV Trend 50	60 x 1.5 mL	F0	0.4	05	* 20°0	€ 1330	VIA154
P0154/02	PO154 ViraQ HBV Trend 50	10 x 1.5 mL	50	9.4	9.4 CE	≤ 30°C	€ 245	KI4154
HCV-RNA Contro	ols							
P0063/01	P0063 ViraQ HCV Check 125	60 x 1.5 mL	105	45.0	05	* 30°0	€ 1330	KIAOFO
P0063/02	P0063 ViraQ HCV Check 125	10 x 1.5 mL	125	45.8	CE	≤ -30°C	€ 245	KI4059
P0067/01	P0067 ViraQ HCV Trend 25	60 x 1.5 mL	05	0.4	05	2000	€ 1330	1/14063
P0067/02	P0067 ViraQ HCV Trend 25	10 x 1.5 mL	25	9.4	CE	≤ -30°C	€ 245	KI4063
HIV-1 RNA Cont	rols							
P0064/01	P0064 ViraQ HIV-1 Check 125	60 x 1.5 mL	105	015	05	* 20°0	€ 1330	1/14066
P0064/02	P0064 ViraQ HIV-1 Check 125	10 x 1.5 mL	125	215	CE	≤ -30°C	€ 245	KI4060
P0068/01	P0068 ViraQ HIV-1 Trend 25	60 x 1.5 mL	0.5	42.1	05	* 20°0	€ 1330	1/14064
P0068/02	P0068 ViraQ HIV-1 Trend 25	10 x 1.5 mL	25	43.1	CE	≤ -30°C	€ 245	KI4064
Multi-Marker H	BV-DNA, HCV-RNA, HIV-1 RNA Controls							
P0273/01	P0273 ViraQ Multi-Marker Check 75	60 x 1.6 mL#	75	14.1/07.5/1000	05	* 20°0	€ 2120	1/14000
P0273/02	P0273 ViraQ Multi-Marker Check 75	10 x 1.6 mL#	75	14.1/27.5/129\$	CE	≤ -30°C	€ 390	KI4268
HIV-2 RNA Cont	rols							
P0318/01	P0318 ViraQ HIV-2 Check 125	60 x 1.6 mL#	105	150.0	DEO		€ 1330	KINOOO
P0318/02	P0318 ViraQ HIV-2 Check 125	10 x 1.6 mL#	125	158.2	PEO ≤ -30°C	€ 245	KI4282	

<sup>^</sup> Pxxx/01 = 60 x 10 mL vials in rack/box, Pxxxx/02 = 10 x 10 mL vials in zip bag, PEO = for performance evaluation only, limited supply to predefined customers CE = CE registered product, market authorization for the European Union \$ for HBV, HCV and HIV-1 respectively #unique barcode per sample

# VIRAQ CHECK CONTROLS FOR OTHER NAT ASSAYS

# NON-ENVELOPED VIRUSES

ViraQ Check Controls for NAT methods detecting non-enveloped viruses are prepared from native plasma standards. The Controls are diluted in a plasma matrix containing neutralising antibodies. The infectivity thresholds are expected to be above the concentrations in the run controls. Hence, inactivation of the viral standards is not necessary. The controls are at close distance to the 95% LOD of the NAT assays except for parvo B19V that contains 10,000 IU/mL of the secondary VQC-Sanquin standard. This reference plasma has been extensively calibrated against the 1st WHO 99/800 standard. The dual ViraQ B19V/ HAV control and HEV control are suitable for both the Grifols Procleix and the Roche cobas assays.

# ARBOVIRUS

West Nile Virus (WNV) Lineage 1 and 2 standards before and after chemical inactivation have been extensively calibrated in copies/mL against Italian ISS standards using three different NAT methods. A ViraQ WNV Check Control of 125 copies/mL (of Lineage 2) has been developed that is suitable for both the Grifols Procleix and Roche cobas WNV assays.



P0264/01 ViraQ HEV Check 125, 60 x 1.6 mL (60 tubes in rack/box)



P0247 ViraQ WNV Check 125, 60 x 1.6 mL (60 tubes in rack/box)

#### ViraQ Check Controls for ensuring sufficient analytical sensitivity of parvo B19V, HAV and HEV NAT assays

Cat. No^	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
Dual marker pa	rvo B19V, HAV Controls							
P0266/01	P0266 ViraQ Parvo B19/HAV Check	60 x 1.6 mL#		10.000/10	DEO	* 20°0	€ 2120	KIAOFO
P0266/02	P0266 ViraQ Parvo B19/HAV Check	10 x 1.6 mL#		10,000/10	PEO	≤ 30°C	€ 390	KI4259
HEV-RNA Contro	ols							
P0264/01	P0264 ViraQ HEV Check 125	60 x 1.6 mL#		100	05	. 20°0	€ 1330	IVIAOCA
P0264/02	P0264 ViraQ HEV Check 125	10 x 1.6 mL#		100 CE	≤ -30°C	€ 245	KI4264	

^ Pxxxx/01 =  $60 \times 10 \text{ mL}$  vials in rack/box, Pxxxx/02 =  $10 \times 10 \text{ mL}$  vials in zip bag, PEO = for performance evaluation only, limited supply to predefined customers #unique barcode per sample

#### ViraQ Check Controls for ensuring sufficient analytical sensitivity of WNV NAT assays

Cat. No^	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
WNV-RNA Controls	,							
P0247/01	P0247 ViraQ WNV Check 125	60 x 1.6 mL#	105		OF.	* 30°0	€ 1330	KI4247
P0247/02	P0247 ViraQ WNV Check 125	10 x 1.6 mL#	125		CE	≤ 30°C	€ 245	N/424/

<sup>^</sup> Pxxxx/01 = 60 x 10 mL vials in rack/box, Pxxxx/02 = 10 x 10 mL vials in zip bag



## ANALYTICAL SENSITIVITY PANELS FOR HBV-DNA ASSAYS

In the mid 1990s the Eurohep and VQC-Sanguin HBV genotype A standards were the first reference materials used for evaluation of NAT methods. Thereafter the Eurohep standard was used for preparation of the WHO standards. The Eurohep and VQC-Sanguin HBV genotype A standards were independently quantified in equivalent nucleic acid copies. A series of standards of different genotypes have been cross calibrated in copies/ mL against the VQC-Sanguin standard by multiple replicate DNA 3.0 assays as the reference method for quantification. The VQC-Sanguin standard has also been extensively calibrated against the 1st and 2nd lyophilised WHO standards and the conversion factors (95% CI) were established at 5.33 (5-11-5.55) and 5.20 (4.61-5.80) copies per IU respectively. The VQC-Sanguin HBV genotype A standard was also calibrated against a chimpanzee plasma of known infectivity and according to this experiment the 50% chimpanzee minimum infectious dose (range) was determined at 4.0 (1.3-12.6) HBV-DNA copies or virions. The VQC-Sanguin standard has been used for preparation of a pasteurised standard from which the ViraQ Check and Trend Controls are prepared. A lyophilised WHO HBV genotype reference panel has been made available by PEI and again the panel members were cross calibrated in copies/mL against the VQC-Sanguin standard in multiple replicate bDNA 3.0 assays. The results were comparable to the bDNA 3.0 calibration data in the WHO evaluation report.

Over the last two decades we manufactured 10 member dilution panels from these standards. Reference panels of (approximately) 3000, 1000, 300, 100, 30, 10, 3, 1, 0.3 and 0.1 copies/mL of the HBV genotype standards were tested in multiple replicate tests in different NAT

blood screening assays in order to determine the 95% and 50% LOD by probit analysis. More recently we manufacture 8 member dilution panels of the same HBV genotype standards starting at 300 copies/mL. Similar dilution panels were prepared from the 2nd WHO 97/750 standard.

There is one package insert for all these HBV reference panels and the proportions of reactive results of multiple replicate tests in different NAT blood screening assays are available for comparison. One can just as well use the VQC-Sanquin standard dilution panels as the 3rd WHO standard for testing the 95% and 50% LODs in IU/mL values because our standard is directly traceable to the 1st and 2nd WHO standards.



P0280 HBV-DNA genotype A, 8 x 4.0 mL (8 tubes in zip bag)

HBV-DNA genotype standard dilution panels for testing analytical sensitivity of NAT assays

Cat. No	Source/Standard	HBV-DNA genotype reference panel <sup>\$</sup>	Quantity	range copies/mL	range IU/mL	Storage Temp.	List Price
P0277	Eurohep	P0277 HBV-DNA genotype A	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0279	2nd WHO 97/750	P0279 HBV-DNA genotype A	8 x 4 mL	0.11 - 320	0.02 - 60	≤ -30°C	€ 805
P0280	VQC-Sanquin§	P0280 HBV-DNA genotype A	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0295	VQC-Sanquin inactivated	P0295 HBV-DNA genotype A inact	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0106	WHO 5086/08-1	P0106 HBV-DNA genotype A1 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0107	WHO 5086/08-2	P0107 HBV-DNA genotype A1 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0108	WHO 5086/08-3	P0108 HBV-DNA genotype A2	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0009	Di-00-strel	P0009 HBV-DNA genotype B	10 x 4 mL^	0.1 - 3035	0.02 - 569	≤ -30°C	€ 805
P0281	BioQControl	P0281 HBV-DNA genotype B	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0109	WHO 5086/08-4	P0109 HBV-DNA genotype B1	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0110	WHO 5086/08-5	P0110 HBV-DNA genotype B2	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0111	WHO 5086/08-6	P0111 HBV-DNA genotype B4	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0010	5: 00	P0010 HBV-DNA genotype C	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0282	BioQControl	P0282 HBV-DNA genotype C	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0112	WHO 5086/08-7	P0112 HBV-DNA genotype C2 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0113	WHO 5086/08-8	P0113 HBV-DNA genotype C2 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0114	WHO 5086/08-9	P0114 HBV-DNA genotype C2 (3)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0002	-	P0002 HBV-DNA genotype D	10 x 4 mL^	0.1 - 2923	0.02 - 548	≤ -30°C	€ 805
P0278	Eurohep	P0278 HBV-DNA genotype D	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0011	5: 00	P0011 HBV-DNA genotype D	10 x 4 mL^	0.1 - 3134	0.02 - 588	≤ -30°C	€ 805
P0283	BioQControl	P0283 HBV-DNA genotype D	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0115	WHO 5086/08-10	P0115 HBV-DNA genotype D1 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0116	WHO 5086/08-11	P0116 HBV-DNA genotype D3	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0117	WHO 5086/08-12	P0117 HBV-DNA genotype D1 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0012	D: 00 1 1	P0012 HBV-DNA genotype E	10 x 4 mL^	0.11 - 3213	0.02 - 603	≤ -30°C	€ 805
P0284	BioQControl	P0284 HBV-DNA genotype E	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0118	WHO 5086/08-13	P0118 HBV-DNA genotype E1	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0013	Di- CO- other!	P0013 HBV-DNA genotype F	10 x 4 mL^	0.12 - 3606	0.02 - 676	≤ -30°C	€ 805
P0285	BioQControl	P0285 HBV-DNA genotype F	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0119	WHO 5086/08-14	P0119 HBV-DNA genotype F3	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0014	D: 00 1 1	P0014 HBV-DNA genotype G	10 x 4 mL^	0.11 -3188	0.02 - 598	≤ -30°C	€ 805
P0286	BioQControl	P0286 HBV-DNA genotype G	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805
P0120	WHO 5086/08-15	P0120 HBV-DNA genotype G	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 805



## ANALYTICAL SENSITIVITY PANELS FOR HCV-RNA ASSAYS

Since we prepared our first Eurohep reference panel in 1992 several HCV standards of different genotypes have been tested in VQC proficiency programs and in validation studies. Over the years the HCV-RNA concentration in the VQC-Sanguin HCV genotype 1 standard has been quantified in copies/mL by several methods, but the results of the bDNA 3.0 assay have been used as the reference method for calibration. Thereafter the VQC-Sanguin standard has been compared with the 1st and 2nd International Standards in two WHO collaborative studies. When taking the calibration data of these and other multi-center studies together the number of HCV-RNA copies per IU (95% CI) was estimated at 2.73 (1.4-4.8). We also calibrated a chimpanzee plasma of known infectivity against the VQC-Sanguin standard and the 50% minimum infectious dose (range) was estimated at 8.1 (2.6-25.6) HCV-RNA copies or virions.

Our company has prepared several batches of dilution panels from the 1st, 2nd and 3rd WHO standards which over time have been tested in hundreds of replicates in validation studies of the Procleix Ultrio versions. Consistent 95% and 50% LODs were found on all standards, but for the 3rd WHO HCV 06/100 standard significantly higher LODs were found over time (indicating reduced stability of the lyophilised virus). Our degradation studies at different temperatures show significantly higher stability of the VQC-Sanquin genotype 1 standard at -30°C and 4°C than of the WHO 06/100 standard. Since the VQC-Sanquin standard is directly traceable to the 1st WHO 96/790 and 2nd WHO 96/798

standards one can use our more stable standard dilution panels for estimating 95% and 50% LODs in IU/mL. All other HCV genotype standards have been calibrated against the VQC-Sanquin standard in multiple replicate bDNA 3.0 assays, including an inactivated genotype 3a standard used for preparation of the ViraQ Controls.

The ten member HCV genotype standard dilution panels starting at around 3000 copies/mL will be replaced by 8 member panels composed of 300, 100, 30, 10, 3, 1, 0.3 and 0.1 copies/mL. The package insert gives an overview of all HCV genotype standard dilution panels and the proportion of reactive results in different NAT methods.



P0288 HCV-RNA genotype 1, 8 x 4.0 mL (8 tubes in zip bag)

#### HCV-RNA genotype standard dilution panels for testing analytical sensitivity of NAT assays

Cat. No	Source/Standard	HCV-RNA genotype reference panels\$	Quantity	range copies/mL	range IU/mL	Storage Temp.	List Price
P0288	VQC-Sanquin§	P0288 HCV-RNA genotype 1	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0131	Egypt-1	P0131 HCV-RNA genotype 1a	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0197	Egypt-2	P0197 HCV-RNA genotype 1a	8 x 4 mL	0.16 - 547	0.06 - 200	≤ -65°C	€ 805
P0198	Japan-1	P0198 HCV-RNA genotype 1b	8 x 4 mL	0.08 - 235	0.03 - 86	≤ -65°C	€ 805
P0199	Japan-2	P0199 HCV-RNA genotype 1b	8 x 4 mL	0.04 - 146	0.02 - 53	≤ -65°C	€ 805
P0035	Di-00-stral	P0035 HCV-RNA genotype 2	10 x 4 mL^	0.10 - 2837	0.04 - 1039	≤ -65°C	€ 805
P0299	BioQControl	P0299 HCV-RNA genotype 2	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0200	Japan-3	P0200 HCV-RNA genotype 2a	8 x 4 mL	0.18 - 542	0.07 - 199	≤ -65°C	€ 805
P0201	Japan-4	P0201 HCV-RNA genotype 2a	8 x 4 mL	0.10 - 342	0.04 - 125	≤ -65°C	€ 805
P0202	Japan-5	P0202 HCV-RNA genotype 2b	8 x 4 mL	0.11 - 328	0.04 - 120	≤ -65°C	€ 805
P0203	Japan-6	P0203 HCV-RNA genotype 2b	8 x 4 mL	0.10 - 343	0.04 - 126	≤ -65°C	€ 805
P0036	D1 00 1 1	P0036 HCV-RNA genotype 3	10 x 4 mL^	0.06 - 1792	0.02 - 656	≤ -65°C	€ 805
P0300	BioQControl	P0300 HCV-RNA genotype 3	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0289	BioQControl inactivated	P0289 HCV-RNA genotype 3 inact.	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0204	Lithuania-1	P0204 HCV-RNA genotype 3a	8 x 4 mL	0.09 - 295	0.03 - 108	≤ -65°C	€ 805
P0205	Lithuania-2	P0205 HCV-RNA genotype 3a	8 x 4 mL	0.15 - 439	0.05 - 161	≤ -65°C	€ 805
P0130	Thailand	P0130 HCV genotype 3b	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0037	P: 00 1 1	P0037 HCV-RNA genotype 4	10 x 4 mL^	0.07 - 1982	0.02 -726	≤ -65°C	€ 805
P0301	BioQControl	P0301 HCV-RNA genotype 4	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0126	Egypt-3	P0126 HCV genotype 4 (2)	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0206	Egypt-4	P0206 HCV genotype 4 (3)	8 x 4 mL	0.22 - 741	0.08 - 272	≤ -65°C	€ 805
P0038	51.00	P0038 HCV-RNA genotype 5	10 x 4 mL^	0.08 - 2465	0.03 - 903	≤ -65°C	€ 805
P0302	BioQControl	P0302 HCV-RNA genotype 5	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0127	Congo	P0127 HCV genotype 5 (2)	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0039	D: 00 1 1	P0039 HCV-RNA genotype 6	10 x 4 mL^	0.07 - 2001	0.02 - 733	≤ -65°C	€ 805
P0303	BioQControl	P0303 HCV-RNA genotype 6	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0128	USA	P0128 HCV genotype 6	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805
P0129	Thailand	P0129 HCV genotype 6n	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 805

<sup>§</sup> extensively calibrated on 1st and 2nd WHO standard \$ regulatory status: ^10 x 4 mL format will be phased out and replaced by 8 x 4 mL format Kit insert: KI4269 # made for IVD manufacturer, available on request

\$ regulatory status: RUO = for research use only Kit insert. KI/1269



# ANALYTICAL SENSITIVITY PANELS FOR HIV-RNA ASSAYS

In the mid1990s we established tissue culture derived HIV-1 RNA standards of different subtypes, which have been used in the international VQC proficiency program until 2004. The VQC-Sanguin HIV-1 subtype B standard has been quantified in copies/mL by different methods but the results obtained in the bDNA 3.0 assays were eventually used for value assignment. The liquid frozen VQC-Sanguin standard was calibrated against the 1st and 2nd International Standards in the WHO collaborative study. When we compared the bDNA 3.0 results the conversion factors (95%CI) were 0.39 (0.34-0.44) copies/IU when comparing the VQC-Sanguin standard against the 1st WHO HIV 97/656 standard, but 0.58 (0.51-0.66) copies/IU when calibrated against the 2nd WHO HIV 97/650 standard. These were data from the same WHO collaborative study showing that there has been a significant shift in the amount of HIV per IU when the 1st WHO standard was replaced by the 2nd WHO standard. Currently the 4th WHO HIV 16/149 replacement standard is in use. It must be emphasised that the IU values assigned to the VQC-Sanguin standard in the package insert are based on calibration to the 2nd WHO 97/650 standard. The latter WHO standard and the VQC-Sanguin subtype B standard have been tested in hundreds of replicates to determine the 95% and 50% LODs of the Procleix Ultrio versions and more recently the cobas MPX assay.

Over the years HIV-1 standards of different subtypes and circulating recombinant forms (CRFs) have been used for validation of different NAT methods.

In addition, HIV-2 and HIV group O standard dilutions were used in evaluation studies. More recently the number of HIV-1 subtypes, CRF, and HIV group O plasmas has been expanded, but so far with fewer replicate NAT data.

The package insert of all the HIV subtype standard dilution panels gives an overview of the reactivity rates found with multiple replicate tests in different NAT methods. The response data in the package insert can be used as a reference when the panels are tested for determining the 95% and 50% LOD in validation studies. Currently the 10 member dilution panels are phased out and replaced by 8 member panels composed of 300, 100, 30, 10, 3, 1, 0.3 and 0.1 copies/mL samples.



P0290 HIV-1 RNA genotype B, 8 x 4.0 mL (8 tubes in zip bag)

HIV-RNA subtype standard dilution panels for testing analytical sensitivity of NAT assays

Cat. No	Source/Standard	HIV-RNA subtype reference panels\$	Quantity	range copies/mL	range IU/mL	Storage Temp.	List Price
P0350	4th WHO 16/149	P0350 HIV-1 RNA subtype B	7 x 4 mL	0.12 - 116	0.2 - 200	≤ -65°C	€ 805
P0290	VQC-Sanquin§	P0290 HIV-1 RNA subtype B	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0291	VQC-Sanquin inactivated	P0291 HIV-1 RNA subtype B inact.	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0032	Di-Oo-starl	P0032 HIV-1 RNA subtype A	10 x 4 mL^	0.2 - 5020	0.3 - 8655	≤ -65°C	€ 805
P0296	BioQControl	P0296 HIV-1 RNA subtype A	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0027	Di-Oo-starl	P0027 HIV-1 RNA subtype C	10 x 4 mL^	0.1 - 2883	0.2 - 4971	≤ -65°C	€ 805
P0292	BioQControl	P0292 HIV-1 RNA subtype C	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0033	Di-Oo-starl	P0033 HIV-1 RNA subtype D	10 x 4 mL^	0.2 - 5610	0.3 - 9672	≤ -65°C	€ 805
P0297	BioQControl	P0297 HIV-1 RNA subtype D	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0028	Di-Oo-starl	P0028 HIV-1 RNA CRF01_AE (1)	10 x 4 mL^	0.1 - 3075	0.2 - 5301	≤ -65°C	€ 805
P0293	BioQControl	P0293 HIV-1 RNA CRF01_AE (1)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0052	Thailand	P0052 HIV-1 RNA CRF01_AE (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0053	Brazil	P0053 HIV-1 RNA subtype F (1)	8 x 4 mL	0.10 - 300	0.2 - 517	≤ -65°C	€ 805
P0054	Romania	P0054 HIV-1 RNA subtype F (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0098	Zaire	P0098 HIV-1 RNA subtype G (1)	8 x 4 mL	0.10 - 300	0.2 - 517	≤ -65°C	€ 805
P0099	Kenya	P0099 HIV-1 RNA subtype G (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0051	Ghana	P0051 HIV-1 RNA CRF02_AG	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0100	Zaire	P0100 HIV-1 RNA subtype H	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 805
P0354	2nd WHO 16/296	P0354 HIV-2 subtype A	8 x 4 mL^	0.24 - 237	0.3 - 300	≤ -65°C	€ 805
P0298	BioQControl	P0298 HIV-2 RNA subtype A	8 x 4 mL	0.1 - 300	0.1 - 380	≤ -65°C	€ 805
P0212	Belgium	P0212 HIV-2 RNA subtype B	8 x 4 mL	0.1 - 300	0.1 - 380	≤ -65°C	€ 805
P0015	BioQControl	P0015 HIV RNA group O (1)	10 x 4 mL^	0.1 - 2580	0.1 - 4448	≤ -65°C	€ 805
P0101	USA	P0101 HIV-RNA group O (2)	8 x 4 mL	0.46 - 1382	0.79 - 2383	≤ -65°C	€ 805
P0102	Camaroon	P0102 HIV-RNA group O (3)	8 x 4 mL	0.40 - 1197	0.69 - 2064	≤ -65°C	€ 805
P0103	Spain	P0103 HIV-RNA group O (4)	8 x 4 mL	0.43 - 1281	0.74 - 2209	≤ -65°C	€ 805
P0104	Camaroon	P0104 HIV-RNA group O (5)	8 x 4 mL	0.41 - 1233	0.71 - 2125	≤ -65°C	€ 805

<sup>§</sup> extensively calibrated on 1st and 2nd WHO standard ^10 x 4 mL format will be phased out and replaced by 8 x 4 mL format # made for IVD manufacturer, available on request \$ regulatory status: RUO = for research use only Kit insert: KI4270

## OTHER VIRUS STANDARD DILUTION PANELS

#### NON-ENVELOPED VIRUSES

In the late 1990s VQC-Sanguin had established parvo B19V genotype 1 and HAV genotype 1a standards that were widely used in NAT validation and proficiency studies. Both standards were compared to the first International Standards in WHO collaborative studies. The calibration data were confirmed in studies performed in Sanguin at that time. More recently a secondary HEV standard has been established in collaboration with Sanguin. Since a reference method for calibration of our nonenveloped virus standards in copies/mL is not available we so far quantify our standards only in IU/mL based on calibration against the first WHO standards. The parvo B19V genotype 1 standard dilution panel has been used for validation of the Procleix B19V/HAV assav on the Tigris instrument with comparable quantitative results as on the 2nd WHO 99/802 standard. A new version of the Procleix B19V/HAV assay has been recalibrated on the 3rd WHO 12/208 standard and this assay reports significantly lower values on the VQC-Sanguin standard.

#### **ARBOVIRUS**

West Nile Virus (WNV) Lineage 1 and 2 standard dilution panels with known reactivity in the Grifols Procleix and Roche cobas WNV assays are available for NAT validation and establishing the detection limits in WNV-RNA copies/mL.

#### **RESPIRATORY VIRUS**

An inactivated SARS-CoV-2 reference panel has been used for comparing the analytical sensitivity of different molecular assays and is available for validation of NAT methods. The same SARS-CoV-2 reference standard has been used to compare the analytical sensitivity of different rapid antigen tests.



P0274 HEV-RNA genotype 3, 8 x 4.0 mL (8 tubes in zip bag)



P0346 WNV-RNA Lineage 2 inactivated 10 x 4.0 mL (10 tubes in zip bag)



P0356 SARS CoV-2 RNA, 10 x 1.4 mL (10 vials in zip bag)

#### Non-enveloped virus standard dilution panels for testing analytical sensitivity and precision of NAT assays

Cat. No	Source/Standard	Non envelope virus reference panel <sup>\$</sup>	Quantity	range IU/mL	Storage Temp.	List Price	Kit Insert
Parvo B19\	/ DNA reference panels						
P0143	VQC-Sanquin	P0143 parvo B19-DNA genotype 1 Quant	10 x 4 mL	30 - 1,000,000	≤ -65°C	€ 925	KI4273
P0144	Sanquin	P0144 parvo B19-DNA genotype 2 Quant	8 x 4 mL	30 - 100,000	≤ -65°C	€ 805	KI4273
HAV-RNA re	eference panels						
P0351	VQC-Sanquin	P0351 HAV genotype 1a	8 x 4 mL	0.01 - 30	≤ -65°C	€ 805	KI4272
P0208	France	P0208 HAV-RNA genotype 2a	8 x 4 mL	0.1 - 300	≤ -65°C	€ 805	KI4272
P0209	France	P0209 HAV-RNA genotype 3a	8 x 4 mL	0.1 - 300	≤ -65°C	€ 805	KI4272
HEV-RNA re	eference panels						
P0274	Sanquin	P0274 HEV-RNA genotype 3	8 x 4 mL	0.1 - 300	≤ -65°C	€ 805	KI4276
P0262	1st WHO 6329/10	P0262 HEV-RNA genotype 3	6 x 4 mL	0 - 90	≤ -65°C	€ 805	KI4276

<sup>\$</sup> Regulatory status: RUO = for research use only

#### Arbovirus standard dilution panels for testing analytical sensitivity of NAT assays

Cat. No	Source/Standard	Non envelope virus reference panel <sup>s</sup>	Quantity	range copies/mL	Storage Temp.	List Price	Kit Insert
WNV-RNA r	eference panel						
P0360	Italy	P0360 WNV-RNA Lineage 1		0.1 - 300	≤ -65°C	€ 805	KI4297
P0346	Macedonia	P0346 WNV-RNA Lineage 2 inactivated		0.1 - 300	≤ -65°C	€ 805	KI4297

<sup>\$</sup> Regulatory status: RUO= for research use only

#### Respiratory virus standard dilution panels for testing analytical sensitivity of NAT assays

Cat. No	Source/Standard Non envelope virus reference panel <sup>s</sup>		Quantity	range copies/mL	Storage Temp.	List Price	Kit Insert
SARS-CoV-2	2 standard dilution panel						
P0356	The Netherlands	P0356 SARS-CoV-2 dilution panel	10 x 1.4 mL	1.1 - 33,784	≤ -65°C	€ 1515	KI4300

<sup>\$</sup> Regulatory status: RUO = for research use only

# **MULTIPLE VIRAL GENOTYPE REFERENCE PANELS**

The same cross calibrated HBV, HCV and HIV genotype standards that over the years were tested in several analytical sensitivity studies were also used for preparation of 100 copies/mL and 1000 copies/mL multiple 20-28 member genotype reference panels. So far the HIV and HBV multiple

genotype reference panels have been used for evaluation studies of the quantitative NAT methods of two manufacturers. The HIV subtype reference panel has been expanded with two HIV-2 subtypes. Recently also a cross calibrated HAV genotype reference panel has become available



P0138 HBV 100 copies/mL genotype reference panel. 25 x 4 mL (25 tubes in rack/box)

#### Multiple viral genotype reference panels for testing accuracy and ensuring sufficient analytical sensitivity of (quantitative) NAT assays

Cat. No	Multiple Viral Genotype Reference Panel <sup>\$</sup>	Quantity	copies/mL	IU/mL	Genosubtypes	Storage Temp.	List Price	Kit Insert
HBV-DNA n	nultiple genotype reference panels							
P0138	P0138 HBV 100 copies/mL genotype reference panel	25 x 4 mL	100	18.8	A1, A2, B, B1, B2, B4, C, C2, D, D1, D3, E, E3, F, G	≤ -30°C	€ 2950	KI4138
P0141/01	P0141 HBV 1000 copies/mL genotype reference panel	25 x 4 mL	1000	188	A1, A2, B, B1, B2, B4, C, C2, D, D1, D3, E, E3, F, G	≤ -30°C	€ 5330	KI4141
P0141/02	P0141 HBV 1000 copies/mL genotype reference panel	25 x 1.2 mL	1000	188	A1, A2, B, B1, B2, B4, C, C2, D, D1, D3, E, E3, F, G	≤ -30°C	€ 2100	KI4141
HCV-RNA n	nultiple genotype reference panels							
P0139	P0139 HCV 100 copies/mL genotype reference panel	28 x 4 mL	100	36.6	1, 1a ,1b, 2, 2a, 2b, 3, 3a, 3b, 4, 4a, 4c, 4e, 5, 5a, 6, 6a, 6n	≤ -65°C	€ 2950	KI4139
P0142/01	P0142 HCV 1000 copies/mL genotype reference panel	25 x 4 mL	1000	366	1, 1a ,1b, 2, 2a, 2b, 3, 3a, 3b, 4, 4a, 4c, 4e, 5, 5a, 6, 6a, 6n	≤ -65°C	€ 5330	KI4142
P0142/02	P0142 HCV 1000 copies/mL genotype reference panel	28 x 1.2 mL	1000	366	1, 1a ,1b, 2, 2a, 2b, 3, 3a, 3b, 4, 4a, 4c, 4e, 5, 5a, 6, 6a, 6n	≤ -65°C	€ 2100	KI4142
HIV-RNA m	ultiple genotype reference panels							
P0137	P0137 HIV 125 copies/mL subtype reference panel	20 x 4 mL	125	172	HIV-1 A,B,C,D F,G H, CRF01_AE, CRF01_AG, group O, HIV-2 A, B	≤ -65°C	€ 2950	KI4137
P0140/01	P0140 HIV 1000 copies/mL subtype reference panel	20 x 4 mL	1000	1724	HIV-1 A,B,C,D F,G H, CRF01_AE, CRF01_AG, group O, HIV-2 A, B	≤ -65°C	€ 5330	KI4140
P0140/02	P0140 HIV 1000 copies/mL subtype reference panel	20 x 1.2 mL	1000	1724	HIV-1 A,B,C,D F,G H, CRF01_AE, CRF01_AG, group O, HIV-2 A, B	≤ -65°C	€ 2100	KI4140
HAV-RNA n	nultiple genotype reference panel							
P0153	P0153 HAV genotype reference panel#	5 x 4 mL	~1000	100	1a, 1b, 2a, 3a	≤ -65°C	€ 1235	KI4153

<sup>\$</sup> Regulatory status: RUO = for research use only

# **VIRAQ QUANT CONTROLS FOR VIRAL LOAD ASSAYS**

The ViraQ Quant Controls for HBV-DNA, HCV-RNA and HIV-1 RNA are prepared from the primary VQC-Sanquin standards that have been characterised in international proficiency programs since the mid-1990s. The viral standards are not inactivated and extensively calibrated in both copies/mL and IU/mL. Recently the ViraQ HIV-1 Quant 1000 Control has been evaluated in several viral load assays.

This control of 1000 copies/mL can be used as an independent standard in consecutive viral load test runs and provides a threshold value indicative of lack of virological control in therapy monitoring. The herpes virus controls have not yet been calibrated against the WHO standards. This series of controls can be made available for performance evaluation studies only.



P0327 ViraQ HIV-1 Quant 1000, 10 x 1.2 mL (10 vials in zip bag)

#### ViraQ Quant Controls for ensuring sufficient accuracy and precision of viral load assays

Cat. No	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert		
HBV-DNA, HCV-RNA, HIV-1 RNA, CMV-DNA and HSV-1 and 2 DNA Controls										
P0345	P0345 ViraQ HBV Quant 1000	10 x 1.2 mL	1000	188	PEO#	≤30°C	€ 520	KI4296		
P0344	P0344 ViraQ HCV Quant 1000	10 x 1.2 mL	1000	366	PEO#	≤65°C	€ 520	KI4295		
P0327	P0327 ViraQ HIV-1 Quant 1000	10 x 1.2 mL	1000	1724	PEO#	≤65°C	€ 520	KI4292		
P0146	P0146 ViraQ CMV Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	€ 520	KI4146		
P0147	P0147 ViraQ HSV-1 Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	€ 520	KI4147		
P0148	P0148 ViraQ HSV-2 Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	€ 520	KI4148		

<sup>#</sup> Available for performance evaluation studies only



# **LINEARITY PANELS FOR VIRAL LOAD ASSAYS**

The well characterised VQC-Sanquin standards for HBV-DNA, HCV-RNA, HIV-1 RNA and HIV-2 RNA are also used for preparation of linearity panels to be tested in quantitative NAT methods. Since these standards have been extensively calibrated in both copies/mL and IU/mL the dilution panels are also suitable for testing the accuracy of the quantitative results reported by the NAT methods. The CMV-DNA standard has not yet been calibrated against the WHO standard.



P0041 HBV-DNA genotype A Quant, 7 x 1.2 mL (7 vails in zip bag)

#### Linearity Panels for testing accuracy and precision of viral load assays

Cat. No	Source/Standard	Virus linearity panel <sup>\$</sup>	Quantity	range copies/mL	range IU/mL	Storage Temp.	List Price	Kit Insert	
HBV-DNA, HCV-RNA, HIV-1 RNA, HIV-2 RNA, CMV-DNA linearity panels									
P0041	VQC-Sanquin	P0041 HBV-DNA genotype A Quant	7 x 1.2 mL	10 - 10,000,000	1.87 - 1.876,173	≤ -30°C	€ 890	KI4036	
P0042	VQC-Sanquin	P0042 HCV-RNA genotype 1 Quant	5 x 1.2 mL	500 - 250,000	183 - 91,575	≤ -65°C	€ 890	KI4037	
P0043	VQC-Sanquin	P0043 HIV-1 RNA subtype B Quant	7 x 1.2 mL	50 - 250,000	86 - 431,034	≤ -65°C	€ 890	KI4038	
P0319	VQC-Sanquin	P0319 HIV-2 RNA subtype A Quant	5 x 1.2 mL	10 - 100,000		≤ -65°C	€ 890	KI4283	
P0044	DDL	P0044 CMV-DNA Quant	7 x 1.2 mL	100 - 100,000	*	≤ -65°C	€ 890	KI4039	

<sup>\$</sup> Regulatory status: RUO = for research use only \*calibration on WHO international standard not yet performed

# www.bioqcontrol.com

# CREATING CONFIDENCE



# **BIOLOGICALS QUALITY CONTROL B.V.**

De Droogmakerij 31h 1851 LX Heiloo the Netherlands **t:** +31 72 20 20 730 **e:** info@bioqcontrol.com