Pre-evaluation of the EQA Schemes in Virus Diagnostics March 2016

DAkkS
Deutsche
Akkreditierungsstelle
D-EP-15027-02-00

INSTAND e.V.

in cooperation with:

Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV)
Gesellschaft für Virologie e.V. (GfV)
Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (DGHM)

Prof. Dr. Heinz Zeichhardt

Priv.-Doz. Dr. Oliver Donoso Mantke

Issued by:

INSTAND e.V.
Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V.

Düsseldorf/Berlin, 03.05.2016

EQAS Adviser:
Prof. Dr. Heinz Zeichhardt
Professor of Virology (retired)
Charité - University Medicine Berlin
Campus Benjamin Franklin - Institute of Virology
Email: Heinz.Zeichhardt@charite.de

Correspondence address:
Prof. Dr. Heinz Zeichhardt
Institut für Qualitätssicherung in der Virusdiagnostik - IQVD
Potsdamer Chaussee 80, D-14129 Berlin, Germany
Tel.: +49-(0)30-81054-300; Fax: +49-(0)30-81054-303
Email: Heinz.Zeichhardt@iqvd.de

Assistant EQAS Adviser:
Priv.-Doz. Dr. Oliver Donoso Mantke
c/o INSTAND e.V.
Ubierstr. 20, D-40223 Düsseldorf, Germany
Tel.: +49-(0)30-81054-305; Fax: +49-(0)30-81054-303
Email: donoso@instand-ev.de

Organisation and Logistics:

INSTAND e.V.
Ubierstr. 20
D-40223 Düsseldorf, Germany
Tel.: +49 (0)211 - 1592 13 0
Fax: +49 (0)211 - 1592 1330
Email: instand@instand-ev.de
Internet: www.instand-ev.de

Pre-Evaluation
and
Mailing of Participation Documents

INSTAND External Quality Assessment Schemes – March 2016

Virus Immunology
Virus Genome Detection by PCR/NAT

Dear colleagues,

You have participated in one or several of the INSTAND external quality assessment (EQA) schemes in virus diagnostics of March 2016. Today you receive the **pre-evaluation.**

By mail, you receive the following **participation documents** of those EQA schemes in which you have participated this time:

- certificate of successful participation
- statement of participation
- statement of individual results

The **EQA schemes** having been performed in March 2016 are **highlighted in bold** in Tables 1 and 2. For these highlighted EQA schemes, the corresponding participation documents will be sent out by mail together with this pre-evaluation.

Please note:
The participation documents of the following EQA schemes will be sent out later by mail:

- Cytomegalovirus training program (368)
- Hepatitis B virus training program (378)
- Hepatitis C virus training program (379)
- HIV-1 (RNA) training program (382)
- Special EQA program in accordance with the RKI-entero surveillance programm - virus detection - Enterovirus - PCR / Cultivation and Typing (374)

Table 1: EQA schemes performed with a frequency of four times per year	
VIRUS IMMUNOLOGY:	VIRUS GENOME DETECTION:
Cytomegalovirus (351) **Hepatitis A virus (343)** **Hepatitis B virus Prog. 1 (344)** **Hepatitis B virus Prog. 2 (345)** **Hepatitis C virus (346)** **HIV-1/HIV-2 (335)** **HIV-1 p24 Ag (337)**	**Cytomegalovirus (365)** **Hepatitis A virus (377)** **Hepatitis B virus (361)** **Hepatitis C virus (362)** **HIV-1 (RNA) (360)** **Parvovirus B19 (367)**

The EQA schemes having been performed in March 2016 are highlighted in bold (Table 1). For these highlighted EQA schemes, the corresponding participation documents will be sent out by mail together with this pre-evaluation.

Table 2: EQA schemes performed twice per year or with lower frequency (EQA schemes having been performed in March 2016 are highlighted in bold)	
VIRUS IMMUNOLOGY:	VIRUS GENOME DETECTION:
Chikungunya virus (402) **Dengue viruses (Ab/NS1-Ag) (350)** *Epstein Barr virus (352)* *TBE (FSME) virus (358)* **Hantaviruses (355)** *Hepatitis D virus (347)* *Hepatitis E virus (348)* *Herpes simplex viruses (354)* *HTLV-1/HTLV-2 (339)* *Measles virus (357)* *Mumps virus (356)* *Parvovirus B19 (342)* *Rubella virus (341)* *Rabies (Tollwut) virus (336)* *Varicella zoster virus (353)* *Zika virus (338)*	*Adenoviruses (371)* **BK virus (364)** **Chikungunya virus (392)** *Coronaviruses (340)* **Cytomegalovirus training program (368)** *Cytomegalovirus resistance determination (349)* **Dengue viruses (369)** *Enteroviruses (372)* **RKI-Entero-Surveillance (every two years) (374)** *Epstein Barr virus (376)* **Hepatitis B virus training program (378)** *Hepatitis B virus genotyping (396)* *Hepatitis B virus resistance determination (397)* **Hepatitis C virus training program (379)** *Hepatitis C virus geno-/subtyping (375)* *Hepatitis C virus resistance determination (399)* **Hepatitis D virus (400)** *Hepatitis E virus (380)* *Herpes simplex virus type 1/2 (363)* **HIV-1 (RNA) training program (382)** *HIV-1 drug resistance determ. (standard progr.) (383)* *HIV-1 drug resistance determ. (additional progr.) (384)* *HIV-2 (RNA) (395)* *Human Metapneumovirus (385)* *Human Papilloma viruses (373)* *Human Rhinoviruses (393)* **Influenza viruses (genome/Ag) (370)** **JC virus (394)** *Measles virus (386)* *Mumps virus (387)* **Norovirus (381)** **Parainfluenza viruses (388)** *Respiratory syncytial virus (Ag/genome) (359)* *Rotaviruses (401)* *Rubella virus (389)* *Rabies (Tollwut) virus (390)* *Varicella zoster virus (366)* **West Nile virus (391)** *Zika virus (403)*

The EQA schemes having been performed in March 2016 are highlighted in bold (Table 2). For these highlighted EQA schemes, the corresponding participation documents will be sent out by mail together with this pre-evaluation.

Please note:
The participation documents of the following EQA schemes will be sent out later by mail:

- Cytomegalovirus training program (368)
- Hepatitis B virus training program (378)
- Hepatitis C virus training program (379)
- HIV-1 (RNA) training program (382)
- Special EQA program in accordance with the RKI-entero surveillance programm - virus detection - Enterovirus - PCR / Cultivation and Typing (374)

EQA schemes in Table 2 marked in italics were not performed in March 2016.

Please see the following Tables 3, 4 and 5 for details on sample properties and the expected target values for this EQA scheme March 2016. You received information on sample properties already per email on 25.04.2016.

The reports of all EQA schemes will be released on the INSTAND homepage immediately after completion. For details please see the INSTAND homepage under
"EQAS / Reports / Year and Category (Virus immunology / Virus genome detection)"
in English language: http://www.instandev.de/en/eqas/reports/ and
in German language: http://www.instandev.de/ringversuche/kommentare/.

Please note:

- **RiliBÄK**
  A compilation of the "Guidelines of the German Medical Association on quality assurance in medical laboratory testing (Bundesärztekammer / RiliBÄK = Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen)" with all Sections including Section B 2 "Qualitative medical laboratory testing = Qualitative laboratoriumsmedizinische Untersuchungen" and Section B 3 "Direct detection and characterisation of infectious agents = Direkter Nachweis und Charakterisierung von Infektionserregern" has recently been published (in German language: Deutsches Ärzteblatt, Jg. 111, Heft 38, 19. September 2014, A 1583 - A 1618) (please see link). PDF

  An English version of the guideline translated by INSTAND e.V. with the consent of the Executive Board of the German Medical Association has been published in "German Medical Science" (in English language: Bundesärztekammer (German Medical Association), Instand e.V., Guidelines of the German Medical Association on quality assurance in medical laboratory testing. GMS Z Forder Qualitatssich Med Lab. 2015;6:Doc03. DOI: 10.3205/lab000018, URN: urn:nbn:de:0183-lab0000182) (please see link). PDF

  Notice for German laboratories:
  The requirements laid down in Specified Section B 3 - effective since 01.04.2013 and with a transition period until 31.05.2015 - should now be fulfilled.

- **INSTAND EQA schemes in virus diagnostics and INSTAND ordering documents 2016**
  For details please see the INSTAND ordering documents 2016 incl. brochure and order form (please see link). PDF

- **Additional training programs in virus genome detection**
  Additional training programs were provided for the fifth time with the EQAS term March 2016.

Cytomegalovirus (368)	Hepatitis B virus (378)	Hepatitis C virus (379)	HIV-1 (RNA) (382)

  Please note:
  Additional training programs for virus genome detection of CMV, HBV, HCV and HIV-1 (RNA), respectively, containing low virus concentrations, are offered once only in March. The integration of the previous EQA scheme terms (March and September) will make it possible to evaluate a larger number of analyses with improved statistics.
  A training program contains low-concentration samples for each of the viruses to verify test sensitivities. The low-concentration samples are used as a complement to the respective main EQA scheme and contain samples with virus concentrations within the requirements of the new Guidelines of the German Medical Association on quality assurance in medical laboratory testing (Bundesärztekammer/RiliBÄK = Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen) as specified in Table B 3-2a of the RiliBÄK.

  Please note: A training program can only be ordered together with the corresponding main EQA scheme in March 2017.

  Separate certificates will be issued for each main EQA scheme (subject to RiliBÄK-B 3) and training program.

Surplus samples of the current and previous EQA schemes in virus diagnostics are available for test assessment of your virus diagnostics. Please contact INSTAND for details.

Thank you for your kind cooperation

Prof. Dr. H. Zeichhardt

Priv.-Doz. Dr. O. Donoso Mantke

Table 3: EQA Schemes Virus Immunology - March 2016
Pre-evaluation

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
Cyto-megalo-virus (Ab) serum	351	*conform to B 2*	anti-CMV-IgG anti-CMV-IgM	351047	positive avidity: high negative		past CMV infection (two healthy blood donors)
			anti-CMV-IgG anti-CMV-IgM	351048	positive avidity: high negative		past CMV infection (two healthy blood donors)
Dengue-viruses* (Ab and NS1-Ag) serum	350*	*conform to B 2*	anti-Dengue-IgG anti-Dengue-IgM Dengue NS1-Ag	350046	positive positive positive	1 : 2	Patient D12 with an **acute** primary dengue virus infection (DENV-1), negative for dengue virus RNA; traveller returned from South Thailand, blood collected **8 days after onset of disease**
			anti-Dengue-IgG anti-Dengue-IgM Dengue NS1-Ag	350047	negative negative positive	1 : 14	Dengue virus serum D21, representing an **acute** primary dengue virus infection **positive for NS1-Ag only:** serum of a healthy blood donor without signs of an acute or past dengue virus infection spiked with a cell culture propagated virus (DENV-2; heat inactivated)
			anti-Dengue-IgG anti-Dengue-IgM Dengue NS1-Ag	350048	positive negative negative	1 : 1.08	Pool of sera from one and the same patient D22 with a **past** primary dengue virus infection (DENV-2), traveller returned from Zanzibar, blood collected **4 - 18 months after onset of disease**
			anti-Dengue-IgG anti-Dengue-IgM Dengue NS1-Ag	350049	positive positive negative	1 : 1.56	Pool of sera from one and the same patient D23 with a **recent** primary dengue virus infection (DENV-2), traveller returned from Thailand, blood collected **3 - 4 weeks after onset of disease**

Non-marked samples derive from independent preparations.

* The EQA program Dengue viruses (350) is performed in cooperation with Bernhard-Nocht-Institut, Hamburg (Nationales Referenzzentrum für tropische Infektionserreger und WHO Collaborating Centre for Arbovirus and Haemorrhagic Fever Reference and Research; Prof. Dr. Stephan Günther, Prof. Dr. Dr. Jonas Schmidt-Chanasit and Dr. Petra Emmerich).

Table 3 (contd.): EQA Schemes Virus Immunology - March 2016
Pre-evaluation

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
Hanta-viruses* (Ab) serum	355*	*conform to B 2*	anti-Dobrava-IgG anti-Dobrava-IgM	355045	positive negative	1 : 3	Patient H13 with a **past Dobrava-Belgrade virus infection, probably acquired in Brandenburg, Germany,** anamnesis concerning a stay abroad outside Europe excluded at onset of disease hospitalization necessary, characteristic symptoms such as elevated creatinine, flu-like symptoms and abnormal fatigue blood collected **approx. 3 years and 7 month after onset of disease** diluted with sera from healthy blood donors (pool)
			anti-Dobrava-IgG anti-Dobrava-IgM	355046	positive positive	1 : 2	Patient H20 with an **acute Dobrava-Belgrade virus infection, acquired in Brandenburg, Germany**, anamnesis concerning a stay abroad outside Europe excluded at onset of disease hospitalization necessary, characteristic flu-like symptoms with fever and in addition acute renal failure blood collected **approx. 3 weeks after onset of disease (serum is negative for Hantavirus RNA)** diluted with sera from healthy blood donors (pool)
			anti-Puumala-IgG anti-Puumala-IgM	355047	positive negative/ low positive *detection of IgM 4 weeks after onset of disease possible*	1 : 2	Patient H11 with a **past Puumala virus infection acquired in North Rhine Westphalia, Germany**, anamnesis concerning a stay abroad outside Europe excluded at onset of disease hospitalization necessary, characteristic flu-like symptoms with fever blood collected **approx. 4 weeks after onset of disease** diluted with sera from healthy blood donors (pool)
			anti-Hanta-IgG anti-Hanta-IgM	355048	negative negative		Serum of healthy blood donors (pool) without signs of an acute or past hanta virus infection

Non-marked samples derive from independent preparations.

* The EQA program Hantaviruses (355) is performed in cooperation with Nationalen Konsiliarlaboratorium für Hantaviren (Charité - Universitätsmedizin Berlin, Campus Mitte, Institut für Medizinische Virologie, Labor Berlin-Charité Vivantes GmbH, Prof. Dr. D. H. Krüger, Prof. Dr. J. Hofmann).

Table 3 (contd.): EQA Schemes Virus Immunology - March 2016
Pre-evaluation

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
Hepatitis A virus (Ab) serum	343	mandatory: B 2	anti-HAV	343093	positive ≥ 50 mIU/ml *(60 mIU/ml)**	(a) 1 : 200	anti-HAV-IgG positive healthy blood donor
			anti-HAV	343094	positive ≥ 60 mIU/ml *(60 mIU/ml)**	(a) 1 : 100	
			anti-HAV-IgM	343095	positive	1 : 20	acute hepatitis A infection
			anti-HAV-IgM	343096	positive	1 : 25	acute hepatitis A infection
Hepatitis B virus (prog. 1) (HBsAg anti-HBs anti-HBc) serum	344	mandatory: B 3	HBsAg	344277	negative 0.00 – 0.05 IU/ml (0.00 IU/ml Sollwert)		negative healthy blood donors (pool)
			HBsAg	344278	positive 3.30 – 7.20 IU/ml (4.67 IU/ml Sollwert)	(b) 1 : 3 000	chronic hepatitis B
			HBsAg	344279	positive 9.90 – 21.60 IU/ml (13.63 IU/ml Sollwert)	(b) 1 : 1 000	
			HBsAg	344280	positive 1.10 – 2.40 IU/ml (1.61 IU/ml Sollwert)	(b) 1 : 9 000	
		mandatory: B 2	anti-HBs	344281	positive 60 – 320 IU/l (140 IU/l Sollwert)	(c) 1 : 1 250	anti-HBs positive healthy blood donor
			anti-HBs	344282	negative 0 – 9 IU/l (0 IU/l Sollwert)		negative healthy blood donors (pool)
			anti-HBs	344283	positive 30 – 160 IU/l (71 IU/l Sollwert)	(c) 1 : 2 500	anti-HBs positive healthy blood donor
			anti-HBs	344284	positive 15 – 80 IU/l (36 IU/l Sollwert)	(c) 1 : 5 000	
		mandatory: B 2	anti-HBc	344285	positive	(d) 1 : 300	chronic hepatitis B (negative for HBeAg)
			anti-HBc	344286	positive	(d) 1 : 600	
			anti-HBc	344287	positive	(d) 1 : 150	
			anti-HBc	344288	negative		negative healthy blood donors (pool)
Hepatitis B virus (prog. 2) (anti-HBc-IgM HBeAg anti-HBe) serum	345	mandatory: B 2	anti-HBc-IgM	345139	positive	1 : 55	acute hepatitis B infection
			anti-HBc-IgM	345140	negative		negative healthy blood donors (pool)
		mandatory: B 3	HBeAg	345141	positive	(e) 1 : 350	chronic hepatitis B
			HBeAg	345142	positive	(e) 1 : 700	
		mandatory: B 2	anti-HBe	345143	positive	(f) 1 : 80	chronic hepatitis B (negative for HBeAg)
			anti-HBe	345144	positive	(f) 1 : 40	

a, b, c, d, e, f: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

* For highly concentrated samples some commercial tests for the detection of **anti-HAV-IgG** or **anti-HAV-total** reveal values > 60 mIU/ml, which are outside the linear measurement range of the respective test system. Therefore a final target value derived from a consensus value from all results stated in mIU/ml could not be assigned to highly concentrated samples. In this case a lower limit value in mIU/ml is indicated in order to assess a reported result of a laboratory as a "correct" result.

Table 3 (contd.): EQA Schemes Virus Immunology - March 2016
Pre-evaluation

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
Hepatitis C virus (Ab and HCV-Ag) serum* plasma**	346	anti-HCV **mandatory: B 2** HCV Ag **mandatory: B 3**	anti-HCV HCV antigen	346093*	positive negative	1 : 7.1	Condition after chronic hepatitis C (subtype 1b; successful therapy)
			anti-HCV HCV antigen	346094**	positive positive	1 : 50	chronic hepatitis C (subtype 1b)
			anti-HCV HCV antigen	346095*	negative negative		negative healthy blood donors (pool)
			anti-HCV HCV antigen	346096**	positive positive	1 : 10	chronic hepatitis C (subtype 3a)
HIV-1/ HIV-2 (Ab) serum	335	**mandatory: B 2**	anti-HIV-1	335093	positive	(g) 1 : 80	HIV-1 infection
			anti-HIV-1/2	335094	negative		negative healthy blood donors (pool)
			anti-HIV-1	335095	positive	(g) 1 : 320	HIV-1 infection
			anti-HIV-1	335096	positive	(g) 1 : 160	
HIV-1 p24 Ag serum	337	**mandatory: B 3**	p24 Ag	337047	positive	(h) 1 : 76 000	HIV-1 infection (spiked serum pool of negative blood donors; HIV-1 heat inactivated)
			p24 Ag	337048	positive	(h) 1 : 19 000	

g, h: Marked samples represent dilutions from the corresponding stock materials.

Non-marked samples derive from independent preparations.

EQA Schemes Virus Genome Detection by PCR/NAT
March 2016

Pre-evaluation

Notices

Evaluation of results for quantitative genome detection of CMV

1) *Notice for German and foreign participants of EQA scheme 365:*
   For evaluation, "IU/ml" have primarily been considered as measurement units of the quantitative results for the analyte CMV. This is in accordance to the "Guideline of the German Medical Association (Bundesärztekammer / RiliBÄK)", Specified RiliBÄK Section B 3, Table B. 3-2a,

   When applying CE-marked tests, which not (yet) allow reporting of results in IU/mL, it should be continued to report the results as stated by the manufacturer.

Evaluation of results for quantitative genome detection of HBV and HCV

2) *Notice for German participants of EQA schemes 361 and 362:*
   For evaluation, "IU/ml" have been considered as measurement units of the quantitative results for the analytes HBV and HCV. This is in accordance to the "Guideline of the German Medical Association (Bundesärztekammer / RiliBÄK)", Specified RiliBÄK Section B 3, Table B. 3-2a.
   Statements in "copies/ml" will not be accepted anymore.

3) *Notice for foreign participants of EQA schemes 361 and 362:*
   Please note that quantitative results in "copies/ml" for the genome detection of HBV and HCV, respectively, have not been evaluated due to the low number of analyses or missing analyses.

Evaluation of results for quantitative genome detection of HIV-1 (RNA)

4) *Notice for German participants of EQA scheme 360:*
   For evaluation, "copies/ml" have been considered as measurement unit of the quantitative results for the analyte HIV-1 (RNA). This is in accordance to the "Guideline of the German Medical Association (Bundesärztekammer / RiliBÄK)", Specified RiliBÄK Section B 3, Table B. 3-2a.
   Statements in "IU/ml" will not be accepted anymore.

5) *Notice for foreign participants of EQA scheme 360:*
   Please note that quantitative results in "IU/ml" for the genome detection of HIV-1 (RNA) have not been evaluated due to the low number of analyses or missing analyses.

Table 4: EQA Schemes Virus Genome Detection by PCR/NAT
March 2016
Pre-evaluation

Program	Group	RiliBÄK	Sample	Sample properties				
				qualitative (note on geno-/*subtype*)	dilution		Target value of all methods (provisional data)	
							copies/ml	IU/ml
BK virus (DNA) suspension of urine	364	*conform to B 3*	364017	positive	(a)	1 : 1 000	approx. 1 763 372	-----
			364018	positive		1 : 1 000	approx. 312 550	-----
			364019	negative		1 : 100	0	-----
			364020	positive	(a)	1 : 100 000	approx. 14 007	-----
Chikungunya virus (RNA) cell lysates	392	*conform to B 3*	392009	positive	(b)	1 : 100 (inactivated)	*Quantitative results were not reported*	-----
			392010	positive		1 : 100 (inactivated)		-----
			392011	positive	(b)	1 : 1 000 (inactivated)		-----
			392012	negative		-----		-----
CMV (DNA) plasma	365	**manda-tory: B 3**					***For evaluation of results in copies/ml or IU/ml:*** *see notice 1, page 10*	
			365093	positive	(c)	1 : 1 000	approx. 28 125	approx. 45 345
			365094	positive	(c)	1 : 316	approx. 86 727	approx. 157 233
			365095	positive	(c, d)	1 : 3 162	approx. 8 872	approx. 17 148
			365096	positive	(c)	1 : 100	approx. 258 498	approx. 430 748
CMV (DNA) **training progr.** plasma	368	*conform to B 3*	368017	positive	(c)	1 : 10 000	approx. 2 970	approx. 5 233
			368018	positive	(c)	1 : 31 628	approx. 884	approx. 2 050
			368019	positive	(c)	1 : 100 000	approx. 155	approx. 511
			368020	positive	(c, d)	1 : 3 162	approx. 10 637	approx. 16 213
HAV (RNA) spiked plasma	377	**manda-tory: B 3**	377093	positive	(e)	1 : 20 000	not evaluated[#]	not evaluated[#]
			377094	positive	(e)	1 : 5 000	not evaluated[#]	not evaluated[#]
			377095	positive	(e)	1 : 1 250	not evaluated[#]	not evaluated[#]
			377096	positive	(e)	1 : 10 000	not evaluated[#]	not evaluated[#]
HBV (DNA) plasma	361	**manda-tory: B 3**	361093	positive	(f, g)	1 : 50 000	***Results in copies/ml: not accepted or not evaluated*** *(see notices 2 and 3, page 10)*	approx. 841
			361094	positive	(f)	1 : 400		approx. 101 814
			361095	negative		-----		0
			361096	positive	(f)	1 : 2 000		approx. 22 544
HBV (DNA) **training progr.** plasma	378	*conform to B 3*	378017	positive	(f)	1 : 250 000	***Results in copies/ml: not accepted or not evaluated*** *(see notices 2 and 3, page 10)*	approx.187
			378018	positive	(f, g)	1 : 50 000		approx.813
			378019	positive	(f)	1 : 1 250 000		approx.41
			378020	positive	(f)	1 : 6 250 000		approx.13
HCV (RNA) plasma	362	**manda-tory: B 3**	362093	positive (subtype 3a)	(h)	1 : 135	***Results in copies/ml: not accepted or not evaluated*** *(see notices 2 and 3, page 10)*	approx. 4 448
			362094	positive (subtype 3a)	(h)	1 : 45		approx. 11 847
			362095	positive (subtype 3a)	(h, i)	1 : 405		approx. 1 649
			362096	positive (subtype 3a)	(h)	1 : 15		approx. 34 863
HCV (RNA) **training progr.** plasma	379	*conform to B 3*	379017	positive (subtype 3a)	(h)	1 : 3 645	***Results in copies/ml: not accepted or not evaluated*** *(see notices 2 and 3, page 10)*	approx. 218
			379018	positive (subtype 3a)	(h)	1 : 10 935		approx. 71
			379019	positive (subtype 3a)	(h, i)	1 : 405		approx. 1 493
			379020	positive (subtype 3a)	(h)	1 : 32 805		approx. 33

[#] The quantitative results are not evaluated due to the low number of analysis (without disadvantage for the certificates).

a, b, c, e, f, h: Marked samples derive from corresponding stock materials diluted in consecutive steps.
Non-marked samples derive from independent preparations.

d, g, i,: Marked samples represent overlapping samples deployed in the respective main EQA scheme (mandatory according to RiliBÄK Section B 3 and the corresponding training program.

Table 4 (contd.): EQA Schemes Virus Genome Detection by PCR/NAT
March 2016
Pre-evaluation

Program	Group	RiliBÄK	Sample	Sample properties			
				qualitative (note on geno-/*subtype*)	dilution	Target value of all methods (provisional data)	
						copies/ml	IU/ml
HDV (DNA) plasma	400	*conform to B 3*	400009	negative	-----	not evaluated[#]	not evaluated[#]
			400010	positive	(j) 1 : 100	not evaluated[#]	not evaluated[#]
			400011	positive	(j) 1 : 1 000	not evaluated[#]	not evaluated[#]
			400012	positive	(j) 1 : 10	not evaluated[#]	not evaluated[#]
HIV-1 (RNA) spiked plasma	360	**manda-tory: B 3**	360093	positive (subtype B)	(k) 1 : 160 000	approx. 110 047	***Results in IU/ml: not accepted or not evaluated*** *(see notices 4 and 5, page 10)*
			360094	negative	-----	0	
			360095	positive (subtype B)	(k, l) 1 : 16 000 000	approx.1 502	
			360096	positive (subtype B)	(k) 1 : 1 600 000	approx. 13 775	
HIV-1 (RNA) **training progr.** spiked plasma	382	*conform to B 3*	382017	positive (subtype B)	(k) 1 : 505 964 426	approx. 55	***Results in IU/ml: not accepted or not evaluated*** *(see notices 4 and 5, page 10)*
			382018	positive (subtype B)	(k) 1 : 1 600 000 000	approx. 14	
			382019	positive (subtype B)	(k, l) 1 : 16 000 000	approx. 1 401	
			382020	positive (subtype B)	(k) 1 : 160 000 000	approx. 151	
JC virus (DNA) suspension of urine	394	*conform to B 3*	394009[&] = 394011	negative	1 : 1 000	0	-----
			394010	positive	1 : 92	approx. 35 252	-----
			394011[&] = 394009	negative	1 : 1 000	0	-----
			394012	positive	1 : 920	approx. 10 324	-----
Parvovirus B19 (DNA) plasma	367	**manda-tory: B 3**	367093	positive	(m) 1 : 300 000	approx. 57 188	approx. 63 464
			367094	negative	-----	0	0
			367095	positive	(m) 1 : 2 700 000	approx. 5 832	approx. 8 810
			367096	positive	(m) 1 : 900 000	approx. 20 571	approx. 25 866

[#] The quantitative results are not evaluated due to the low number of analysis (without disadvantage for the certificates).

j, k, m: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

l: Marked samples represent overlapping samples deployed in the respective main EQA scheme (mandatory according to RiliBÄK Section B 3 and the corresponding training program.

[&] The samples 394009 and 394011 are identical.

Table 5: EQA Schemes Virus Genome Detection by PCR/NAT incl. typing
March 2016
Pre-evaluation

Program	Group	RiliBÄK	Sample	Sample properties			
				qualitative	Target value of all methods copies/ml	species	type (note on dilution)
Dengue viruses (RNA) cell lysates	369	*conform to B 3*	369017	positive	*Quantitative results were not reported*	----	DENV-2 (inactivated) 1 : 50 diluted
			369018	positive		----	DENV-1 (inactivated) 1 : 25 diluted
			369019	negative		----	-----
			369020	positive		----	DENV-4 (inactivated) 1 : 10 diluted
Entero-viruses-PCR/ Cultivation and Typing suspension of feces	374	*according to RKI-Entero-Sur-veillance Progr.*	374013	positiv	-----	----	Poliovirus type 3 (Sabin) vaccine strain
			374014	positiv	-----	----	Coxsackievirus B3
			374015	positiv	-----	----	Coxsackievirus A4
			374016	positiv	-----	----	Poliovirus type 1 (Sabin) vaccine strain
			374017	positiv	-----	----	Echovirus 6
Norovirus (RNA) suspension of feces	381	*conform to B 3*	381025	negative	*not evaluated*[#]	----	1 : 200 diluted
			381026	positive	*not evaluated*[#]	----	genogroup I 1 : 740 diluted
			381027[$] = 381028	positive	*not evaluated*[#]	----	genogroup II 1 : 220 diluted
			381028[$] = 381027	positive	*not evaluated*[#]	----	genogroup II 1 : 220 diluted
Para-influenza viruses (RNA) cell lysates	388	*conform to B 3*	388017	positive	*not evaluated*[#]	----	PIV-3 1 : 1 000 diluted
			388018	negative	*not evaluated*[#]	----	-----
			388019	positive	*not evaluated*[#]	----	PIV-2 1 : 50 diluted (n)
			388020	positive	*not evaluated*[#]	----	PIV-2 1 : 500 diluted (n) *Virus type corrected to PIV-2*[§]
West Nile virus (RNA) cell lysates	391	*conform to B 3*	391023	positive	*not evaluated*[#]	----	WNV-2 (inactivated) 1 : 3 diluted (o)
			391024	positive	*not evaluated*[#]	----	WNV-1 (inactivated) 1 : 300 diluted (p)
			391025	positive	*not evaluated*[#]	----	WNV-1 (inactivated) 1 : 30 000 diluted (p)
			391026	positive	*not evaluated*[#]	----	WNV-2 (inactivated) 1 : 30 diluted (o)
			391027	positive	*not evaluated*[#]	----	WNV-2 (inactivated) 1 : 300 000 diluted
			391028	negative	*not evaluated*[#]	----	-----

* The Special EQA program in accordance with the RKI-entero surveillance programm - virus detection - Enterovirus - PCR / Cultivation and Typing (374) is performed in cooperation with Nationales Referenzzentrum für Poliomyelitis und Enteroviren, Regionales Referenzlabor der WHO/EURO für Poliomyelitis, Robert Koch-Institut, Berlin, Dr. Sabine Diedrich.

[#] The quantitative results are not evaluated due to the low number of analysis (without disadvantage for the certificates).

n, o, p: Marked samples derive from corresponding stock materials diluted in consecutive steps.

Non-marked samples derive from independent preparations.

[$] The samples 381027 and 381028 are identical.

[§] Sample 388020:
The virus type has been corrected to PIV-2 in respect to our "Information on sample properties" (released on 25 April 2016).

Table 5 (contd.): EQA Schemes Virus Genome Detection incl. Typing
March 2016
Pre-evaluation

Program	Group	RiliBÄK	Sample	Sample properties and results considered as "correct" (target values)		
				type/subtype	strain	origin
Influenza A- and B-viruses* inclusive influenza A(H1N1) pdm09 virus and avian influenza A virus (different subtypes) (genome/ antigen)	370*	**manda-tory:** **B 3**	370071	**positive** for seasonal influenza A(H3N2) virus	A/Switzerland/9715293/ 2013 (vaccine strain)	infected MDCK-cells (lysate) (1 : 200 diluted)
			370072	**negative**	-----	non-infected MDCK cells (lysate)
			370073	**positive** for seasonal influenza B virus	B/Phuket/3073/2013 (vaccine strain)	infected MDCK-cells (lysate) (1 : 100 diluted)
			370074	**positive** for avian Influenza A(H5N8) virus (accepted target value for rapid tests for the detection of influenza A virus antigen: positive / borderline)§	A/Turkey/Germany R2485+86/2014	allantoic fluid (inactivated) (1 : 160 diluted)
			370075	**positive** for seasonal influenza B virus	B/Brisbane/60/2008 (vaccine strain)	infected MDCK-cells (lysate) (1 : 17 diluted)
			370076	**positive** for Influenza A(H1N1) pdm09 virus (accepted target value for rapid tests for the detection of influenza A virus antigen: positive / borderline)§	A/California/7/2009/ (vaccine strain)	infected MDCK-cells (lysate) (1 : 150 diluted)

* The EQA program for influenza A and B viruses, incl. influenza A(H1N1) pdm09 virus and avian influenza A virus (different subtypes) (370), is performed in cooperation with Nationales Referenzzentrum für Influenza, Robert Koch-Institut, Berlin, Dr. Brunhilde Schweiger and Nationales Referenzlabor für Aviäre Influenza, Bundesforschungsinstitut für Tiergesundheit, Friedrich-Loeffler-Institut, Insel Riems, Prof. Dr. Timm C. Harder.

§ For samples 370074 and 370076, the reporting of "borderline" in test category 30 (Antigen detection of influenza A virus) was accepted as additional correct result for tests for antigen detection of influenza A virus (in general rapid tests). Considering also the result "borderline" ensured that these positive samples would not have been misinterpreted as negative.