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INSTAND

Summary of Sample Properties and Target Values of the External Quality Assessment Schemes in Virus Diagnostics

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INSTAND EQA schemes in virology

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INSTAND External Quality Assessment Schemes – November 2019

Virus Immunology
Virus Genome Detection by PCR/NAT

Dear colleagues,

You have registered for one or several of the INSTAND external quality assessment (EQA) schemes in virus diagnostics of November 2019. Today you receive information on the provision of your participation documents and the provision of the *summary of sample properties and target values*.

Since the EQAS term September 2019, your participation documents are available only online. Paper based documents are not sent by mail anymore.

1. Participation documents

With the "EQAS (RV) Online system", you have direct access to your individual participation documents for the corresponding EQA scheme via the button "Evaluation" after login on the INSTAND website https://rv-online.instandev.de/ .

For download are available:

- certificate (button "Certificate Download")
- certificate, certificate of participation, listing and evaluation of results (button "Evaluation Download")
- individual summary of results (button "General overview Download")

Please note:
The participation documents of the following EQA schemes for drug resistance determination will be provided at a later date:

- cytomegalovirus (349)
- hepatitis B virus (397)
- hepatitis C virus (399)
- HIV-1 standard program (383)
- HIV-1 additional program (384)

2. Summary of sample properties and target values

The summary of sample properties and target values is available:

- by email with a link to the document "Summary of sample properties and target values"

and

- on the INSTAND homepage under
  "EQAS Online / Service for EQA tests / EQA area (Virus immunology / Virus genome detection)"
  in English language: http://www.instand-ev.de/en/eqas-online/service-for-eqa-tests.html and
  in German language: http://www.instand-ev.de/ringversuche-online/ringversuche-service.html.

Please see the following Tables 1 - 5 for details on sample properties and the expected target values for this EQA scheme November 2019.

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 Online / Service for EQA tests / EQA area (Virus immunology / Virus genome detection)"
in English language: http://www.instand-ev.de/en/eqas-online/service-for-eqa-tests.html and
in German language: http://www.instand-ev.de/ringversuche-online/ringversuche-service.html.

Please note:

- **RiliBAEK**
  A compilation of the "Guidelines of the German Medical Association on quality assurance in medical laboratory testing (Bundesaerztekammer / RiliBAEK = Richtlinie der Bundesaerztekammer zur Qualitaetssicherung 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 been published (in German language: Deutsches Aerzteblatt, 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: Bundesaerztekammer (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] (please see link).

  PDF

- **INSTAND EQA schemes in virus diagnostics and INSTAND brochure 2020**

  PDF

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

Thank you for your kind cooperation.

Prof. Dr. Heinz Zeichhardt

Dr. Martin Kammel

Table 1: EQA Schemes Virus Immunology – November 2019
Summary of Sample Properties and Target Values

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	351077	positive avidity: high negative		past CMV infection (one healthy blood donor)
			anti-CMV IgG anti-CMV IgM	351078	negative avidity: no avidity / not done negative		negative healthy blood donors (pool)
Epstein Barr virus (Ab) serum	352	*conform to B 2*	anti-EBV IgG anti-EBV IgM[$]	352039[$]	*The accepted results will be shown in the report.*[$]		past EBV infection (two healthy blood donors)
			anti-EBV IgG anti-EBV IgM	352040			negative healthy blood donors (pool)
Tick-borne encephalitis virus (TBE = FSME)[#] (Ab) serum	358	*conform to B 2*	anti-TBE IgG anti-TBE IgM	358039	positive avidity: high negative		two healthy blood donors with indication of a past TBE virus infection/vaccination
			anti-TBE IgG anti-TBE IgM	358040	negative avidity: no avidity / not done negative		one negative healthy blood donor
Hepatitis A virus (Ab) serum	343	**manda-tory: B 2**	anti-HAV IgG / anti- HAV total	343153	negative		negative healthy blood donors (pool)
			anti-HAV IgG / anti- HAV total	343154	positive	1 : 400	anti-HAV IgG positive healthy blood donor
			anti-HAV IgM	343155	negative		negative healthy blood donors (pool)
			anti-HAV IgM	343156	positive	1 : 10	acute hepatitis A
Hepatitis B virus (prog. 1) (HBsAg anti-HBs anti-HBc) serum	344	**manda-tory: B 3**	HBsAg	344457	negative 0.00 – 0.08 IU/ml (0.00 IU/ml target value)		negative healthy blood donors (pool)
			HBsAg	344458	positive 3.80 - 6.50 IU/ml (4.78 IU/ml target value)	(a) 1 : 3 000	chronic hepatitis B
			HBsAg	344459	positive 1.90 – 3.25 IU/ml (2.41 IU/ml target value)	(a) 1 :6 000	
			HBsAg	344460	positive 7.60 - 13.0 IU/ml (9.53 IU/ml target value)	(a) 1 :1 500	
		manda-tory: B 2	anti-HBs	344461	positive 160 - 600 IU/l (370 IU/l target value)	(b) 1 : 500	anti-HBs positive healthy blood donor
			anti-HBs	344462	positive 20 - 75 IU/l (51.0 IU/l target value)	(b) 1 : 4 000	
			anti-HBs	344463	positive 80 - 300 IU/l (191 IU/l target value)	(b) 1 : 1 000	
			anti-HBs	344464	positive 40 - 150 IU/l (98.0 IU/l target value)	(b) 1 : 2 000	

Non-marked samples derive from independent preparations.

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

[$] Sample 352039 (negative for anti-EBV IgM): Some participants (13 of 15) reported unexpected positive results for this sample by using the test of one manufacturer (Viramed, EBV ViraStripe test kit IgM). These results have not been evaluated for this EQA scheme (without disadvantage for the certificate). The "Nationales Konsiliarlabor für Herpes-simplex-Virus (HSV) und Varizella-Zoster-Virus (VZV)" (Universitätsklinikum Freiburg) and the manufacturer have been informed. The Joint Diagnostic Council of DVV and GfV will consider this problem.

Table 1 (contd.): EQA Schemes Virus Immunology – November 2019
Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
Hepatitis B virus (prog. 1) (HBsAg anti-HBs anti-HBc) serum	344	**manda-tory: B 2**	anti-HBc	344465	positive	(c) 1 : 600	chronic hepatitis B (negative for HBeAg, negative for anti-HBc-IgM)
			anti-HBc	344466	positive	(c) 1 : 150	
			anti-HBc	344467	negative		negative healthy blood donors (pool)
			anti-HBc	344468	positive	(c) 1 : 300	chronic hepatitis B (negative for HBeAg, negative for anti-HBc-IgM)
Hepatitis B virus (prog. 2) (anti-HBc-IgM HBeAg anti-HBe) serum	345	**manda-tory: B 2**	anti-HBc IgM	345229	negative		negative healthy blood donors (pool)
			anti-HBc IgM	345230	positive	1 : 150	acute hepatitis B
		manda-tory: B 3	HBeAg	345231	positive	1 :700	chronic hepatitis B
			HBeAg	345232	negative		negative healthy blood donors (pool)
		manda-tory: B 2	anti-HBe	345233	negative		negative healthy blood donors (pool)
			anti-HBe	345234	positive	1 : 160	chronic hepatitis B (negative for HBeAg)
Hepatitis C virus (Ab and HCV-Ag) serum* plasma**	346	anti-HCV **manda-tory: B 2**	anti-HCV HCV antigen	346153**	positive positive	(d) 1 : 100	chronic hepatitis C (subtype 1b)
			anti-HCV HCV antigen	346154**	positive$ positive	(d) 1 : 200	
		HCV Ag **manda-tory: B 3**	anti-HCV HCV antigen	346155**	positive positive	(d) 1 : 50	
			anti-HCV HCV antigen	346156**	negative negative		negative healthy blood donors (pool)
Hepatitis D virus (Ab) serum	347	*conform to B 2*	anti-HDV IgG/ anti-HDV total anti-HDV IgM	347039	positive negative	1 : 3.750	chronic hepatitis D
			anti-HDV IgG/ anti-HDV total anti-HDV IgM	347040	negative negative		negative healthy blood donors (pool)
Hepatitis E virus (Ab) serum	348	*conform to B 2*	anti-HEV IgG anti-HEV IgM	348039	negative negative		negative healthy blood donor
			anti-HEV IgG anti-HEV IgM	348040	positive negative		past hepatitis E (one healthy blood donor)
Herpes simplex viruses (Ab) serum	354	*conform to B 2*	anti-HSV IgG anti-HSV IgM	354039	negative negative		negative healthy blood donor
			anti-HSV IgG anti-HSV IgM§	354040§	positive negative§		past HSV-1 infection (one healthy blood donor)

Non-marked samples derive from independent preparations.

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

$ Sample 346154: Accepted target values for complementary tests (parameter 20) are positive and indeterminate.

§ Sample 354040 (negative for anti-HSV 1 IgM): Some participants (6 of 7) reported unexpected positive and borderline results, respectively, for this sample by using the test of one manufacturer (Virotech Diagnostics GmbH, HSV 1 (gG1) ELISA IgM). These results have not been evaluated for this EQA scheme (without disadvantage for the certificate). The "Nationales Konsiliarlabor für Herpes-simplex-Virus (HSV) und Varizella-Zoster-Virus (VZV)" (Universitätsklinikum Freiburg) and the manufacturer have been informed. The Joint Diagnostic Council of DVV and GfV will consider this problem.

Table 1 (contd.): EQA Schemes Virus Immunology – November 2019
Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
HIV-1/ HIV-2 (Ab) serum	335	**manda-tory: B 2**	anti-HIV-1/2	335153	negative		negative healthy blood donors (pool)
			anti-HIV-1	335154	positive	(e) 1 : 150	HIV-1 infection
			anti-HIV-2	335155	positive	1 : 4	HIV-2 infection
			anti-HIV-1	335156	positive	(e) 1 : 75	HIV-1 infection
HIV-1 p24 Ag serum	337	**manda-tory: B 3**	p24 Ag	337077	positive	1 : 25 000	HIV-1 infection (spiked serum pool of negative blood donors; HIV-1 heat inactivated)
			p24 Ag	337078	negative		negative healthy blood donors (pool)
HTLV-1/ HTLV-2 (Ab) serum* plasma**	339	*conform to B 2*	anti-HTLV-1/2	339053*	negative		negative healthy blood donor
			anti-HTLV-2	339054**	positive	1 : 3	HTLV-2 infection
			anti-HTLV-2	339055**	positive	1 : 3	HTLV-2 infection
			anti-HTLV-1	339056*	positive	1 : 400	HTLV-1 infection
Measles virus (Ab) serum	357	*conform to B 2*	anti-measles IgG anti-measles IgM	357039	positive avidity: high negative		one healthy blood donor with indication of a past measles virus infection/vaccination
			anti-measles IgG anti-measles IgM	357040	positive avidity: high negative		one healthy blood donor with indication of a past measles virus infection/vaccination
Mumps virus (Ab) serum	356	*conform to B 2*	anti-mumps IgG anti-mumps IgM	356039	positive avidity: high negative		one healthy blood donor with indication of a past mumps virus infection/vaccination
			anti-mumps IgG[$] anti-mumps IgM	356040[$]	positive[$] avidity: high negative		one healthy blood donor with indication of a past mumps virus infection/vaccination
Parvovirus B19 (Ab) serum* plasma**	342	*conform to B 2*	anti-parvo B19 IgG anti-parvo B19 IgM	342077*	positive avidity: high negative		past parvo B19 infection (one healthy blood donor)
			anti-parvo B19 IgG anti-parvo B19 IgM	342078*	positive avidity: high negative		past parvo B19 infection (pool of healthy blood donors)
			anti-parvo B19 IgG anti-parvo B19 IgM	342079*	positive avidity: high negative		past parvo B19 infection (one healthy blood donor)
			anti-parvo B19 IgG anti-parvo B19 IgM	342080*	negative avidity: no avidity / not done negative		one negative healthy blood donor

Non-marked samples derive from independent preparations.

e: Marked samples derive from corresponding stock materials diluted in consecutive steps.

[$] Sample 356040 (positive for anti-mumps IgG): Some participants (14 of 16) reported unexpected negative results for this sample by using the test of one manufacturer (Virotech Diagnostics GmbH, Mumps ELISA IgG/IgM test). Unexpected negative results have already been observed in the EQA term June 2019 when this test was applied for an independent anti-mumps IgG positive sample. These discrepancies are known to the manufacturer and refer to lot numbers 199 and 200. These unexpected negative results have not been evaluated for this EQA scheme (without disadvantage for the certificate). The "Nationales Referenzzentrum für Masern, Mumps und Röteln" (Robert Koch-Institut, Berlin) has been informed. The Joint Diagnostic Council of DVV and GfV will consider this problem.

Table 1 (contd.): EQA Schemes Virus Immunology – November 2019
Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Analyte	Sample	Sample properties		
					qualitative	dilution	sample source
Rubella virus (Ab) serum	341	**manda-tory: B 2**	titer HI test	341039	8 – 128 (32 target value)		two healthy blood donors with indication of a past rubella virus infection or vaccination
			anti-rubella IgG		positive 15 – 200 IU/ml (46.2 IU/ml target value) avidity: high		
			anti-rubella IgM		negative		
			titer HI test	341040	8 – 128 (32 target value)		three healthy blood donors with indication of a past rubella virus infection or vaccination
			anti-rubella IgG		positive 25 – 350 IU/ml (60.1 IU/ml target value) avidity: high		
			anti-rubella IgM		negative		
Varicella zoster virus (Ab) serum	353	*conform to B 2*	anti-VZV IgG	353039	positive avidity: high		past VZV infection (two healthy blood donors)
			anti-VZV IgM		negative		
			anti-VZV IgG	353040	positive avidity: high		past VZV infection (two healthy blood donors)
			anti-VZV IgM		negative		

Non-marked samples derive from independent preparations.

EQA Schemes Virus Genome Detection by PCR/NAT
November 2019

Summary of Sample Properties and Target Values

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 (Bundesaerztekammer / RiliBAEK)", Specified RiliBAEK Section B 3, Table B. 3-2a,

When applying CE-marked tests, which not (yet) allow reporting of results in IU/ml, you should continue 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 (Bundesaerztekammer / RiliBAEK)", Specified RiliBAEK 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 (Bundesaerztekammer / RiliBAEK)", Specified RiliBAEK 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 2: EQA Schemes Virus Genome Detection – November 2019
Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties				
				qualitative (note on geno-/*subtype*)	dilution		Target value of all methods (provisional data)	
							copies/ml	IU/ml
CMV (DNA) spiked plasma	365	mandatory: B 3					*For evaluation of results in copies/ml or IU/ml: see notice 1, page 9*	
			365153	positive	(a)	1 : 250	920 654	1 030 421
			365154	negative		----	0	0
			365155	positive	(a)	1 : 6 250	41 016	42 167
			365156	positive	(a)	1 : 1 250	212 630	222 979
EBV (DNA) cell lysate	376	mandatory: B 3	376077	positive		1 : 150	10 304	12 625
			376078	positive	(b)	1 : 360	4 696	5 205
			376079	positive	(b)	1 : 40	36 072	43 811
			376080	negative		----	0	0
HAV (RNA) spiked plasma	377	mandatory: B 3	377153	positive	(c)	1 : 1 050	----	----#
			377154	positive	(c)	1 : 350	----	----#
			377155	negative		----	----	----#
			377156	positive	(c)	1 : 9 450	----	----#
HBV (DNA) plasma	361	mandatory: B 3	361153	positive	(d)	1 : 46 446	***Results in copies/ml: not accepted or not evaluated*** *(see notices 2 and 3, page 9)*	982
			361154	positive (genosubtype D1)		1 : 31 623		8 832
			361155	positive	(d)	1 : 14 687.5		2 907
			361156	negative		----		0
HCV (RNA) plasma	362	mandatory: B 3	362153	positive (genotype 3)	(e)	1 : 500	***Results in copies/ml: not accepted or not evaluated*** *(see notices 2 and 3, page 9)*	19 219
			362154	negative		----		0
			362155	positive (genotype 3)	(e)	1 : 50		213 908
			362156	positive (genotype 3)	(e)	1 : 5 000		2 133
HEV (RNA) spiked plasma* suspension of feces**	380	*conform to B 3*	380061**	positive		1 : 500	----#	641
			380062*	positive	(f)	1 : 60	----#	17 319
			380063*	negative		----	----#	0
			380064*	positive	(f)	1 : 6	----#	265 011
HIV-1 (RNA) spiked plasma	360	mandatory: B 3	360153	positive (group M / subtype B) (heat inactivated)	(g)	1 : 252 982	1 348	***Results in IU/ml: not accepted or not evaluated*** *(see notices 4 and 5, page 9)*
			360154	positive (group M / subtype F) (heat inactivated)		1 : 4 235	13 988	
			360155	negative		----	0	
			360156	positive (group M / subtype B) (heat inactivated)	(g)	1 : 80 000	4 106	

Non-marked samples derive from independent preparations.

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

A target value has not been assigned due to the limited number of quantitative analyses. An evaluation interval has instead been set for each of the corresponding positive samples by the EQA scheme adviser (ET), considering the results of the INSTAND Expert Laboratories. The evaluation interval is shown in "listing and evaluation of the results" and in the report.

Table 2 (contd.): EQA Schemes Virus Genome Detection – November 2019
Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties			
				qualitative (note on geno-/*subtype*)	dilution	Target value of all methods (provisional data)	
						copies/ml	IU/ml
HIV-2 (RNA) spiked plasma	395	*conform to B 3*	395041	positive strain: ROD10 (heat inactivated)	(h) 1 : 8 000	6 565	----#
			395042	positive strain: ROD10 (heat inactivated)	(h) 1 : 2 000	18 996	----#
			395043	negative	----	0	----#
			395044	positive strain: ROD10 (heat inactivated)	(h) 1 : 4 000	14 200	----#
HMPV (RNA) cell lysate	385	*conform to B 3*	385045	positive (type A)	(i) 1 : 750	----#	----
			385046	negative	----	----#	----
			385047	positive (type A)	(i) 1 : 3 000	----#	-
			385048	positive (type A)	(i) 1 : 1 500	----#	----
Parvovirus B19 (DNA) plasma	367	**mandatory: B 3**	367153	positive (genotype 1)	(k) 1 : 250 000	----#	80 737
			367154	negative	----	----#	0
			367155	positive (genotype 1)	(k) 1 : 79 000	----#	240 569
			367156	positive (genotype 1)	(k) 1 : 2 500 000	----#	8 243
Respiratory syncytial virus (antigen/ genome) cell lysate	359	**mandatory: B 3**	359057	positive RSV A	(l) 1 : 30	----#	-----
			359058	negative	----	----#	-----
			359059	positive* RSV B	1 : 60	----#	-----
			359060	positive RSV A	(l) 1 : 120	----#	-----
VZV (DNA) cell lysate	366	**mandatory: B 3**	366077	positive (genotype 3)	(m) 1 : 2 000	151 176	-----
			366078	positive (genotype 3)	(m) 1 : 200	1 513 556	-----
			366079	positive (genotype 3)	(m) 1 : 20 000	18 125	-----
			366080	negative	----	0	-----

Non-marked samples derive from independent preparations.

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

A target value has not been assigned due to the limited number of quantitative analyses. An evaluation interval has instead been set for each of the corresponding positive samples by the EQA scheme adviser (ET), considering the results of the INSTAND Expert Laboratories. The evaluation interval is shown in "listing and evaluation of the results" and in the report.

* For sample 359059 (1 : 60 diluted), the reporting of "borderline" in parameter 30 (RSV antigen) was accepted as additional correct result for rapid tests for antigen detection of RSV. Considering also the result "borderline" ensured that this positive sample would not have been misinterpreted as negative.

Table 3: EQA Schemes Virus Genome Detection incl. Typing
November 2019 - Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties			
				qualitative	type (species, if applicable)	dilution	Target value of all methods copies/ml
Adeno-viruses (DNA) cell lysate	371	**manda-tory: B 3**	371077	positive	adenovirus 37 (species D)	1 : 160 000	288 260
			371078	positive	adenovirus 11 (species B)	1 : 90 000	1 669 930
			371079	negative	----	----	0
			371080	positive	adenovirus 31 (species A)	1 : 5 000	3 842 058
Corona-viruses (RNA) cell lysate	340	*conform to B 3*	340053	positive	CoV 229E	1 : 1 000	----#
			340054	positive	MERS-CoV (inactivated)	(n) 1 : 20 000	----#
			340055	positive	CoV OC43	1 : 1 000	----#
			340056	positive	CoV NL63	1 : 10 000	----#
			340057	negative	----	----	----#
			340058	positive	MERS-CoV (inactivated)	(n) 1 : 2 000	----#
Entero-viruses (RNA) cell lysate	372	**manda-tory: B 3**	372078	positive	enterovirus D68	1 : 1 000	----#
			372079	positive	coxsackievirus B6	1 : 500	----#
			372080	positive	echovirus 7	1 : 250	----#
			372081	negative	----	----	----#
HBV-Geno-typing* plasma	396*	*conform to B 3*	396017	positive	genosubtype D3	1 : 4 900	----
			396018	positive	genosubtype B2	1 : 14 400	----
			396019	positive	genosubtype A2	1 : 12 000	----
			396020	positive	genosubtype A1	1 : 30 000	----
HSV-1/ HSV-2 (DNA) cell lysate	363	**manda-tory: B 3**	363115	positive	HSV-1	1 : 25 000	HSV-1: 37 699 HSV-2: 0
			363116	positive	HSV-2	(o) 1 : 187.5	HSV-1: 0 HSV-2: 150 708
			363117	positive	HSV-1	(p) 1 : 5 000	HSV-1: 185 880 HSV-2: 0
			363118	positive	HSV-1	(p) 1 : 20 000	HSV-1: 51 554 HSV-2: 0
			363119	positive	HSV-2	(o) 1 : 750	HSV-1: 0 HSV-2: 40 556
			363120	negative	----	----	HSV-1: 0 HSV-2: 0

Non-marked samples derive from independent preparations.

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

A target value has not been assigned due to the limited number of quantitative analyses. An evaluation interval has instead been set for each of the corresponding positive samples by the EQA scheme adviser (ET), considering the results of the INSTAND Expert Laboratories. The evaluation interval is shown in "listing and evaluation of the results" and in the report.

* The EQA program Virus Genome Detection - HBV-Genotyping (396) is performed in cooperation with Paul-Ehrlich-Institut (WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Abteilung Virologie, PD Dr. Micha Nübling, Dr. Michael Chudy, Dr. Sally A. Baylis und Dr. Julia Kreß)

Table 3 (contd.): EQA Schemes Virus Genome Detection incl. Typing November 2019 - Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties			
				qualitative	type (species, if applicable)	dilution	Target value of all methods copies/ml
Human papilloma viruses (DNA) biopsy* cell lysate**	373	**manda-tory: B 3**	373096*	positive	HPV 11 (Low Risk)	1 : 120	-----
			373097**	positive	HPV 18 (High Risk)	(q) 1 : 30	-----
			373098**	negative	----	----	-----
			373099**	positive	HPV 18 (High Risk)	(q) 1 : 15	-----
			373100**	positive	HPV 16 (High Risk)	1 : 12	-----
Human Rhinoviruses (RNA) cell lysate	393	*conform to B 3*	393037	positive	HRV A type 30	1 : 1 000	----#
			393038	positive	HRV A type 49	(r) 1 : 300	----#
			393039	negative	----	----	----#
			393040	positive	HRV A type 49	(r) 1 : 1 200	----#
Measles virus (RNA) FTA cards$	386	*conform to B 3*	386045	positive	genotype D8	----	----#
			386046	negative	----	----	----#
			386047	positive	genotype H1	----	----#
			386048	positive	genotype B3	----	----#
Mumps virus (RNA) FTA cards$	387	*conform to B 3*	387041	positive	genotype G	----	----
			387042	positive	genotype C	----	----
			387043	positive	genotype H	----	----
			387044	negative	----	----	----
Norovirus (RNA) suspension of feces	381	*conform to B 3*	381054	positive	genogroup II	1 : 500	----#
			381055	positive	genogroup II	1 : 500	----#
			381056	negative	----	1 : 20	----#
			381057	positive	genogroup II	1 : 500	----#

Non-marked samples derive from independent preparations.

q, r: Marked samples derive from corresponding stock materials diluted in consecutive steps.

A target value has not been assigned due to the limited number of quantitative analyses. An evaluation interval has instead been set for each of the corresponding positive samples by the EQA scheme adviser (ET), considering the results of the INSTAND Expert Laboratories. The evaluation interval is shown in "listing and evaluation of the results" and in the report.

$ Infectious viruses are chemically inactivated on the sample disk (FTA card).
(see also *B. Bankamp et al., Journal of Clinical Virology 58 (2013) 176– 182*)

Table 3 (contd.): EQA Schemes Virus Genome Detection incl. Typing November 2019 - Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties			
				qualitative	type (species, if applicable)	dilution	Target value of all methods copies/ml
Rotaviruses (RNA) suspension of feces	401	*conform to B 3*	401037	positive	G2P[4]	1 : 700	----[#]
			401038	positive	G1P[8]	1 : 5 500	----[#]
			401039	positive	G3P[8]	1 : 2 000	----[#]
			401040	negative	----	----	----[#]
Rubella virus (RNA) FTA cards[$]	389	*conform to B 3*	389041	positive	genotype 1E	----	----
			389042	positive	genotype 1A	----	----
			389043	negative	----	----	----
			389044	positive	genotype 1J	----	----
West Nile virus[&] (RNA) plasma	391[&]	*conform to B 3*	391077	positive	WNV-1 (inactivated)	(s) 1 : 3 000	----[#]
			391078	negative	----	----	----[#]
			391079	positive	WNV-1 (inactivated)	(s) 1 : 750	----[#]
			391080	positive	WNV-2 (inactivated)	(t) 1 : 3 000	----[#]
			391081	positive	WNV-2 (inactivated)	(t) 1 : 27 000	----[#]
			391082	positive	WNV-1 (inactivated)	(s) 1 : 12 000	----[#]

Non-marked samples derive from independent preparations.

s, t: Marked samples derive from corresponding stock materials diluted in consecutive steps.

[&] The EQA program Virus Genome Detection – West Nile Virus (391) is performed in cooperation with Bernhard-Nocht-Institut, Hamburg (Nationales Referenzzentrum für tropische Infektionserreger, Abteilung für Virologie 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).

[#] A target value has not been assigned due to the limited number of quantitative analyses. An evaluation interval has instead been set for each of the corresponding positive samples by the EQA scheme adviser (ET), considering the results of the INSTAND Expert Laboratories. The evaluation interval is shown in "listing and evaluation of the results" and in the report.

[$] Infectious viruses are chemically inactivated on the sample disk (FTA card).
(see also *B. Bankamp et al., Journal of Clinical Virology 58 (2013) 176– 182*)

Table 3 (contd.): EQA Schemes Virus Genome Detection incl. Typing November 2019 - Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties and results considered as "correct" (target values)		
				type/subtype	type/subtype	origin
Influenza A-und B-viruses* inclusive influenza A(H1N1) pdm09 virus and avian influenza A virus (different subtypes) (genome/ antigen)	370*	**manda-tory:** **B 3**	370113	**positive** for seasonal influenza A(H1N1)pdm09 virus	A/Brisbane/02/2018 (H1N1)pdm09-like (vaccine strain)	infected MDCK-cells (lysate) (1 : 100 diluted)
			370114	**positive** for seasonal influenza B virus	B/Phuket/3073/2013-like (B/Yamagata-line) (vaccine strain)	infected MDCK-cells (lysate) (1 : 100 diluted)
			370115	negative	----	not-infected MDCK cells (lysate)
			370116	**positive** for avian influenza A(H5N1) virus	A/Whooper Swan/R65/2006 (H5N1)	allantoic fluid (inactivated) (1 : 300 diluted)
			370117	**positive** for seasonal influenza B virus	B/Colorado/06/2017-like (B/Victoria-line) (vaccine strain)	infected MDCK-cells (lysate) (1 : 60 diluted)
			370118	**positive** for seasonal influenza A(H3N2) virus	A/Kansas/14/2017 (H3N2)-like (vaccine strain)	infected MDCK-cells (lysate) (1 : 200 diluted)

Non-marked samples derive from independent preparations.

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

EQA Schemes Virus Genome Detection of Multiplex Tests
November 2019 - Summary of Sample Properties and Target Values

The aim of the EQA schemes listed in Table 4 is the co-detection of various pathogens using multiplex tests.

For this EQA term, the certification was based on the correct positive or negative virus detection considering:
- results in regard to the expected performance requirement(s) of the applied multiplex test,
- results of more than one multiplex test.

We did not consider for certification:
- results of "singleplex" tests.

Please note for the multiplex EQA schemes in Table 4 that these EQA schemes are not suitable for:
- "singleplex" tests,
- tests for antigen detection,
- testing of method linearity,
- virus typing.

For this purpose, we refer to the INSTAND EQA schemes for the corresponding viruses.

Table 4: EQA Schemes Virus Genome Detection of Multiplex Tests - November 2019 Summary of Sample Properties and Target Values

Program	Group	RiliBÄK	Sample	Sample properties			
				quali-tative	contained pathogens with corresponding dilution		
Gastro-intestinal Virus Panel for Multiplex Tests cell lysates and suspension of feces, resp.	430	*conform to B 3*	430004	positive	**sapovirus** 1 : 10 dil.	----	----
			430005	positive	**adenovirus 41** 1 : 3 000 dil.	**coxsackievirus B3** 1 : 700 dil.	**norovirus GG II** 1 : 500 dil.
			430006	negative	----	----	---
			The sample set was negative for: astroviruses, parechoviruses and rotaviruses				
Respiratory Virus Panel 1 for Multiplex Tests cell lysates	431	*conform to B 3*	431005	positive	**adenovirus C2** 1 : 2 000 dil.	**enterovirus D68** 1 : 6 000 dil.	**influenza A virus (H1N1)pdm09** (A/Brisbane/02/2018 (H1N1)pdm09-like) 1 : 2 000 dil.
			431006	positive	**influenza B virus** (B/Phuket/3073/2013-like (B/Yamagata-line)) 1 : 5 000 dil.	**RSV B** 1 : 40 dil.	---
			431007	positive	**human bocavirus** 1 : 1 222 dil.	---	---
			431008	positive	**coronavirus 229E** 1 : 2 000 dil.	**human rhinovirus A30** 1 : 200 dil.	**parechovirus 3** 1 : 100 dil.
			The sample set was negative for: human metapneumoviruses and parainfluenza viruses				
Respiratory Virus Panel 2 for Multiplex Tests cell lysates	432	*conform to B 3*	432005	positive	**influenza A virus (H3N2)** (A/Kansas/14/2017 (H3N2)-like) 1 : 1 000 dil.	---	---
			432006	negative	---	---	---
			432007	positive	**influenza B virus** (B/Phuket/3073/2013-like (B/Yamagata-line)) 1 : 5 000 dil.	**RSV B** 1 : 40 dil.	---
			432008	positive	**influenza A virus (H1N1)pdm09** (A/Brisbane/02/2018 (H1N1)pdm09-like) 1 : 2 000 dil.	**RSV A/ON1** 1 : 1 000 dil.	---

Non-marked samples derive from independent preparations.

Table 5: EQA Schemes Virus Genome Detection for Drug Resistance Determination November / December 2019 - Evaluation

Program	Group	RiliBÄK	Sample	Sample properties and results considered as "correct" (target values)
CMV drug resistance plasma	349[a)]	*conform to B 3*	349017	The EQA scheme (349) has been closed and is currently under evaluation. The target values will be specified in a separate evaluation. You will be notified by email.
			349018	
			349019	
			349020	
HBV drug resistance plasmid	397[b)]	*conform to B 3*	397017	The EQA scheme (397) has been closed and is currently under evaluation. The target values will be specified in a separate evaluation. You will be notified by email.
			397018	
			397019	
			397020	
HCV drug resistance serum	399[c)]	*conform to B 3*	399018	The EQA scheme (399) has been closed and is currently under evaluation. The target values will be specified in a separate evaluation. You will be notified by email.
			399019	
			399020	
			399021	
HIV-1 drug resistance standard program plasma* plasmid**	383[d)]	*conform to B 3*	383023*	The EQA scheme (383) has been closed and is currently under evaluation. The target values will be specified in a separate evaluation. You will be notified by email.
			383024*	
			383025*	
			383026**	
HIV-1 drug resistance additional program plasma	384[d)]	*conform to B 3*	384013	The EQA scheme (384) has been closed and is currently under evaluation. The target values will be specified in a separate evaluation. You will be notified by email.
			384014	

The above mentioned EQA schemes are performed in cooperation with:

a) CMV drug resistance (349)
Nationales Konsiliarlaboratorium für Cytomegalievirus (CMV) - (Schwerpunkt) CMV-Infektionen bei immunsupprimierten Personen
Universitätsklinikum Ulm, Institut für Virologie: Prof. Dr. Thomas Stamminger, Prof. Dr. Detlef Michel
Nationales Konsiliarlaboratorium für Cytomegalievirus (CMV) - (Schwerpunkt) kongenitale/postnatale CMV-Infektionen
Universitätsklinikum Tübingen, Institut für Medizinische Virologie: Prof. Dr. Thomas Iftner, Prof. Dr. Klaus Hamprecht

b) HBV drug resistance (397)
Nationales Referenzzentrum für Hepatitis-B-Virus und Hepatitis-D-Virus
Justus-Liebig-Universität Gießen, Institut für Medizinische Virologie:
Prof. Dr. Dieter Glebe, Dr. Christian Schüttler, Dr. Heiko Slanina, M. Sc. Felix Lehmann, Prof. Dr. Wolfram Gerlich,
Prof. Dr. John Ziebuhr

c) HCV drug resistance (399)
Nationales Referenzzentrum für Hepatitis-C-Viren, Universitätsklinikum Essen, Institut für Virologie:
Prof. Dr. Ulf Dittmer, Prof. Dr. Stefan Ross
Universitätsklinikum Düsseldorf, Institut für Virologie:
Prof. Dr. Jörg Timm, Prof. Dr. Ortwin Adams, Dr. Nadine Lübke

d) HIV-1 drug resistance - standard program (383) and additional program (384)
Nationales Referenzzentrum für Retroviren, Ludwig-Maximilians-Universität München, Max-von-Pettenkofer Institut,
Klinische Virologie: Prof. Dr. Oliver T. Keppler, Prof. Dr. Josef Eberle, Prof. Dr. Lutz Gürtler, Dr. Hans Nitschko
Friedrich-Alexander-Universität Erlangen-Nürnberg, Universitätsklinikum Erlangen, Institut für Klinische und Molekulare Virologie:
Prof. Dr. Klaus Überla, Dr. Klaus Korn
IMD Medizinisches Versorgungszentrum, Frankfurt: PD Dr. Dr. Martin Stürmer
Medizinisches Infektiologiezentrum Berlin: Dr. Martin Obermeier, M. Schütze
Uniklinik Köln, Institut für Virologie: Prof. Dr. Florian Klein, Prof. Dr. Ulrike Wieland, Dr. Steffi Silling, Dr. Rolf Kaiser,
Dr. Eva Heger, Dr. Elena Knops
Universitätsklinikum Frankfurt, Institut für Medizinische Virologie: Prof. Dr. Sandra Ciesek, Prof. Dr. Holger F. Rabenau,
Prof. Dr. Annemarie Berger