PRODUCT CATALOGUE 2021

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Bio QControl

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

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- WNV-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.

P0316/01 SeraQ Alinity V1, 60 x 2 mL
(60 tubes in rack/box)

Serum matrix

P0079/02 SeraQ PRISM V1, 10 x 5.0 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.	Kit Insert
Multi-Marker HBsAg, anti-HCV, anti-HIV-1 Controls					
P0078/01	P0078 SeraQ ARCHITECT	60 x 2 mL	PEO	≤ 20°C	KI4075
P0078/02	P0078 SeraQ ARCHITECT	10 x 2 mL			
P0179/01	P0179 SeraQ Elecsys	60 x 2 mL	PEO	≤ 20°C	KI4179
P0179/02	P0179 SeraQ Elecsys	10 x 2 mL			
P0180/01	P0180 SeraQ LIAISON	60 x 2 mL	PEO	≤ 20°C	KI4180
P0180/02	P0180 SeraQ LIAISON	10 x 2 mL			
P0259/01	P0259 SeraQ Murex	60 x 2 mL	PEO	≤ 20°C	KI4260
P0259/02	P0259 SeraQ Murex	10 x 2 mL			
P0309/01	P0309 SeraQ BIO-RAD	60 x 2 mL	PEO	≤ 20°C	KI4277
P0309/02	P0309 SeraQ BIO-RAD	10 x 2 mL			
P0316/01	P0316 SeraQ Alinity V1	60 x 2 mL	PEO	≤ 20°C	KI4280
P0316/02	P0316 SeraQ Alinity V1	10 x 2 mL			
Multi-Marker HBsAg, anti-HBc, anti-HCV, anti-HIV-1, anti-HTLV-I Controls					
P0320/01	P0320 SeraQ Alinity V2	60 x 2 mL	PEO	≤ 20°C	KI4286
P0320/02	P0320 SeraQ Alinity V2	10 x 2 mL			

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)

SeraQ Controls for ensuring sufficient analytical sensitivity of Syphilis assays

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

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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), but are also instrumental for testing the precision of viral load assays in the immediate range above the quantification limit. 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 (and quantification) 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)

P0063/03 ViraQ HCV Check 125, 10 x 1.5 mL
(10 vials in zip bag)

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

Cat. No^	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	Kit Insert
HBV-DNA Controls							
P0065/01	P0065 ViraQ HBV Check 125	60 x 1.5 mL					
P0065/02	P0065 ViraQ HBV Check 125	10 x 1.5 mL	125	23.5	CE	≤ 30°C	KI4061
P0065/03	P0065 ViraQ HBV Check 125	10 x 1.5 mL					
P0154/01	P0154 ViraQ HBV Trend 50	60 x 1.5 mL	50	9.4	CE	≤ 30°C	KI4154
P0154/02	PO154 ViraQ HBV Trend 50	10 x 1.5 mL					
P0069/01	P0069 ViraQ HBV Trend 25	60 x 1.5 mL	25	4.7	CE	≤ 30°C	KI4065
P0069/02	P0069 ViraQ HBV Trend 25	10 x 1.5 mL					
HCV-RNA Controls							
P0063/01	P0063 ViraQ HCV Check 125	60 x 1.5 mL					
P0063/02	P0063 ViraQ HCV Check 125	10 x 1.5 mL	125	45.8	CE	≤ -30°C	KI4059
P0063/03	P0063 ViraQ HCV Check 125	10 x 1.5 mL					
P0067/01	P0067 ViraQ HCV Trend 25	60 x 1.5 mL	25	9.4	CE	≤ -30°C	KI4063
P0067/02	P0067 ViraQ HCV Trend 25	10 x 1.5 mL					
HIV-1 RNA Controls							
P0064/01	P0064 ViraQ HIV-1 Check 125	60 x 1.5 mL					
P0064/02	P0064 ViraQ HIV-1 Check 125	10 x 1.5 mL	125	215	CE	≤ -30°C	KI4060
P0064/03	P0064 ViraQ HIV-1 Check 125	10 x 1.5 mL					
P0068/01	P0068 ViraQ HIV-1 Trend 25	60 x 1.5 mL	25	43.1	CE	≤ -30°C	KI4064
P0068/02	P0068 ViraQ HIV-1 Trend 25	10 x 1.5 mL					
Multi-Marker HBV-DNA, HCV-RNA, HIV-1 RNA Controls							
P0273/01	P0273 ViraQ Multi-Marker Check 75	60 x 1.6 mL#	75	14.1/27.5/129$	CE	≤ -30°C	KI4268
P0273/02	P0273 ViraQ Multi-Marker Check 75	10 x 1.6 mL#					
HIV-2 RNA Controls							
P0318/01	P0318 ViraQ HIV-2 Check 125	60 x 1.6 mL#	125	158.2	PEO	≤ -30°C	KI4282
P0318/02	P0318 ViraQ HIV-2 Check 125	10 x 1.6 mL#					

^ Pxxx/01 = 60 x 10 mL vials in rack/box, Pxxxx/02 = 10 x 10 mL vials in zip bag, Pxxxx/03 = 10 x 2 mL vials in zip bag for use in viral load assays
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 NON-ENVELOPED VIRUS NAT ASSAYS

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)

P0264/02 ViraQ HEV Check 125, 10 x 1.6 mL
(10 tubes in zip bag)

VIRAQ CHECK CONTROLS FOR ARBOVIRUS NAT ASSAYS

Recently a ViraQ Check Control for WNV NAT assays has been developed from a chemically inactivated WNV Lineage 2 standard.

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

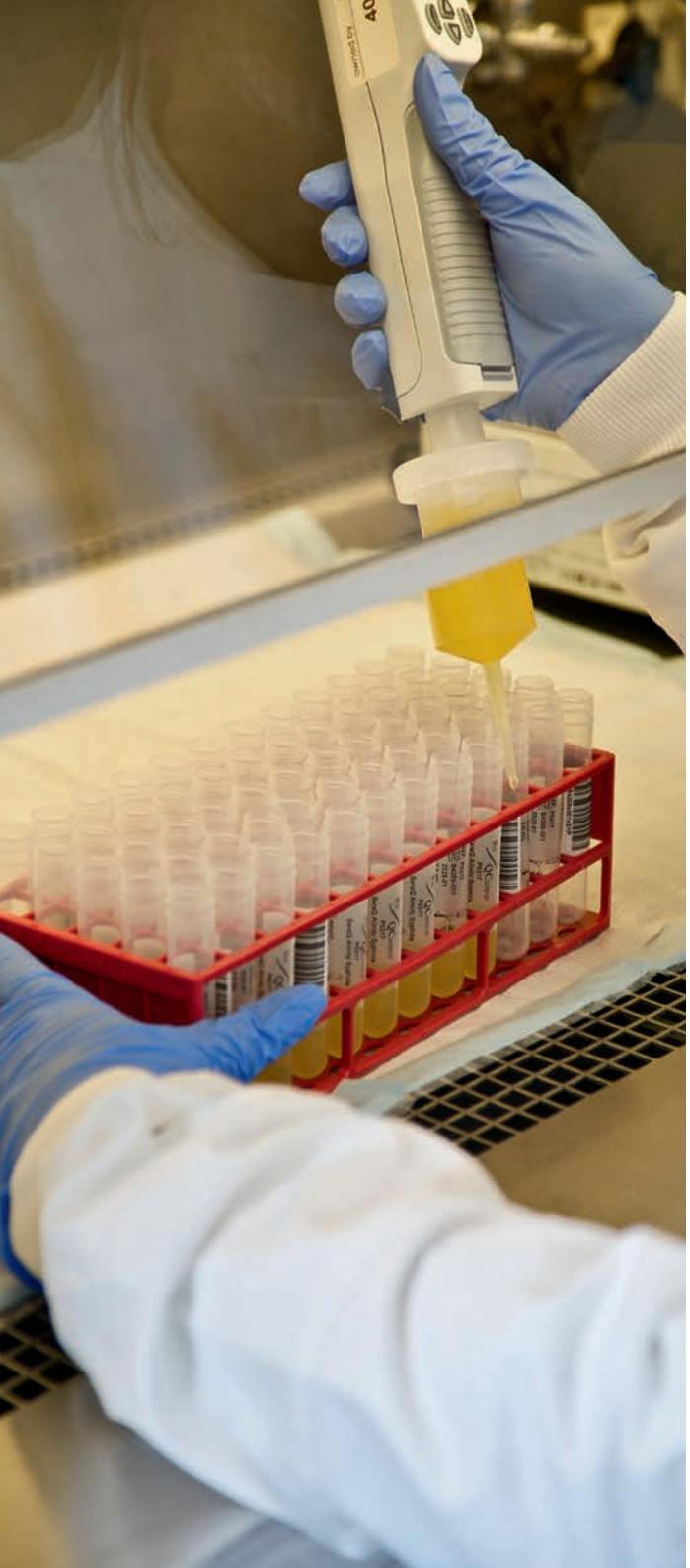
Cat. No^	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	Kit Insert
Dual marker parvo B19V, HAV Controls							
P0266/01	P0266 ViraQ Parvo B19/HAV Check	60 x 1.6 mL#		10,000/10	PEO	≤ 30°C	KI4259
P0266/02	P0266 ViraQ Parvo B19/HAV Check	10 x 1.6 mL#					
HEV-RNA Controls							
P0264/01	P0264 ViraQ HEV Check 125	60 x 1.6 mL#		100	PEO	≤ -30°C	KI4264
P0264/02	P0264 ViraQ HEV Check 125	10 x 1.6 mL#					

^ 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^	ViraQ Control	Quantity	copies/mL	IU/mL	Regul. Status	Storage Temp.	Kit Insert
WNV-RNA Controls							
P0247/01	P0247 ViraQ WNV Check 125	60 x 1.6 mL#	125		PEO	≤ 30°C	KI4247
P0247/02	P0247 ViraQ WNV Check 125	10 x 1.6 mL#					

^ 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



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[$]	Quantity	range copies/mL	range IU/mL	Storage Temp.
P0001	Eurohep	P0001 HBV-DNA genotype A	10 x 4 mL^	0.11 - 3300	0.02 - 619	≤ -30°C
P0277		P0277 HBV-DNA genotype A	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0279	2nd WHO 97/750	P0279 HBV-DNA genotype A	8 x 4 mL	0.11 - 320	0.02 - 60	≤ -30°C
P0007	VQC-Sanquin §	P0007 HBV-DNA genotype A	10 x 4 mL^	0.11 - 3225	0.02 - 605	≤ -30°C
P0280		P0280 HBV-DNA genotype A	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0031	VQC-Sanquin inactivated	P0031 HBV-DNA genotype A inact	10 x 4 mL^	0.12 - 3538	0.02 - 664	≤ -30°C
P0295		P0295 HBV-DNA genotype A inact	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0106	WHO 5086/08-1	P0106 HBV-DNA genotype A1 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0107	WHO 5086/08-2	P0107 HBV-DNA genotype A1 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0108	WHO 5086/08-3	P0108 HBV-DNA genotype A2	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0009	BioQControl	P0009 HBV-DNA genotype B	10 x 4 mL^	0.1 - 3035	0.02 - 569	≤ -30°C
P0281		P0281 HBV-DNA genotype B	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0109	WHO 5086/08-4	P0109 HBV-DNA genotype B1	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0110	WHO 5086/08-5	P0110 HBV-DNA genotype B2	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0111	WHO 5086/08-6	P0111 HBV-DNA genotype B4	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0010	BioQControl	P0010 HBV-DNA genotype C	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0282		P0282 HBV-DNA genotype C	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0112	WHO 5086/08-7	P0112 HBV-DNA genotype C2 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0113	WHO 5086/08-8	P0113 HBV-DNA genotype C2 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0114	WHO 5086/08-9	P0114 HBV-DNA genotype C2 (3)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0002	Eurohep	P0002 HBV-DNA genotype D	10 x 4 mL^	0.1 - 2923	0.02 - 548	≤ -30°C
P0278		P0278 HBV-DNA genotype D	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0011	BioQControl	P0011 HBV-DNA genotype D	10 x 4 mL^	0.1 - 3134	0.02 - 588	≤ -30°C
P0283		P0283 HBV-DNA genotype D	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0115	WHO 5086/08-10	P0115 HBV-DNA genotype D1 (1)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0116	WHO 5086/08-11	P0116 HBV-DNA genotype D3	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0117	WHO 5086/08-12	P0117 HBV-DNA genotype D1 (2)	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0012	BioQControl	P0012 HBV-DNA genotype E	10 x 4 mL^	0.11 - 3213	0.02 - 603	≤ -30°C
P0284		P0284 HBV-DNA genotype E	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0118	WHO 5086/08-13	P0118 HBV-DNA genotype E1	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0013	BioQControl	P0013 HBV-DNA genotype F	10 x 4 mL^	0.12 - 3606	0.02 - 676	≤ -30°C
P0285		P0285 HBV-DNA genotype F	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0119	WHO 5086/08-14	P0119 HBV-DNA genotype F3	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0014	BioQControl	P0014 HBV-DNA genotype G	10 x 4 mL^	0.11 -3188	0.02 - 598	≤ -30°C
P0286		P0286 HBV-DNA genotype G	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C
P0120	WHO 5086/08-15	P0120 HBV-DNA genotype G	8 x 4 mL	0.1 - 300	0.02 - 56.3	≤ -30°C

§ extensively calibrated on 1st and 2nd WHO standard ^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
Kit insert: KI4271

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[$]	Quantity	range copies/mL	range IU/mL	Storage Temp.
P0288	VQC-Sanquin §	P0288 HCV-RNA genotype 1	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0131	Egypt-1	P0131 HCV-RNA genotype 1a	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0197	Egypt-2	P0197 HCV-RNA genotype 1a	8 x 4 mL	0.16 - 547	0.06 - 200	≤ -65°C
P0198	Japan-1	P0198 HCV-RNA genotype 1b	8 x 4 mL	0.08 - 235	0.03 - 86	≤ -65°C
P0199	Japan-2	P0199 HCV-RNA genotype 1b	8 x 4 mL	0.04 - 146	0.02 - 53	≤ -65°C
P0035	BioQControl	P0035 HCV-RNA genotype 2	10 x 4 mL^	0.10 - 2837	0.04 - 1039	≤ -65°C
P0299		P0299 HCV-RNA genotype 2	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0200	Japan-3	P0200 HCV-RNA genotype 2a	8 x 4 mL	0.18 - 542	0.07 - 199	≤ -65°C
P0201	Japan-4	P0201 HCV-RNA genotype 2a	8 x 4 mL	0.10 - 342	0.04 - 125	≤ -65°C
P0202	Japan-5	P0202 HCV-RNA genotype 2b	8 x 4 mL	0.11 - 328	0.04 - 120	≤ -65°C
P0203	Japan-6	P0203 HCV-RNA genotype 2b	8 x 4 mL	0.10 - 343	0.04 - 126	≤ -65°C
P0036	BioQControl	P0036 HCV-RNA genotype 3	10 x 4 mL^	0.06 - 1792	0.02 - 656	≤ -65°C
P0300		P0300 HCV-RNA genotype 3	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0020	BioQControl inactivated	P0020 HCV-RNA genotype 3 inact.	10 x 4 mL^	0.12 - 3450	0.04 - 1264	≤ -65°C
P0289		P0289 HCV-RNA genotype 3 inact.	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0204	Lithuania-1	P0204 HCV-RNA genotype 3a	8 x 4 mL	0.09 - 295	0.03 - 108	≤ -65°C
P0205	Lithuania-2	P0205 HCV-RNA genotype 3a	8 x 4 mL	0.15 - 439	0.05 - 161	≤ -65°C
P0130	Thailand	P0130 HCV genotype 3b	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0037	BioQControl	P0037 HCV-RNA genotype 4	10 x 4 mL^	0.07 - 1982	0.02 -726	≤ -65°C
P0301		P0301 HCV-RNA genotype 4	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0126	Egypt-3	P0126 HCV genotype 4 (2)	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0206	Egypt-4	P0206 HCV genotype 4 (3)	8 x 4 mL	0.22 - 741	0.08 - 272	≤ -65°C
P0038	BioQControl	P0038 HCV-RNA genotype 5	10 x 4 mL^	0.08 - 2465	0.03 - 903	≤ -65°C
P0302		P0302 HCV-RNA genotype 5	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0127	Congo	P0127 HCV genotype 5 (2)	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0039	BioQControl	P0039 HCV-RNA genotype 6	10 x 4 mL^	0.07 - 2001	0.02 - 733	≤ -65°C
P0303		P0303 HCV-RNA genotype 6	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0128	USA	P0128 HCV genotype 6	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C
P0129	Thailand	P0129 HCV genotype 6n	8 x 4 mL	0.10 - 300	0.04 - 110	≤ -65°C

¥ stability of WHO standard not guaranteed § 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, availble on request $ regulatory status: RUO = for research use only Kit insert: KI4269

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-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.

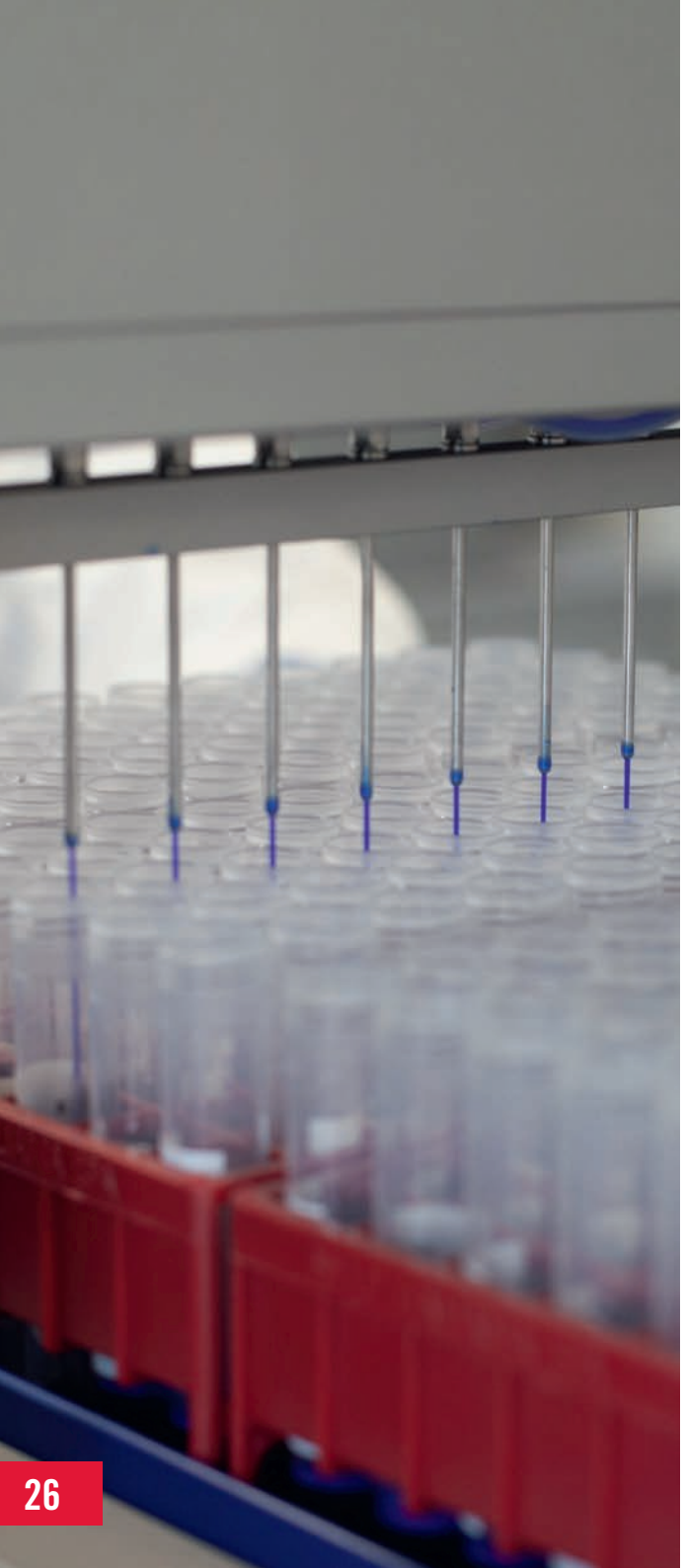
The package insert of all the HIV subtype standard dilution panels gives an overview of the reactivity rates found with multiple replicate tests in different NAT methods. The response data in the package insert can be used as a reference when the panels are tested for determining the 95% and 50% LOD 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[$]	Quantity	range copies/mL	range IU/mL	Storage Temp.
P0350	4th WHO 16/149	P0350 HIV-1 RNA subtype B	7 x 4 mL	0.12 - 116	0.2 - 200	≤ -65°C
P0025	VQC-Sanquin §	P0025 HIV-1 RNA subtype B	10 x 4 mL^	0.1 - 2590	0.15 - 4466	≤ -65°C
P0290		P0290 HIV-1 RNA subtype B	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0026	VQC-Sanquin inactivated	P0026 HIV-1 RNA subtype B inact.	10 x 4 mL^	0.1 - 2446	0.1 - 4217	≤ -65°C
P0291		P0291 HIV-1 RNA subtype B inact.	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0032	BioQControl	P0032 HIV-1 RNA subtype A	10 x 4 mL^	0.2 - 5020	0.3 - 8655	≤ -65°C
P0296		P0296 HIV-1 RNA subtype A	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0027	BioQControl	P0027 HIV-1 RNA subtype C	10 x 4 mL^	0.1 - 2883	0.2 - 4971	≤ -65°C
P0292		P0292 HIV-1 RNA subtype C	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0033	BioQControl	P0033 HIV-1 RNA subtype D	10 x 4 mL^	0.2 - 5610	0.3 - 9672	≤ -65°C
P0297		P0297 HIV-1 RNA subtype D	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0028	BioQControl	P0028 HIV-1 RNA CRF01_AE (1)	10 x 4 mL^	0.1 - 3075	0.2 - 5301	≤ -65°C
P0293		P0293 HIV-1 RNA CRF01_AE (1)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0052	Thailand	P0052 HIV-1 RNA CRF01_AE (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0053	Brazil	P0053 HIV-1 RNA subtype F (1)	8 x 4 mL	0.10 - 300	0.2 - 517	≤ -65°C
P0054	Romania	P0054 HIV-1 RNA subtype F (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0098	Zaire	P0098 HIV-1 RNA subtype G (1)	8 x 4 mL	0.10 - 300	0.2 - 517	≤ -65°C
P0099	Kenya	P0099 HIV-1 RNA subtype G (2)	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0051	Ghana	P0051 HIV-1 RNA CRF02_AG	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0100	Zaire	P0100 HIV-1 RNA subtype H	8 x 4 mL	0.1 - 300	0.2 - 517	≤ -65°C
P0354	2nd WHO 16/296	P0354 HIV-2 subtype A	7 x 4 mL^	0.24 - 237	0.3 - 300	≤ -65°C
P0298	BioQControl	P0298 HIV-2 RNA subtype A	8 x 4 mL	0.1 - 300	0.1 - 380	≤ -65°C
P0212	Belgium	P0212 HIV-2 RNA subtype B	8 x 4 mL	0.1 - 300	0.1 - 380	≤ -65°C
P0015	BioQControl	P0015 HIV RNA group O (1)	10 x 4 mL^	0.1 - 2580	0.1 - 4448	≤ -65°C
P0101	USA	P0101 HIV-RNA group O (2)	8 x 4 mL	0.46 - 1382	0.79 - 2383	≤ -65°C
P0102	Camaroon	P0102 HIV-RNA group O (3)	8 x 4 mL	0.40 - 1197	0.69 - 2064	≤ -65°C
P0103	Spain	P0103 HIV-RNA group O (4)	8 x 4 mL	0.43 - 1281	0.74 - 2209	≤ -65°C
P0104	Camaroon	P0104 HIV-RNA group O (5)	8 x 4 mL	0.41 - 1233	0.71 - 2125	≤ -65°C

§ 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



NON-ENVELOPED VIRUS STANDARD DILUTION PANELS

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 non-envelope 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.

The Roche DPX assay has not been recalibrated and was found to report significantly lower values on the 3rd WHO 12/208 standard. The VQC-Sanquin standard dilution panels can be used for quantification in IU values assigned to the 1st WHO 99/800 and 2nd WHO 99/802 standards, but not to the IU values assigned to the 3rd WHO 12/208 standard. The parvo B19V genotype 2 standard has been calibrated in IU/mL by Sanquin, but the original quantification of the HAV genotype 2a and 3a standards needs to be reassessed.

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

ARBOVIRUS STANDARD DILUTION PANELS

Recently a WNV Lineage 2 standard dilution panel has been developed that has been calibrated in copies/mL.

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

Cat. No	Source/Standard	Non envelope virus reference panel[$]	Quantity	range IU/mL	Storage Temp.	Kit Insert
Parvo B19V DNA reference panels						
P0143	VQC-Sanquin	P0143 parvo B19-DNA genotype 1 Quant	10 x 4 mL	30 - 1,000,000	≤ -65°C	KI4273
P0144	Sanquin	P0144 parvo B19-DNA genotype 2 Quant	8 x 4 mL	30 - 100,000	≤ -65°C	KI4273
HAV-RNA reference panels						
P0351	VQC-Sanquin	P0351 HAV genotype 1a	8 x 4 mL	0.01 - 30	≤ -65°C	KI4272
P0208	France	P0208 HAV-RNA genotype 2a	8 x 4 mL	0.1 - 300	≤ -65°C	KI4272
P0209	France	P0209 HAV-RNA genotype 3a	8 x 4 mL	0.1 - 300	≤ -65°C	KI4272
HEV-RNA reference panels						
P0274	Sanquin	P0274 HEV-RNA genotype 3	8 x 4 mL	0.1 - 300	≤ -65°C	KI4276
P0262	1st WHO 6329/10	P0262 HEV-RNA genotype 3	6 x 4 mL	0 - 90	≤ -65°C	KI4276

#made for IVD manufacturer, panel available on request
$ 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[$]	Quantity	range copies/mL	Storage Temp.	Kit Insert
WNV-RNA reference panel						
P0360	Italy	P0360 WNV-RNA Lineage 1		0.1 - 300	≤ -65°C	KI4297
P0346	Macedonia	P0346 WNV-RNA Lineage 2 inactivated		0.1 - 2000	≤ -65°C	KI4297

$ 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.

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[$]	Quantity	copies/mL	IU/mL	Genosubtypes	Storage Temp.	Kit Insert
HBV-DNA multiple 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	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	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	KI4141
HCV-RNA multiple 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	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	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	KI4142
HIV-RNA multiple 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	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	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	KI4140
HAV-RNA multiple genotype reference panel							
P0153	P0153 HAV genotype reference panel#	5 x 4 mL	100		1a, 1b, 2a, 3a	≤ -65°C	KI4153

$ Regulatory status: RUO = for research use only
# in development

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.	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	KI4296
P0344	P0344 ViraQ HCV Quant 1000	10 x 1.2 mL	1000	366	PEO#	≤65°C	KI4295
P0327	P0327 ViraQ HIV-1 Quant 1000	10 x 1.2 mL	1000	1724	PEO#	≤65°C	KI4292
P0146	P0146 ViraQ CMV Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	KI4146
P0147	P0147 ViraQ HSV-1 Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	KI4147
P0148	P0148 ViraQ HSV-2 Quant 10,000	10 x 1.2 mL	10,000		PEO#	≤30°C	KI4148

Available for performance evaluation studies only


Polymerase
cobas p 680

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[$]	Quantity	range copies/mL	range IU/mL	Storage Temp.	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	KI4036
P0042	VQC-Sanquin	P0042 HCV-RNA genotype 1 Quant	5 x 1.2 mL	500 - 250,000	183 - 91,575	≤ -65°C	KI4037
P0043	VQC-Sanquin	P0043 HIV-1 RNA subtype B Quant	7 x 1.2 mL	50 - 250,000	86 - 431,034	≤ -65°C	KI4038
P0319	VQC-Sanquin	P0319 HIV-2 RNA subtype A Quant	5 x 1.2 mL	10 - 100,000		≤ -65°C	KI4283
P0044	DDL	P0044 CMV-DNA Quant	7 x 1.2 mL	100 - 100,000	*	≤ -65°C	KI4039

$ Regulatory status: RUO = for research use only *calibration on WHO international standard not yet performed