

# PRODUCT CATALOGUE 2023



Bio  QCControl

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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.

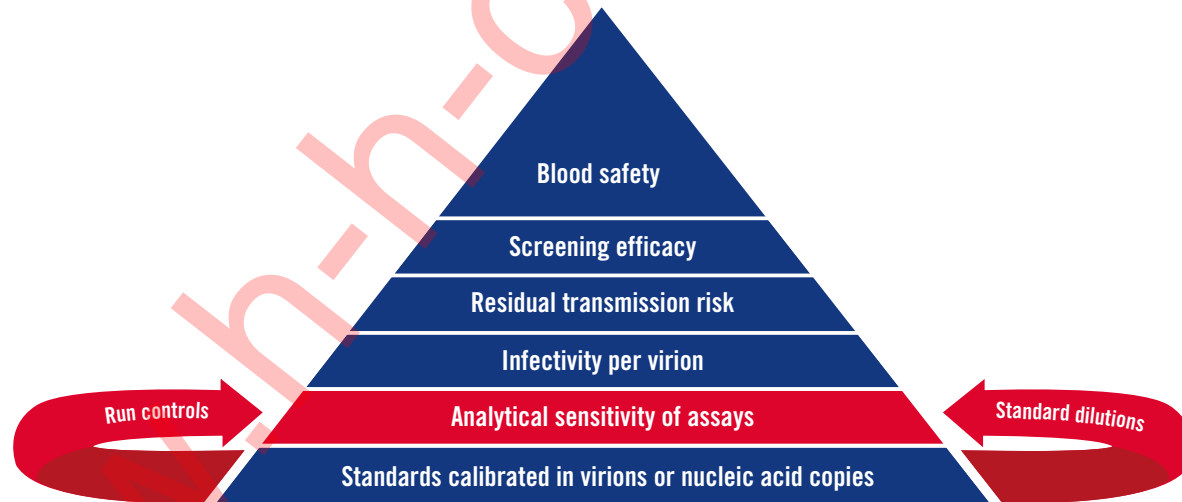


Figure. Standards for reference panels and run controls: foundations for monitoring blood safety



## 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  $-80^{\circ}\text{C}$ . 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  $-80^{\circ}\text{C}$  or  $-30^{\circ}\text{C}$  (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.

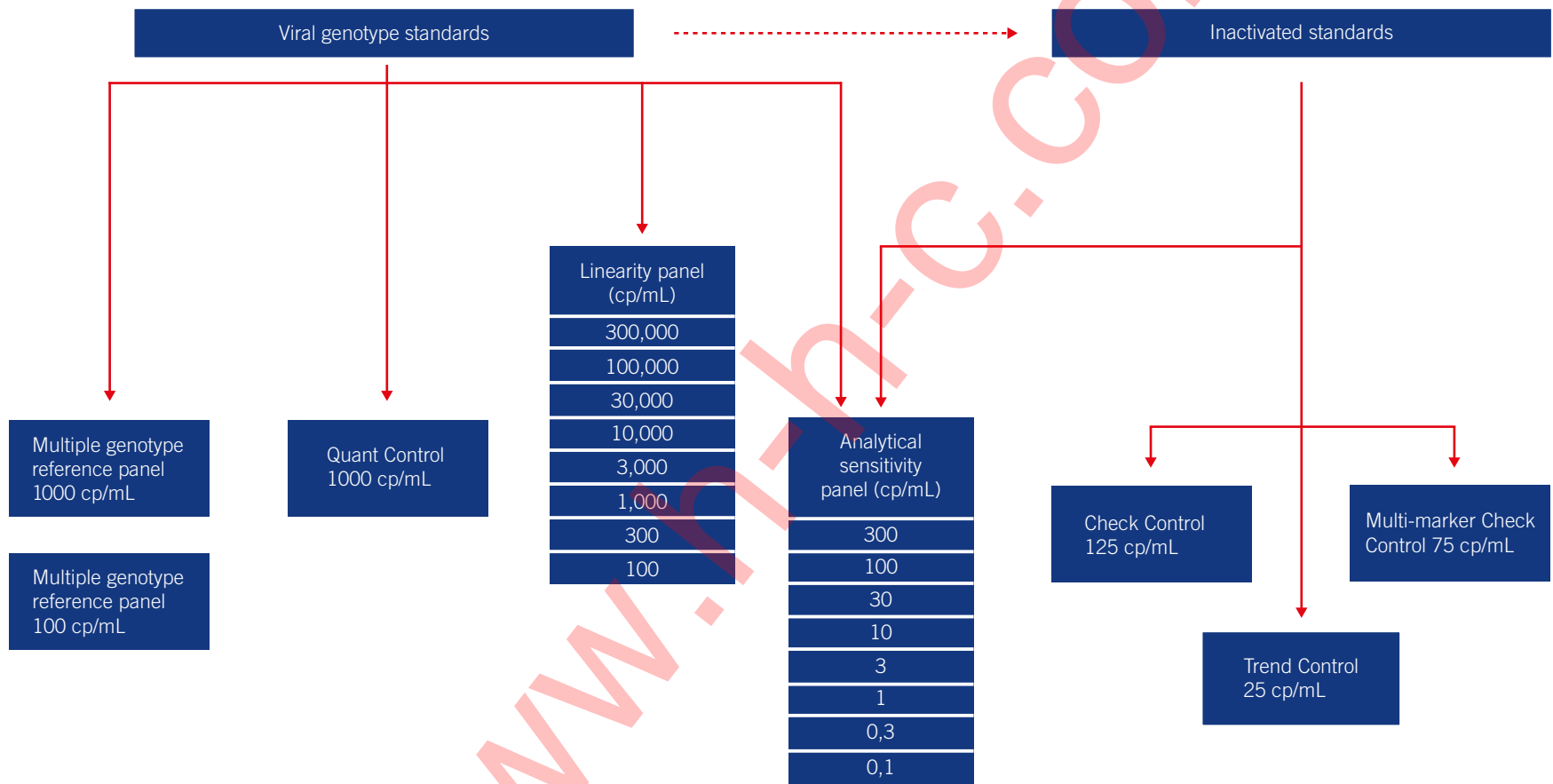


Figure. Schematic overview of preparation of reference panels and run controls from native and inactivated viral standards

# 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.

## Twenty-five 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 mid 1990s 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.

Twenty-five 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

### ViraQ Check Control for Respiratory virus NAT assays

- SARS-CoV-2 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

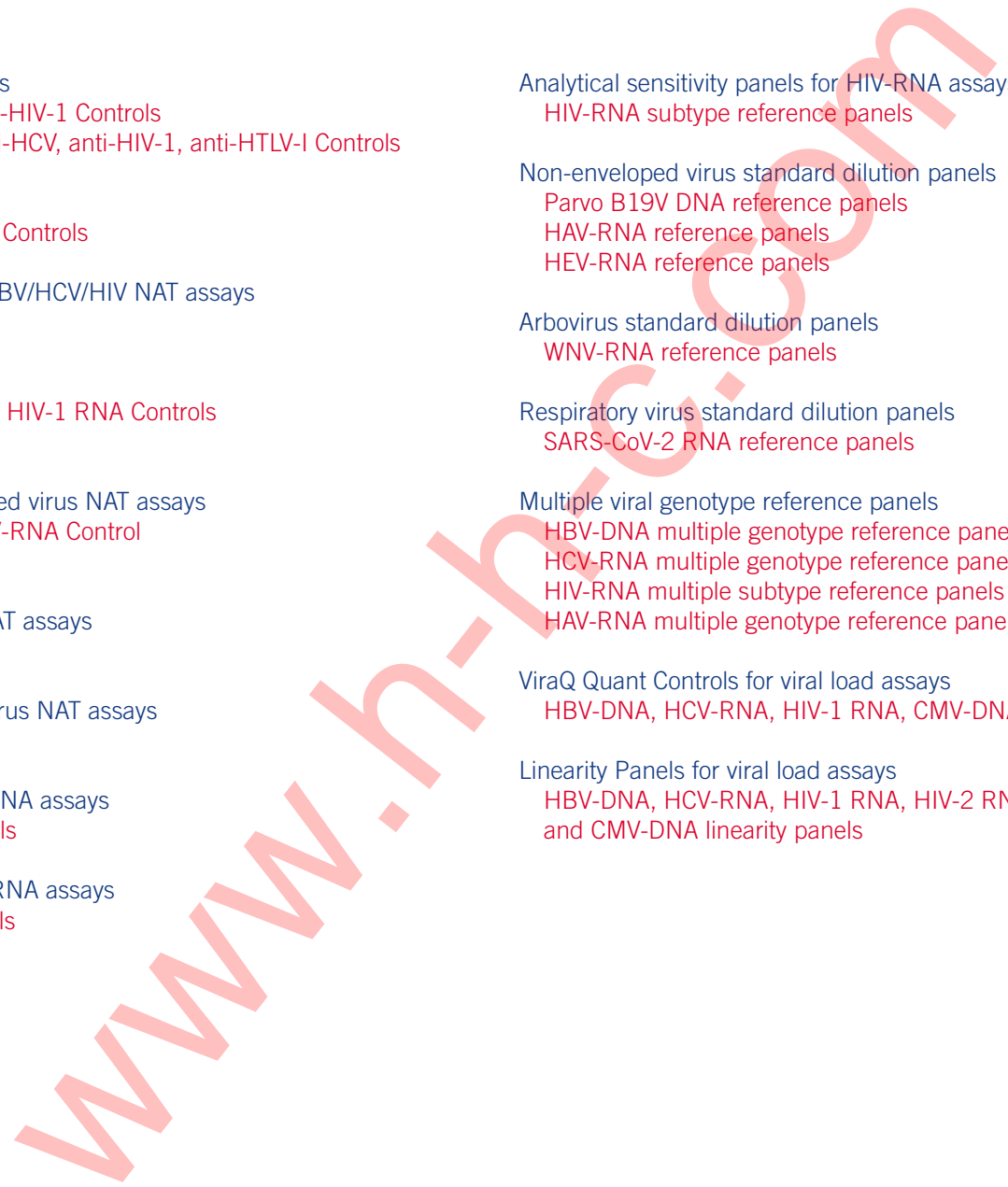
- HBV-DNA multiple genotype reference panels
- HCV-RNA multiple genotype reference panels
- HIV-RNA multiple subtype reference panels
- HAV-RNA multiple genotype reference panels

### 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 (around 2-3 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)

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

Cat. No	SeraQ Control	Quantity	Regul. Status	Storage Temp.	List Price	Kit Insert
<b>Multi-Marker HBsAg, anti-HCV, anti-HIV-1 Controls</b>						
P0078/01	P0078 SeraQ ARCHITECT	60 x 2 mL	PEO	≤ 20°C	€ 3425	KI4075
P0078/02	P0078 SeraQ ARCHITECT	10 x 2 mL			€ 570	
P0179/01	P0179 SeraQ Elecsys	60 x 2 mL	PEO	≤ 20°C	€ 3425	KI4179
P0179/02	P0179 SeraQ Elecsys	10 x 2 mL			€ 570	
P0180/01	P0180 SeraQ LIAISON	60 x 2 mL	PEO	≤ 20°C	€ 3425	KI4180
P0180/02	P0180 SeraQ LIAISON	10 x 2 mL			€ 570	
P0259/01	P0259 SeraQ Murex	60 x 2 mL	PEO	≤ 20°C	€ 3425	KI4260
P0259/02	P0259 SeraQ Murex	10 x 2 mL			€ 570	
P0309/01	P0309 SeraQ BIO-RAD	60 x 2 mL	PEO	≤ 20°C	€ 3425	KI4277
P0309/02	P0309 SeraQ BIO-RAD	10 x 2 mL			€ 570	
P0374/01	P0374 SeraQ Alinity V3	60 x 2.3 mL	PEO	≤ 20°C	€ 3725	KI4280
P0374/02	P0374 SeraQ Alinity V3	10 x 2.3 mL			€ 620	
<b>Multi-Marker HBsAg, anti-HBc, anti-HCV, anti-HIV-1, anti-HTLV-I Controls</b>						
P0386/01	P0386 SeraQ Alinity V4	60 x 3 mL	PEO	≤ 20°C	€ 5155	KI4286
P0386/02	P0386 SeraQ Alinity V4	10 x 3 mL			€ 860	

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 (around 2-3 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)

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## SeraQ Controls for ensuring sufficient analytical sensitivity of Syphilis assays

Cat. No	SeraQ Control	Quantity	Regul. Status	Storage Temp.	List Price	Kit Insert
<b>Anti-Treponema pallidum (Syphilis) Controls</b>						
P0267/01	P0267 SeraQ TPHA Syphilis V2	60 x 2 mL	PEO	≤ 20°C	€ 1895	KI4266
P0267/02	P0267 SeraQ TPHA Syphilis V2	10 x 2 mL			€ 315	
P0218/01	P0218 SeraQ ARCHITECT Syphilis	60 x 2 mL	CE	≤ 20°C	€ 1895	KI4218
P0218/02	P0218 SeraQ ARCHITECT Syphilis	10 x 2 mL			€ 315	
P0237/01	P0237 SeraQ LIAISON Syphilis	60 x 2 mL	CE	≤ 20°C	€ 1895	KI4237
P0237/02	P0237 SeraQ LIAISON Syphilis	10 x 2 mL			€ 315	
P0260/01	P0260 SeraQ Murex Syphilis	60 x 2 mL	PEO	≤ 20°C	€ 1895	KI4261
P0260/02	P0260 SeraQ Murex Syphilis	10 x 2 mL			€ 315	
P0312/01	P0312 SeraQ Elecsys Syphilis	60 x 2 mL	PEO	≤ 20°C	€ 1895	KI4278
P0312/02	P0312 SeraQ Elecsys Syphilis	10 x 2 mL			€ 315	
P0313/01	P0313 SeraQ BIO-RAD Syphilis	60 x 2 mL	PEO	≤ 20°C	€ 1895	KI4279
P0313/02	P0313 SeraQ BIO-RAD Syphilis	10 x 2 mL			€ 315	
P0317/01	P0317 SeraQ Alinity Syphilis	60 x 2 mL	PEO	≤ 20°C	€ 1895	KI4281
P0317/02	P0317 SeraQ Alinity Syphilis	10 x 2 mL			€ 315	

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 (Plus and Elite) 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 (Plus and Elite) reagent batches and performance of individual Tigris/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 <sup>^</sup>	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
<b>HBV-DNA Controls</b>								
P0065/01	P0065 ViraQ HBV Check 125	60 x 1.5 mL	125				€ 1240	KI4061
P0065/02	P0065 ViraQ HBV Check 125	10 x 1.5 mL		23.5	CE	≤ 30°C	€ 210	
P0154/01	P0154 ViraQ HBV Trend 50	60 x 1.5 mL	50	9.4	CE	≤ 30°C	€ 1240	KI4154
P0154/02	P0154 ViraQ HBV Trend 50	10 x 1.5 mL					€ 210	
P0069/01	P0069 ViraQ HBV Trend 25	60 x 1.5 mL	25	4.7	CE	≤ 30°C	€ 1240	KI4065
P0069/02	P0069 ViraQ HBV Trend 25	10 x 1.5 mL					€ 210	
<b>HCV-RNA Controls</b>								
P0063/01	P0063 ViraQ HCV Check 125	60 x 1.5 mL					€ 1240	KI4059
P0063/02	P0063 ViraQ HCV Check 125	10 x 1.5 mL	125	45.8	CE	≤ -30°C	€ 210	
P0067/01	P0067 ViraQ HCV Trend 25	60 x 1.5 mL	25	9.4	CE	≤ -30°C	€ 1240	KI4063
P0067/02	P0067 ViraQ HCV Trend 25	10 x 1.5 mL					€ 210	
<b>HIV-1 RNA Controls</b>								
P0064/01	P0064 ViraQ HIV-1 Check 125	60 x 1.5 mL					€ 1240	KI4060
P0064/02	P0064 ViraQ HIV-1 Check 125	10 x 1.5 mL	125	215	CE	≤ -30°C	€ 210	
P0068/01	P0068 ViraQ HIV-1 Trend 25	60 x 1.5 mL	25	43.1	CE	≤ -30°C	€ 1240	KI4064
P0068/02	P0068 ViraQ HIV-1 Trend 25	10 x 1.5 mL					€ 210	
<b>Multi-Marker HBV-DNA, HCV-RNA, HIV-1 RNA Controls</b>								
P0273/01	P0273 ViraQ Multi-Marker Check 75	60 x 1.6 mL#	75	14.1/27.5/129\$	CE	≤ -30°C	€ 1975	KI4268
P0273/02	P0273 ViraQ Multi-Marker Check 75	10 x 1.6 mL#					€ 330	
<b>HIV-2 RNA Controls</b>								
P0318/01	P0318 ViraQ HIV-2 Check 125	60 x 1.6 mL#	125	158.2	PEO	≤ -30°C	€ 1240	KI4282
P0318/02	P0318 ViraQ HIV-2 Check 125	10 x 1.6 mL#					€ 210	

<sup>^</sup> Pxxx/01 = 60 x 10 mL vials in rack/box, Pxxx/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.



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

## 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.



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

## RESPIRATORY VIRUS

ViraQ Check Controls for SARS-CoV-2 NAT assays have been developed from a chemically inactivated pool of swab fluid samples used for comparing the analytical sensitivity of different NAT methods and laminar flow devices for rapid antigen detection. The ViraQ SARS-CoV-2 Control of 125 copies/mL is suitable for the Roche cobas PCR and Hologic Aptima TMA assays (or other PCR methods of similar sensitivity). The ViraQ SARS-CoV-2 Control of 10,000 copies/mL has been developed for ensuring sufficient analytical sensitivity of faster NAT methods of lower sensitivity such as a LAMP assay that was used in the Netherlands.



P0378 ViraQ SARS CoV-2 Check 125, 60 x 1.6 mL  
(10 vials in zip bag)



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

Cat. No <sup>^</sup>	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
<b>Dual marker parvo B19V, HAV Controls</b>								
P0266/01	P0266 ViraQ Parvo B19/HA V Check	60 x 1.6 mL#		10,000/10	PEO	≤ 30°C	€ 1975	KI4259
P0266/02	P0266 ViraQ Parvo B19/HA V Check	10 x 1.6 mL#					€ 330	
<b>HEV-RNA Controls</b>								
P0264/01	P0264 ViraQ HEV Check 125	60 x 1.6 mL#		100	CE	≤ -30°C	€ 1240	KI4264
P0264/02	P0264 ViraQ HEV Check 125	10 x 1.6 mL#					€ 210	

<sup>^</sup> Pxxxx/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 #unique barcode per sample

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

Cat. No <sup>^</sup>	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
<b>WNV-RNA Controls</b>								
P0247/01	P0247 ViraQ WNV Check 125	60 x 1.6 mL#	125		CE	≤ 30°C	€ 1240	KI4247
P0247/02	P0247 ViraQ WNV Check 125	10 x 1.6 mL#					€ 210	

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

### ViraQ Check Control for ensuring sufficient analytical sensitivity of SARS-CoV-2 NAT assays

Cat. No	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	List Price	Kit Insert
<b>SARS-CoV-2 Control</b>								
P0378	P0378 ViraQ SARS-CoV-2 Check 125	10 x 0.6 mL	125	536	PEO	≤ 30°C	€ 210	KI4299





## ANALYTICAL SENSITIVITY PANELS FOR HBV-DNA ASSAYS

In the mid 1990s the Eurohep and VQC-Sanquin 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-Sanquin 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-Sanquin standard by multiple replicate DNA 3.0 assays as the reference method for quantification. The VQC-Sanquin 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-Sanquin 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-Sanquin 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-Sanquin 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
P0001	Eurohep	P0001 HBV-DNA genotype A	10 x 4 mL <sup>^</sup>	0.11 - 3300	0.02 - 619	≤ -30°C	€ 750
P0277		P0277 HBV-DNA genotype A	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0279	2nd WHO 97/750	P0279 HBV-DNA genotype A	8 x 4 mL	0.11 - 320	0.02 - 60	≤ -30°C	€ 750
P0007	VQC-Sanquin §	P0007 HBV-DNA genotype A	10 x 4 mL <sup>^</sup>	0.11 - 3225	0.02 - 605	≤ -30°C	€ 750
P0280		P0280 HBV-DNA genotype A	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0031	VQC-Sanquin inactivated	P0031 HBV-DNA genotype A inact	10 x 4 mL <sup>^</sup>	0.12 - 3538	0.02 - 664	≤ -30°C	€ 750
P0295		P0295 HBV-DNA genotype A inact	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0106	WHO 5086/08-1	P0106 HBV-DNA genotype A1 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0107	WHO 5086/08-2	P0107 HBV-DNA genotype A1 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0108	WHO 5086/08-3	P0108 HBV-DNA genotype A2	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0009	BioQControl	P0009 HBV-DNA genotype B	10 x 4 mL <sup>^</sup>	0.1 - 3035	0.02 - 569	≤ -30°C	€ 750
P0281		P0281 HBV-DNA genotype B	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0109	WHO 5086/08-4	P0109 HBV-DNA genotype B1	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0110	WHO 5086/08-5	P0110 HBV-DNA genotype B2	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0111	WHO 5086/08-6	P0111 HBV-DNA genotype B4	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0010	BioQControl	P0010 HBV-DNA genotype C	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0282		P0282 HBV-DNA genotype C	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0112	WHO 5086/08-7	P0112 HBV-DNA genotype C2 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0113	WHO 5086/08-8	P0113 HBV-DNA genotype C2 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0114	WHO 5086/08-9	P0114 HBV-DNA genotype C2 (3)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0002	Eurohep	P0002 HBV-DNA genotype D	10 x 4 mL <sup>^</sup>	0.1 - 2923	0.02 - 548	≤ -30°C	€ 750
P0278		P0278 HBV-DNA genotype D	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0011	BioQControl	P0011 HBV-DNA genotype D	10 x 4 mL <sup>^</sup>	0.1 - 3134	0.02 - 588	≤ -30°C	€ 750
P0283		P0283 HBV-DNA genotype D	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0115	WHO 5086/08-10	P0115 HBV-DNA genotype D1 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0116	WHO 5086/08-11	P0116 HBV-DNA genotype D3	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0117	WHO 5086/08-12	P0117 HBV-DNA genotype D1 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0012	BioQControl	P0012 HBV-DNA genotype E	10 x 4 mL <sup>^</sup>	0.11 - 3213	0.02 - 603	≤ -30°C	€ 750
P0284		P0284 HBV-DNA genotype E	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0118	WHO 5086/08-13	P0118 HBV-DNA genotype E1	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0013	BioQControl	P0013 HBV-DNA genotype F	10 x 4 mL <sup>^</sup>	0.12 - 3606	0.02 - 676	≤ -30°C	€ 750
P0285		P0285 HBV-DNA genotype F	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0119	WHO 5086/08-14	P0119 HBV-DNA genotype F3	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0014	BioQControl	P0014 HBV-DNA genotype G	10 x 4 mL <sup>^</sup>	0.11 - 3188	0.02 - 598	≤ -30°C	€ 750
P0286		P0286 HBV-DNA genotype G	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750
P0120	WHO 5086/08-15	P0120 HBV-DNA genotype G	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C	€ 750

§ extensively calibrated on 1st and 2nd WHO standard  
Kit insert: K14271

<sup>^</sup>10 x 4 mL format will be replaced by 8 x 4 mL format

§ Regulatory status: RUO = for research use only

# made for IVD manufacturer, available on request



## 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-Sanquin 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-Sanquin 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-Sanquin 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 <sup>§</sup>	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	€ 750
P0131	Egypt-1	P0131 HCV-RNA genotype 1a	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0197	Egypt-2	P0197 HCV-RNA genotype 1a	8 x 4 mL	0.16 - 547	0.06 - 200	≤ -65°C	€ 750
P0198	Japan-1	P0198 HCV-RNA genotype 1b	8 x 4 mL	0.08 - 235	0.03 - 86	≤ -65°C	€ 750
P0199	Japan-2	P0199 HCV-RNA genotype 1b	8 x 4 mL	0.04 - 146	0.02 - 53	≤ -65°C	€ 750
P0035	BioQControl	P0035 HCV-RNA genotype 2	10 x 4 mL <sup>^</sup>	0.10 - 2837	0.04 - 1039	≤ -65°C	€ 750
P0299		P0299 HCV-RNA genotype 2	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0200	Japan-3	P0200 HCV-RNA genotype 2a	8 x 4 mL	0.18 - 542	0.07 - 199	≤ -65°C	€ 750
P0201	Japan-4	P0201 HCV-RNA genotype 2a	8 x 4 mL	0.10 - 342	0.04 - 125	≤ -65°C	€ 750
P0202	Japan-5	P0202 HCV-RNA genotype 2b	8 x 4 mL	0.11 - 328	0.04 - 120	≤ -65°C	€ 750
P0203	Japan-6	P0203 HCV-RNA genotype 2b	8 x 4 mL	0.10 - 343	0.04 - 126	≤ -65°C	€ 750
P0036	BioQControl	P0036 HCV-RNA genotype 3	10 x 4 mL <sup>^</sup>	0.06 - 1792	0.02 - 656	≤ -65°C	€ 750
P0300		P0300 HCV-RNA genotype 3	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0020	BioQControl inactivated	P0020 HCV-RNA genotype 3 inact.	10 x 4 mL <sup>^</sup>	0.12 - 3450	0.04 - 1264	≤ -65°C	€ 750
P0289		P0289 HCV-RNA genotype 3 inact.	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0204	Lithuania-1	P0204 HCV-RNA genotype 3a	8 x 4 mL	0.09 - 295	0.03 - 108	≤ -65°C	€ 750
P0205	Lithuania-2	P0205 HCV-RNA genotype 3a	8 x 4 mL	0.15 - 439	0.05 - 161	≤ -65°C	€ 750
P0130	Thailand	P0130 HCV genotype 3b	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0037	BioQControl	P0037 HCV-RNA genotype 4	10 x 4 mL <sup>^</sup>	0.07 - 1982	0.02 - 726	≤ -65°C	€ 750
P0301		P0301 HCV-RNA genotype 4	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0126	Egypt-3	P0126 HCV genotype 4 (2)	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0206	Egypt-4	P0206 HCV genotype 4 (3)	8 x 4 mL	0.22 - 741	0.08 - 272	≤ -65°C	€ 750
P0038	BioQControl	P0038 HCV-RNA genotype 5	10 x 4 mL <sup>^</sup>	0.08 - 2465	0.03 - 903	≤ -65°C	€ 750
P0302		P0302 HCV-RNA genotype 5	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0127	Congo	P0127 HCV genotype 5 (2)	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0039	BioQControl	P0039 HCV-RNA genotype 6	10 x 4 mL <sup>^</sup>	0.07 - 2001	0.02 - 733	≤ -65°C	€ 750
P0303		P0303 HCV-RNA genotype 6	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0128	USA	P0128 HCV genotype 6	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750
P0129	Thailand	P0129 HCV genotype 6n	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C	€ 750

§ extensively calibrated on 1st and 2nd WHO standard

<sup>^</sup>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: KI4269



## ANALYTICAL SENSITIVITY PANELS FOR HIV-RNA ASSAYS

In the mid 1990s 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-Sanquin 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-Sanquin 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-Sanquin 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-Sanquin standard in the package insert are based on calibration to the 2nd WHO 97/650 standard. The latter WHO standard and the VQC-Sanquin 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 <sup>§</sup>	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	€ 750
P0025	VQC-Sanquin §	P0025 HIV-1 RNA subtype B	10 x 4 mL <sup>^</sup>	0.1 - 2590	0.15 - 4466	≤ -65°C	€ 750
P0290		P0290 HIV-1 RNA subtype B	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0026	VQC-Sanquin inactivated	P0026 HIV-1 RNA subtype B inact.	10 x 4 mL <sup>^</sup>	0.1 - 2446	0.1 - 4217	≤ -65°C	€ 750
P0291		P0291 HIV-1 RNA subtype B inact.	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0032	BioQControl	P0032 HIV-1 RNA subtype A	10 x 4 mL <sup>^</sup>	0.2 - 5020	0.3 - 8655	≤ -65°C	€ 750
P0296		P0296 HIV-1 RNA subtype A	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0027	BioQControl	P0027 HIV-1 RNA subtype C	10 x 4 mL <sup>^</sup>	0.1 - 2883	0.2 - 4971	≤ -65°C	€ 750
P0292		P0292 HIV-1 RNA subtype C	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0033	BioQControl	P0033 HIV-1 RNA subtype D	10 x 4 mL <sup>^</sup>	0.2 - 5610	0.3 - 9672	≤ -65°C	€ 750
P0297		P0297 HIV-1 RNA subtype D	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0028	BioQControl	P0028 HIV-1 RNA CRF01_AE (1)	10 x 4 mL <sup>^</sup>	0.1 - 3075	0.2 - 5301	≤ -65°C	€ 750
P0293		P0293 HIV-1 RNA CRF01_AE (1)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0052	Thailand	P0052 HIV-1 RNA CRF01_AE (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0053	Brazil	P0053 HIV-1 RNA subtype F (1)	8 x 4 mL	0.10 - 300	0.2 - 517	≤ -65°C	€ 750
P0054	Romania	P0054 HIV-1 RNA subtype F (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0098	Zaire	P0098 HIV-1 RNA subtype G (1)	8 x 4 mL	0.10 - 300	0.2 - 517	≤ -65°C	€ 750
P0099	Kenya	P0099 HIV-1 RNA subtype G (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0051	Ghana	P0051 HIV-1 RNA CRF02_AG	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0100	Zaire	P0100 HIV-1 RNA subtype H	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C	€ 750
P0354	2nd WHO 16/296	P0354 HIV-2 subtype A	8 x 4 mL <sup>^</sup>	0.24 - 237	0.3 - 300	≤ -65°C	€ 750
P0298	BioQControl	P0298 HIV-2 RNA subtype A	8 x 4 mL	0.1 - 300	0.1 - 380	≤ -65°C	€ 750
P0212	Belgium	P0212 HIV-2 RNA subtype B	8 x 4 mL	0.1 - 300	0.1 - 380	≤ -65°C	€ 750
P0015	BioQControl	P0015 HIV RNA group O (1)	10 x 4 mL <sup>^</sup>	0.1 - 2580	0.1 - 4448	≤ -65°C	€ 750
P0101	USA	P0101 HIV-RNA group O (2)	8 x 4 mL	0.46 - 1382	0.79 - 2383	≤ -65°C	€ 750
P0102	Cameroon	P0102 HIV-RNA group O (3)	8 x 4 mL	0.40 - 1197	0.69 - 2064	≤ -65°C	€ 750
P0103	Spain	P0103 HIV-RNA group O (4)	8 x 4 mL	0.43 - 1281	0.74 - 2209	≤ -65°C	€ 750
P0104	Cameroon	P0104 HIV-RNA group O (5)	8 x 4 mL	0.41 - 1233	0.71 - 2125	≤ -65°C	€ 750

§ extensively calibrated on 1st and 2nd WHO standard    <sup>^</sup>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-Sanquin 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 Sanquin at that time. More recently a secondary HEV standard has been established in collaboration with Sanquin. 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 assay 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-Sanquin standard.



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

### 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.



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

### 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. In addition a validation panel of 500 and 2000 copies/mL has been developed for laboratories that want to monitor the performance of more rapid SARS-CoV-2 NAT methods.



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>s</sup>	Quantity	range IU/mL	Storage Temp.	List Price	Kit Insert
<b>Parvo B19V DNA reference panels</b>							
P0143	VQC-Sanquin	P0143 parvo B19-DNA genotype 1 Quant	10 x 4 mL	30 - 1,000,000	≤ -65°C	€ 865	KI4273
P0144	Sanquin	P0144 parvo B19-DNA genotype 2 Quant	8 x 4 mL	30 - 100,000	≤ -65°C	€ 750	KI4273
<b>HAV-RNA reference panels</b>							
P0351	VQC-Sanquin	P0351 HAV genotype 1a	8 x 4 mL	0.01 - 30	≤ -65°C	€ 750	KI4272
P0208	France	P0208 HAV-RNA genotype 2a	8 x 4 mL	0.1 - 300	≤ -65°C	€ 750	KI4272
P0209	France	P0209 HAV-RNA genotype 3a	8 x 4 mL	0.1 - 300	≤ -65°C	€ 750	KI4272
<b>HEV-RNA reference panels</b>							
P0274	Sanquin	P0274 HEV-RNA genotype 3	8 x 4 mL	0.1 - 300	≤ -65°C	€ 750	KI4276
P0262	1st WHO 6329/10	P0262 HEV-RNA genotype 3	6 x 4 mL	0 - 90	≤ -65°C	€ 750	KI4276

\$ 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
<b>WNV-RNA reference panel</b>							
P0360	Italy	P0360 WNV-RNA Lineage 1		0.1 - 300	≤ -65°C	€ 750	KI4297
P0346	Macedonia	P0346 WNV-RNA Lineage 2 inactivated		0.1 - 300	≤ -65°C	€ 750	KI4297

\$ 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
<b>SARS-CoV-2 standard dilution panel</b>							
P0356	The Netherlands	P0356 SARS-CoV-2 dilution panel	10 x 1.4 mL	1.1 - 33,784	≤ -65°C	€ 1415	KI4300

\$ 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
<b>HBV-DNA multiple genotype reference panels</b>								
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	€ 2550	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	€ 4690	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	€ 1815	KI4141
<b>HCV-RNA multiple genotype reference panels</b>								
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	€ 2550	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	€ 4690	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	€ 1815	KI4142
<b>HIV-RNA multiple genotype reference panels</b>								
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	€ 2550	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	€ 4690	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	€ 1815	KI4140
<b>HAV-RNA multiple genotype reference panel</b>								
P0153	P0153 HAV genotype reference panel#	5 x 4 mL	~1000	100	1a, 1b, 2a, 3a	≤ -65°C	€ 1065	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.



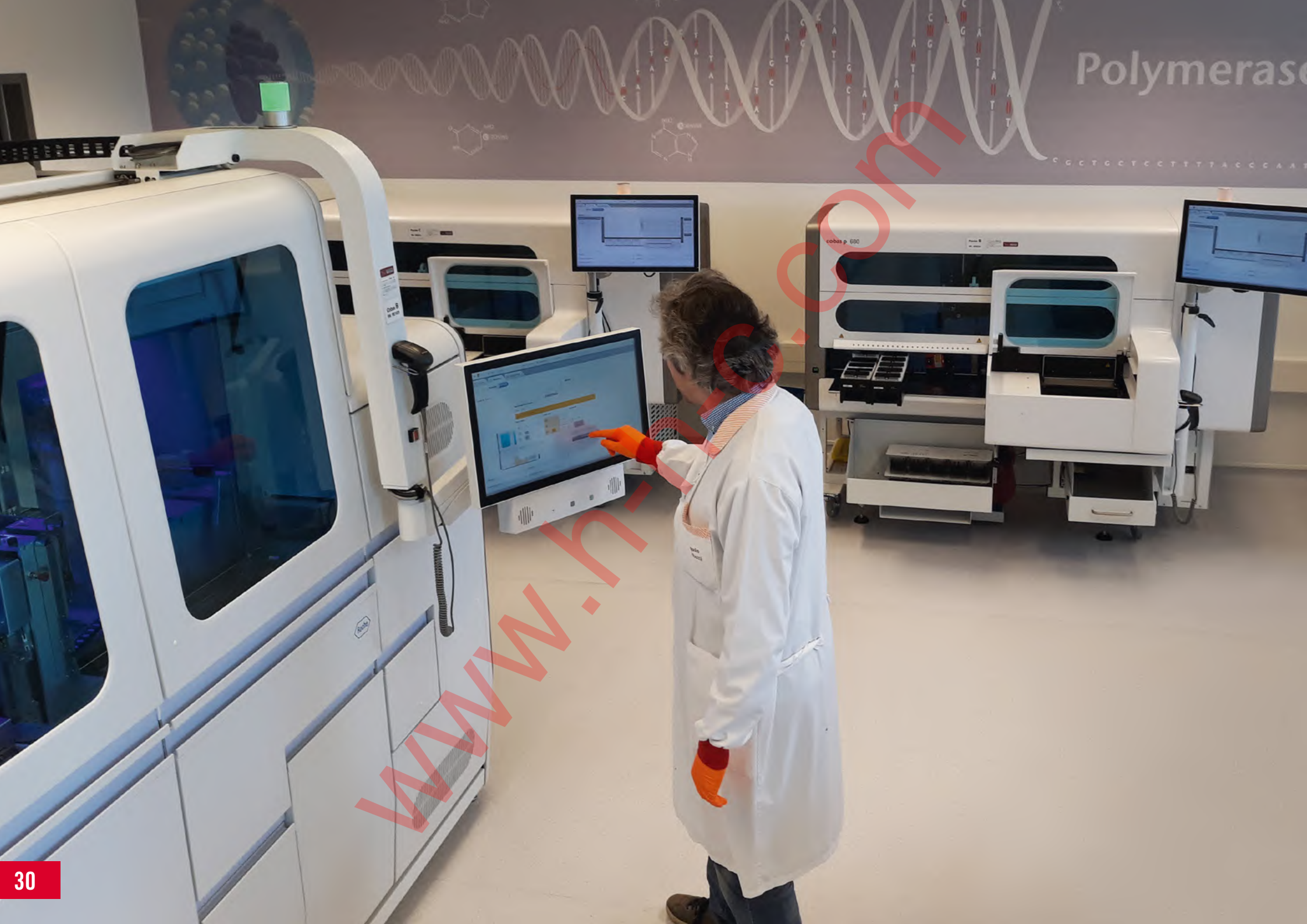
P0327 ViraQ HIV-1 Quant 1000, 10 x 1.2 mL  
(10 vials in zip bag)

### 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
<b>HBV-DNA, HCV-RNA, HIV-1 RNA, CMV-DNA and HSV-1 and 2 DNA Controls</b>								
P0345	P0345 ViraQ HBV Quant 1000	10 x 1.2 mL	1000	188	PEO#	≤30°C	€ 485	KI4296
P0344	P0344 ViraQ HCV Quant 1000	10 x 1.2 mL	1000	366	PEO#	≤65°C	€ 485	KI4295
P0327	P0327 ViraQ HIV-1 Quant 1000	10 x 1.2 mL	1000	1724	PEO#	≤65°C	€ 485	KI4292
P0146	P0146 ViraQ CMV Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	€ 485	KI4146
P0147	P0147 ViraQ HSV-1 Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	€ 485	KI4147
P0148	P0148 ViraQ HSV-2 Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	€ 485	KI4148

# Available for performance evaluation studies only

Polymerase



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## 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 vials 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
<b>HBV-DNA, HCV-RNA, HIV-1 RNA, HIV-2 RNA, CMV-DNA linearity panels</b>								
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	€ 830	KI4036
P0042	VQC-Sanquin	P0042 HCV-RNA genotype 1 Quant	5 x 1.2 mL	500 - 250,000	183 - 91,575	≤ -65°C	€ 830	KI4037
P0043	VQC-Sanquin	P0043 HIV-1 RNA subtype B Quant	7 x 1.2 mL	50 - 250,000	86 - 431,034	≤ -65°C	€ 830	KI4038
P0319	VQC-Sanquin	P0319 HIV-2 RNA subtype A Quant	5 x 1.2 mL	10 - 100,000		≤ -65°C	€ 830	KI4283
P0044	DDL	P0044 CMV-DNA Quant	7 x 1.2 mL	100 - 100,000	*	≤ -65°C	€ 830	KI4039

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

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