

Anhang 1: Ergebnisse der Ringversuchsserie „Bakterien- und Pilzgenom-Nachweis (PCR/NAT)“ November 2019

Anhang 1 zu:

Reischl U, Ehrenschwender M, Hiergeist A, Maaß M, Baier M, Frangoulidis D, Grass G, von Buttlar H, Scholz H, Fingerle V, Sing A, Dumke R, Reiter-Owona I, Anders A. Bakterien- und Pilzgenom-Nachweis PCR/NAT: Auswertung des Ringversuchs November 2019 von INSTAND e.V. zur externen Qualitätskontrolle molekularbiologischer Nachweisverfahren in der bakteriologischen Diagnostik. *GMS Z Forder Qualitätssich Med Lab.* 2020;11:Doc02. DOI: 10.3205/lab000037, URN: urn:nbn:de:0183-lab0000376

Attachment 1: Results of the proficiency testing scheme “Bacterial and fungal genome detection (PCR/NAT)” November 2019

Attachment 1 to:

Reischl U, Ehrenschwender M, Hiergeist A, Maaß M, Baier M, Frangoulidis D, Grass G, von Buttlar H, Scholz H, Fingerle V, Sing A, Dumke R, Reiter-Owona I, Anders A. Bakterien- und Pilzgenom-Nachweis PCR/NAT: Auswertung des Ringversuchs November 2019 von INSTAND e.V. zur externen Qualitätskontrolle molekularbiologischer Nachweisverfahren in der bakteriologischen Diagnostik [Bacterial and fungal genome detection PCR/NAT: comprehensive discussion of the November 2019 distribution for external quality assessment of nucleic acid-based protocols in diagnostic medical microbiology by INSTAND e.V.]. *GMS Z Forder Qualitätssich Med Lab.* 2020;11:Doc02. DOI: 10.3205/lab000037, URN: urn:nbn:de:0183-lab0000376

PCR-/NAT *C. trachomatis* & GO (RV 530) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
1925301	+++ / ++	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁴ CFU/mL)
1925302	+++ / (+)	<i>Chlamydia trachomatis</i> (~ 5x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 1x10 ³ CFU/mL)
1925303	+++ / ∅	<i>Chlamydia trachomatis</i> (~ 5x10 ⁵ IFU/mL)
1925304	∅ / +++	<i>Neisseria gonorrhoeae</i> (~ 5x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Chlamydia trachomatis* dargestellt.

Absolute numbers of reported individual results. Note: only the C. trachomatis-specific results are depicted in this table.

<i>n = 256</i>	Probennummer (Sample no.)			
Befund <i>Result</i>	1925301	1925302	1925303	1925304
Positiv	255	255	254	5
Negativ	1	1	2	251
Fraglich <i>Questionable</i>	0	0	0	0

	Inhibition			
	1925301	1925302	1925303	1925304
n.d.	1	1	1	1
nein / <i>no</i>	255	255	255	255
ja / <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für Chlamydia trachomatis dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods. Note: only the C. trachomatis-specific results are depicted.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925301		1925302		1925303		1925304	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
GenProbe CT/NG [20] (n = 7)	7	100	7	100	7	100	7	100
LightMix CT/NG [21] (n = 6)	6	100	6	100	6	100	6	100
Roche COBAS [22] (n = 52)	52	100	52	100	52	100	52	100
Cepheid Xpert CT/NG [23] (n = 34)	34	100	34	100	34	100	33	97
BD ProbeTec [24] (n = 9)	9	100	9	100	9	100	8	89
Hain CT/NG [25] (n = 18)	18	100	18	100	18	100	17	94
Abbott RealTime CT/NG [26](n =30)	30	100	30	100	30	100	29	97
Other commercial tests [27](n =86)	85	99	85	99	84	98	85	99
In house PCR assay [28] (n = 14)	14	100	14	100	14	100	14	100

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für Neisseria gonorrhoeae dargestellt.

Absolute numbers of reported individual results. Note: only the N. gonorrhoeae-specific results are depicted in this table

n = 256	Probennummer (Sample no.)			
	1925301	1925302	1925303	1925304
Befund <i>Result</i>				
Positiv	255	241	4	255
Negativ	0	15 ¹⁾	252	1
Fraglich <i>Questionable</i>	1	0	0	0

	Inhibition			
	1925301	1925302	1925303	1925304
n.d.	1	1	1	1
nein / <i>no</i>	255	255	255	255
ja / <i>yes</i>	0	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Neisseria gonorrhoeae* dargestellt.

Note: only the *N. gonorrhoeae*-specific results are depicted.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925301		1925302		1925304		1925303	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
GenProbe CT/NG [20] (n = 7)	7	100	0	0	7	100	7	100
LightMix CT/NG [21] (n = 6)	6	100	6	100	6	100	6	100
Roche COBAS [22] (n = 51)	51	100	50	98	51	100	50	98
Cepheid Xpert CT/NG [23] (n = 35)	35	100	35	100	34	97	33	94
BD ProbeTec [24] (n = 9)	9	100	9	100	9	100	8	89
Hain CT/NG [25] (n = 17)	17	100	17	100	17	100	17	100
Abbott RealTime CT/NG [26](n =30)	30	100	30	100	30	100	30	100
Other commercial tests [27](n =88)	87	100	81	92	88	100	88	100
In house PCR assay [28] (n = 13)	13	100	13	100	13	100	13	100

Comments: ¹⁾ As sample #1925302 contained a low number of *Neisseria gonorrhoeae* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

PCR-/NAT *Chlamydia trachomatis* (RV 531) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925311	+++	61	<i>Chlamydia trachomatis</i> (~ 5x10 ⁵ IFU/mL)
1925312	∅	62	<i>Escherichia coli</i> K12
1925313	+++	61	<i>Chlamydia trachomatis</i> (~ 5x10 ⁵ IFU/mL)
1925314	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 65	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1925311	1925312	1925313	1925314		1925311	1925312	1925313	1925314
Befund <i>Result</i>									
Positiv	65	1	65	1	n.d.	1	1	1	1
Negativ	0	64	0	64	nein <i>no</i>	64	64	64	64
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925311		1925313		1925312		1925314	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Hain CT [20] (n = 12)	12	100	12	100	12	100	12	100
TIB Molbiol LightMix CT [21] (n = 7)	7	100	7	100	7	100	7	100
Roche COBAS CT [22] (n = 4)	4	100	4	100	4	100	4	100
Cepheid Xpert CT [23] (n = 5)	5	100	5	100	5	100	5	100
BD ProbeTec [24] (n = 9)	9	100	9	100	9	100	9	100
Artus CT [25] (n = 1)	1	100	1	100	1	100	1	100
Abbott CT [26] (n = 1)	1	100	1	100	1	100	1	100
Other commercial tests [27] (n = 14)	14	100	14	100	13	93	13	93
<i>In house</i> PCR assay [28] (n = 12)	12	100	12	100	12	100	12	100

PCR-/NAT *Bordetella pertussis* (RV 532) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925321	+++	61	<i>Bordetella pertussis</i> (~ 5x10 ⁵ CFU/mL)
1925322	∅	62	<i>Escherichia coli</i> K12
1925323	+	61	<i>Bordetella pertussis</i> (~ 5x10 ³ CFU/mL)
1925324	++	61	<i>Bordetella pertussis</i> (~ 5x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 155	Probennummer (Sample no.)					Inhibition			
	1925321	1925322	1925323	1925324		1925321	1925322	1925323	1925324
Befund <i>Result</i>									
Positiv	155	0	133	153	n.d.	1	1	1	1
Negativ	0	155	21 ¹⁾	2	nein <i>no</i>	154	154	154	154
Fraglich <i>Questionable</i>	0	0	1 ¹⁾	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925321		1925323		1925324		1925322	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
TIB Molbiol LightMix BP [20] (n = 11)	11	100	9	82	11	100	11	100
Diagenode <i>B.pertussis</i> [21] (n = 5)	5	100	4	80	4	80	5	100
GeneProof <i>Bordetella</i> [22] (n = 7)	7	100	5	71	7	100	7	100
r-Biopharm RIDAGENE [23] (n = 27)	27	100	22	85	27	100	27	100
AID CAP Bacteria [24] (n = 4)	4	100	4	100	4	100	4	100
Other commercial tests [27] (n = 63)	63	100	55	87	62	98	63	100
<i>In house</i> PCR assay [28] (n = 38)	38	100	34	89	38	100	38	100

Comments: ¹⁾ As sample #1925323 contained a low number of *Bordetella pertussis* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

PCR-/NAT *Helicobacter pylori* (RV 533) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925331	++	61/72	<i>Helicobacter pylori</i> (~ 5x10 ⁴ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1925332	+	61/72	<i>Helicobacter pylori</i> (~ 5x10 ³ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1925333	+++	61/72	<i>Helicobacter pylori</i> (~ 5x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1925334	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 47	Probennummer (Sample no.)				Inhibition				
	1925331	1925332	1925333	1925334	1925331	1925332	1925333	1925334	
Befund <i>Result</i>									
Positiv	47 ¹⁾	45 ¹⁾	47 ¹⁾	0	n.d.	0	0	0	0
Negativ	0	2	0	47	nein <i>no</i>	47	47	47	47
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925331		1925332		1925333		1925334	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Hain GenoType Helico [20] (n = 15)	15	100	14	93	15	100	15	100
Ingenetix ClariRes [21] (n = 4)	4	100	4	100	4	100	4	100
r-Biopharm RIDAGENE [22] (n = 5)	5	100	5	100	5	100	5	100
Commercial assay [27] (n = 10)	10	100	10	100	10	100	10	100
<i>In house</i> PCR assay [28] (n = 13)	13	100	12	92	13	100	13	100

Comments: ¹⁾ Forty-one of the 47 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 1 laboratory, all reported results were correct.

PCR-/NAT EHEC / STEC (RV 534) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925341	∅	62	<i>S. enterica ser. enteritidis</i>
1925342	+++	61 / 71,72,77,78	EHEC (~1x10 ⁵ CFU/mL) (<i>stx-1, stx-2, eae, hlyA</i> and O157 positive)
1925343	++	61 / 71,77,78	EHEC (~1x10 ⁴ CFU/mL) (<i>stx-1a, eae, hlyA</i> and O103 positive)
1925344	∅	62	<i>Escherichia coli</i> K12 (negative for <i>eae</i> and <i>hlyA</i>)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 133</i>	Probennummer (Sample no.)					Inhibition			
	1925341	1925342	1925343	1925344		1925341	1925342	1925343	1925344
Befund <i>Result</i>									
Positiv	1	133 ¹⁾	132 ¹⁾	0	n.d.	1	1	1	1
Negativ	132	0	1	133	nein <i>no</i>	132	132	132	132
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925342		1925343		1925341		1925344	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Hain GenoType EHEC [20] (n = 20)	20	100	20	100	20	100	20	100
r-Biopharm RIDAGENE [22] (n = 40)	40	100	39	98	40	100	40	100
Other commercial tests [27] (n = 31)	31	100	31	100	31	100	31	100
<i>In house</i> PCR assay [28] (n = 42)	42	100	42	100	41	98	42	100

Comments: ¹⁾ Partial or complete shiga toxin subtyping, *eae*-, and *hlyA*-detection was performed by 113 laboratories. With the exception of 2 laboratories, all reported results were correct.

**PCR-/NAT *Borrelia burgdorferi*
(RV 535) November 2019**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925351	++	61	<i>Borrelia afzelii</i> (~ 5x10 ⁴ organisms/mL)
1925352	+++	61	<i>Borrelia afzelii</i> (~ 5x10 ⁵ organisms/mL)
1925353	+	61	<i>Borrelia afzelii</i> (~ 5x10 ³ organisms/mL)
1925354	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 100</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1925351	1925352	1925353	1925354	1925351	1925352	1925353	1925354	
Befund <i>Result</i>									
Positiv	99	99	97	1	n.d.	0	0	0	0
Negativ	1	1	1	98	nein <i>no</i>	100	100	100	100
Fraglich <i>Questionable</i>	0	0	2	1	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925351		1925352		1925353		1925354	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
artus <i>Borrelia</i> LC Kit [20] (n = 7)	7	100	7	100	7	100	7	100
GeneProof <i>B. burg.</i> [21] (n = 12)	12	100	12	100	12	100	12	100
LightMix <i>Borrelia</i> [22] (n = 6)	6	100	6	100	6	100	6	100
Other/commercial tests [27] (n = 26)	26	100	26	100	26	100	25	100
<i>In house</i> PCR assay [28] (n = 49)	48	98	48	98	46	96	48	98

PCR-/NAT *Legionella pneumophila* (RV 536) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925361	++	61	<i>Legionella pneumophila</i> SG1 (~ 5x10 ⁴ CFU/mL)
1925362	+	61	<i>Legionella pneumophila</i> SG1 (~ 5x10 ³ CFU/mL)
1925363	∅	62	<i>Escherichia coli</i> K12
1925364	+++	61	<i>Legionella pneumophila</i> SG1 (~ 5x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 114</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1925361	1925362	1925363	1925364		1925361	1925362	1925363	1925364
Befund <i>Result</i>									
Positiv	111	92	2	112	n.d.	0	0	0	0
Negativ	3	20 ¹⁾	112	2	nein <i>no</i>	114	114	114	114
Fraglich <i>Questionable</i>	0	2 ¹⁾	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925361		1925362		1925364		1925363	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
LightMix Legionella [20] (n = 9)	8	89	6	67	8	89	9	100
AID CAP Bacteria [21] (n = 3)	3	100	3	100	3	100	3	100
r-Biopharm RIDAGENE [22] (n = 7)	7	100	7	100	7	100	7	100
Other commercial tests [27] (n= 61)	60	98	48	81	60	98	60	98
<i>In house</i> PCR assay [28] (n = 34)	33	97	28	82	34	100	33	97

Comments: ¹⁾ As sample #1925362 contained a low number of *Legionella pneumophila* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

PCR-/NAT *Salmonella enterica* (RV 537) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925371	∅	62	<i>Escherichia coli</i> K12
1925372	++	61	<i>S. enterica</i> ser. paratyphi (~ 5x10 ⁴ CFU/mL)
1925373	+++	61	<i>S. enterica</i> ser. tennessee (~ 5x10 ⁵ CFU/mL)
1925374	+++	61	<i>S. enterica</i> ser. enteritidis (~ 1x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 24	Probennummer (Sample no.)					Inhibition			
	1925371	1925372	1925373	1925374		1925371	1925372	1925373	1925374
Befund <i>Result</i>									
Positiv	0	23	24	23	n.d.	0	0	0	0
Negativ	24	1	0	1	nein <i>no</i>	24	24	24	24
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925372		1925373		1925374		1925371	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
RIDAGENE Bac. Stool Panel [20] (n = 5)	5	100	5	100	5	100	5	100
Foodproof Salmonella Kit [21] (n = 1)	1	100	1	100	1	100	1	100
Other commercial tests [27] (n = 12)	12	100	12	100	12	100	12	100
<i>In house</i> PCR assay [28] (n = 6)	5	83	6	100	5	83	6	100

**PCR-/NAT *Listeria* spp.
(RV 538) November 2019**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925381	+++	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 ⁵ CFU/mL)
1925382	++	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 ⁴ CFU/mL)
1925383	+	61 /71	<i>Listeria monocytogenes</i> (~ 1x10 ³ CFU/mL)
1925384	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 43	Probennummer (Sample no.)				Inhibition				
	1925381	1925382	1925383	1925384	1925381	1925382	1925383	1925384	
Befund <i>Result</i>									
Positiv	43	43	35	0	n.d.	0	0	0	0
Negativ	0	0	8 ¹⁾	43	nein <i>no</i>	43	43	43	43
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925381		1925382		1925383		1925384	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AmpliGnost LM [20] (n = 2)	2	100	2	100	2	100	2	100
TIB Molbiol LightMix LM [21] (n = 4)	4	100	4	100	3	75	4	100
Ingenetix BactoReal LM [22] (n = 4)	4	100	4	100	2	50	4	100
Other commercial tests [27] (n = 15)	15	100	15	100	12	80	15	100
<i>In house</i> PCR assay [28] (n = 18)	18	100	18	100	16	89	18	100

Comments: ¹⁾ As sample #1925383 contained a low number of *Listeria monocytogenes* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

PCR-/NAT MRSA / cMRSA (RV 539) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925391	+++	61 / 72	MRSA (<i>S. aureus</i> , oxa ^R , PVL-neg) (~5x10 ⁵ CFU/mL)
1925392	∅	62	<i>Escherichia coli</i> K12
1925393	+++	61 / 72	MRSA (<i>S. aureus</i> , oxa ^R , PVL-neg) (~1x10 ⁵ CFU/mL)
1925394	∅	62 / 72	MSSA (<i>S. aureus</i> , oxa ^S but SCCmec false pos.) mecA dropout variant (~5x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 288	Probennummer (Sample no.)					Inhibition			
	1925391	1925392	1925393	1925394		1925391	1925392	1925393	1925394
Befund <i>Result</i>									
Positiv	286	3	282	23	n.d.	1	1	1	1
Negativ	2	283	3	261	nein <i>no</i>	287	287	287	287
Fraglich <i>Questionable</i>	0	2	3	4	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925391		1925393		1925392		1925394	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
BD MAX/BD GeneOhm MRSA [20] (n=46)	45	98	45	100	45	100	38	84
Hain FluoroT / GenoT MRSA [21] (n=28)	27	96	27	96	27	96	27	96
r-Biopharm RIDAGENE [22] (n=29)	29	100	28	97	29	100	27	93
Cepheid Xpert / GeneXpert [23] (n=146)	146	100	145	100	143	99	142	99
Other commercial tests [27] (n =21)	21	100	20	100	21	100	16	76
<i>In house</i> PCR assay [28] (n = 18)	18	100	17	94	18	100	11	65

Comments: ¹⁾ For participants who indicated the use of assay concepts for the independent detection of the *mecA* gene and a *S. aureus* species marker gene, "questionable" results were accepted in the course of issuing the official QC certificates

PCR-/NAT *Chlamydia pneumoniae* (RV 540) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925401	+	61	<i>Chlamydia pneumoniae</i> (~ 1x10 ⁴ IFU/mL)
1925402	+++	61	<i>Chlamydia pneumoniae</i> (~ 5x10 ⁵ IFU/mL)
1925403	∅	62	<i>Mycoplasma pneumoniae</i> (~ 1x10 ⁵ genome copies/mL)
1925404	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 120	Probennummer (Sample no.)				Inhibition				
	1925401	1925402	1925403	1925404	1925401	1925402	1925403	1925404	
Befund <i>Result</i>									
Positiv	120	120	1	1	n.d.	0	0	0	0
Negativ	0	0	119	118	nein <i>no</i>	120	120	120	120
Fraglich <i>Questionable</i>	0	0	0	1	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925401		1925402		1925403		1925404	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
TIB Molbiol LightMix CP [21] (n = 12)	12	100	12	100	12	100	12	100
Diagenode MP/CP [22] (n = 3)	3	100	3	100	3	100	3	100
AmpliGnost CP PCR Kit [23] (n = 7)	7	100	7	100	7	100	7	100
AID CAP Bacteria [24] (n = 6)	6	100	6	100	6	100	6	100
Other commercial tests [27] (n = 55)	55	100	55	100	55	100	54	100
<i>In house</i> PCR assay [28] (n = 37)	37	100	37	100	36	97	36	97

PCR-/NAT *Mycoplasma pneumoniae* (RV 541) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925411	++	61	<i>Mycoplasma pneumoniae</i> (~ 5x10 ⁴ genome copies/mL)
1925412	∅	62	<i>Escherichia coli</i> K12
1925413	+++	61	<i>Mycoplasma pneumoniae</i> (~ 5x10 ⁵ genome copies/mL)
1925414	+	61	<i>Mycoplasma pneumoniae</i> (~ 5x10 ³ genome copies/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 139</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1925411	1925412	1925413	1925414		1925411	1925412	1925413	1925414
Befund <i>Result</i>									
Positiv	138	2	138	133	n.d.	0	0	0	0
Negativ	1	137	1	6 ¹⁾	nein <i>no</i>	139	139	139	139
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925411		1925413		1925414		1925412	
	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%
LightMix <i>M.pneumoniae</i> [20] (n = 15)	14	93	15	100	15	100	15	100
AID CAP Bacteria [21] (n = 5)	5	100	5	100	5	100	5	100
AmpliGnost MP PCR Kit [23] (n = 6)	6	100	6	100	6	100	6	100
Diagenode MP/CP [24] (n = 3)	3	100	3	100	3	100	2	67
r-Biopharm RIDAGENE Mp [25] (n = 6)	6	100	6	100	6	100	6	100
GeneProof <i>M. pneumoniae</i> [26] (n = 8)	8	100	8	100	7	88	8	100
Commercial assay / kit [27] (n = 58)	58	100	57	98	54	93	57	98
<i>In house</i> PCR assay [28] (n = 38)	38	100	38	100	37	97	38	100

Comments: ¹⁾ As sample #1925414 contained a low number of *Mycoplasma pneumoniae* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

**PCR-/NAT *C. burnetii* & *B. anthracis*
(RV 542) November 2019**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
1925421	+ / +	<i>Coxiella burnetii</i> (~ 1x10 ⁴ genome copies/mL) <i>B. anthracis</i> Pasteur Stamm (~ 5x10 ³ genome copies/mL)
1925422	∅ / +++	<i>B. anthracis</i> Pasteur Stamm (~ 1x10 ⁶ genome copies/mL)
1925423	∅ / ∅	<i>Escherichia coli</i> K12
1925424	++ / ++	<i>Coxiella burnetii</i> (~ 5x10 ⁴ genome copies/mL) <i>B. anthracis</i> UR-1 Stamm (~ 5x10 ⁴ genome copies/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für ***Coxiella burnetii*** dargestellt.

*Note: only the **C. burnetii-specific results** are depicted in this table*

<i>n = 41</i>	Probennummer (Sample no.)					Inhibition			
	1925421	1925422	1925423	1925424		1925421	1925422	1925423	1925424
Befund <i>Result</i>									
Positiv	41	1	1	41	n.d.	0	0	0	0
Negativ	0	39	40	0	nein <i>no</i>	41	41	41	41
Fraglich <i>Questionable</i>	0	1	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für ***Coxiella burnetii*** dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

*Note: only the **C. burnetii-specific results** are depicted in this table.*

NAT-Methode [Code] (total number)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925421		1925424		1925422		1925423	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
LightMix <i>C. burnetii</i> [20] (n = 1)	1	100	1	100	1	100	1	100
Commercial assay / kit [27] (n = 7)	7	100	7	100	6 §	100	7	100
<i>In house</i> PCR assay [28] (n = 33)	33	100	33	100	32	97	32	97

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für ***Bacillus anthracis*** dargestellt.

Absolute numbers of reported individual results.

*Note: only the **B. anthracis-specific results** are depicted in this table*

<i>n</i> = 22	Probennummer (Sample no.)				Inhibition				
	1925421	1925422	1925423	1925424	1925421	1925422	1925423	1925424	
Befund <i>Result</i>									
Positiv	15	21	0	21	n.d.	0	0	0	0
Negativ	5 ¹⁾	1	22	1	nein <i>no</i>	22	22	22	22
Fraglich <i>Questionable</i>	2 ¹⁾	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für ***Bacillus anthracis*** dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

*Note: only the **B. anthracis-specific results** are depicted in this table.*

NAT-Methode [Code] (total number)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925421		1925422		1925424		1925423	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
LightMix <i>B. anthracis</i> [21] (n = 3)	1	33	2	67	1	100	3	100
Commercial assay / kit [27] (n = 3)	2	67	3	100	2	100	3	100
<i>In house</i> PCR assay [28] (n = 16)	12 [§]	86	16	100	17 [§]	89	16	100

[§] Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

Comments: ¹⁾ As sample #1925421 contained a low number of *Bacillus anthracis* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.

PCR-/NAT *F. tularensis* & *Brucella* (RV 543) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
1925431	∅ / +++	<i>Brucella melitensis</i> (~ 1x10 ⁵ CFU/mL)
1925432	+++ / (+)	<i>Franc. tularensis subsp. holarctica</i> (~ 1x10 ⁵ CFU/mL) <i>B. melitensis</i> (~ 1x10 ³ CFU/mL)
1925433	++ / ++	<i>Franc. tularensis subsp. holarctica</i> (~ 1x10 ⁴ CFU/mL) <i>B. melitensis</i> (~ 1x10 ⁴ CFU/mL)
1925434	∅ / ∅	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Francisella tularensis* dargestellt.

Absolute numbers of reported individual results.
*Note: only the **F.tularensis-specific results** are depicted in this table*

<i>n</i> = 25	Probennummer (Sample no.)				Inhibition			
	1925431	1925432	1925433	1925434	1925431	1925432	1925433	1925434
Befund <i>Result</i>								
Positiv	0	24	22	0	n.d.	0	0	0
Negativ	24	1	1	24	nein <i>no</i>	24	25	24
Fraglich <i>Questionable</i>	1	0	2	1	ja <i>yes</i>	1	0	1

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Francisella tularensis* dargestellt.

*Note: only the **F.tularensis-specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925432		1925433		1925431		1925434	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
LightMix <i>F.tularensis</i> [20] (n = 5)	5	100	5	100	4 §	100	4 §	100
Commercial assay / kit [27] (n = 1)	1	100	0	0	1	100	1	100
In house PCR assay [28] (n = 19)	18	95	17 §	100	19	100	19	100

§ Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für **Brucella** dargestellt.

Absolute numbers of reported individual results.

*Note: only the **Brucella-specific results** are depicted in this table*

n = 23	Probennummer (Sample no.)				Inhibition				
	1925431	1925432	1925433	1925434	1925431	1925432	1925433	1925434	
Befund <i>Result</i>									
Positiv	23	8	20	0	n.d.	0	0	0	0
Negativ	0	12 ¹⁾	2	23	nein <i>no</i>	23	23	23	23
Fraglich <i>Questionable</i>	0	3 ¹⁾	1	0	ja <i>yes</i>	0	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für **Brucella** dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

*Note: only the **Brucella-specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925431		1925432		1925433		1925434	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
LightMix <i>Brucella</i> Genus [21] (n = 1)	1	100	1	100	1	100	1	100
Commercial assay / kit [27] (n =2)	2	100	1	50	2	100	2	100
In house PCR assay [28] (n = 20)	20	100	10	65	17 §	89	20	100

§ Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

Comments: ¹⁾ As sample #1925432 contained a low number of *Brucella melitensis* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.

PCR-/NAT Carbapenemasen (RV 544) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925441	+++	61 / 71,72	<i>K. oxytoca</i> KPC-3, VIM-1 (~ 1x10 ⁶ genome copies/mL)
1925442	∅	62	<i>Escherichia coli</i> K12
1925443	+++	61 / 73	<i>K. pneumoniae</i> OXA-245 (~ 1x10 ⁶ genome copies/mL)
1925444	+++	61 / 75	<i>K. pneumoniae</i> NDM-9 (~ 1x10 ⁶ genome copies/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n = 86</i>	Probennummer (Sample no.)				Inhibition					
Befund <i>Result</i>	1925441	1925442	1925443	1925444	1925441	1925442	1925443	1925444		
Positiv	86	0	78	85	n.d.	1	1	1	1	
Negativ	0	86	8	0	nein <i>no</i>	85	85	85	85	
Fraglich <i>Questionable</i>	0	0	0	1	ja <i>yes</i>	0	0	0	0	

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925441		1925443		1925444		1925442	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Check direct CPE oder MDR [21] (n =2)	2	100	2	100	2	100	2	100
Hyplex Superbug (Amplex) [23] (n =1)	1	100	0	0	1	100	1	100
Eazyplex (Amplex) [23] (n =7)	7	100	1	14	7	100	7	100
LightMix (TIB Molbiol) [24] (n =8)	8	100	8	100	8	100	8	100
GeneXpert CarbaR [25] (n =44)	44	100	44	100	44	100	44	100
Commercial assay / kit [27] (n =13)	13	100	12	92	12 §	100	13	100
<i>In house</i> PCR assay [28] (n = 11)	11	100	11	100	11	100	11	100

§ Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

- Comments:**
- 1) 87 participants reported dedicated carbapenemase identification (carbapenemase genes)
 - 2) One participant did not detect the KPC-3 gene in sample # 1925441.
 - 3) One participant did not detect the VIM-1 gene in sample # 1925441.
 - 4) One participant has wrongly reported detection of the NDM gene and an other participant detection of the IMP gene, in sample 1925441.
 - 5) Eight participants did not detect the OXA-48 gene in sample # 1925443.
 - 6) One participant has wrongly reported detection of the OXA gene and an other participant detection of the VIM gene in sample # 1925444.
 - 7) One participant did not detect the NDM-9 gene in sample # 1925444.

PCR-/NAT *Clostridium difficile* (RV 545) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925451	+++	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ⁶ CFU/mL)
1925452	∅	62	<i>Escherichia coli</i> K12
1925453	∅	62	<i>Escherichia coli</i> K12
1925454	++	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 149	Probennummer (Sample no.)					Inhibition			
	1925451	1925452	1925453	1925454		1925451	1925452	1925453	1925454
Befund <i>Result</i>									
Positiv	148	1	2	146	n.d.	2	2	2	2
Negativ	1	148	147	2	nein <i>no</i>	147	147	147	147
Fraglich <i>Questionable</i>	0	0	0	1	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925451		1925454		1925452		1925453	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Cepheid Xpert <i>C.difficile</i> [20] (n =45)	44	98	43 §	98	45	100	45	100
BD MAX <i>C.difficile</i> [21] (n =18)	18	100	18	100	18	100	17	94
r-Biopharm RIDAGENE Cdif [22] (n =34)	34	100	34	100	34	100	33	97
Commercial assay / kit [27] (n =41)	41	100	40	98	40	98	41	100
<i>In house</i> PCR assay [28] (n = 11)	11	100	11	100	11	100	11	100

§ Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

PCR-/NAT VRE
(RV 546) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925461	++	61 / 71	<i>Enterococcus faecalis vanA</i> (~ 1x10 ⁴ CFU/mL)
1925462	∅	62	<i>Escherichia coli</i> K12
1925463	∅	62	<i>E. faecalis</i> (~ 1x10 ⁵ CFU/mL)
1925464	++	61 / 72	<i>Enterococcus faecium vanA + vanB</i> (~ 1x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 56</i>	Probennummer (Sample no.)					Inhibition			
	1925461	1925462	1925463	1925464		1925461	1925462	1925463	1925464
Befund <i>Result</i>									
Positiv	56 ¹⁾	0	0	54 ¹⁾	n.d.	1	1	1	1
Negativ	0	56	56	2	nein <i>no</i>	55	55	55	55
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	1925461		1925464		1925462		1925463	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Cepheid Xpert vanA / vanB [20] (n = 25)	25	100	25	100	25	100	25	100
Hain GT Enterococcus CT [22] (n = 8)	8	100	8	100	8	100	8	100
Commercial assay / kit [27] (n = 12)	12	100	10	83	12	100	12	100
<i>In house</i> PCR assay [28] (n = 11)	11	100	11	100	11	100	11	100

Comments: ¹⁾ Fifty-three participants reported dedicated vanA / vanB identification. With the exception of 5 laboratories, all reported results were correct.

PCR-/NAT Urogenital Panel (RV 547) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>	<i>Probenzusammensetzung / Sample composition</i>
1925471	+++	<i>Trichomonas vaginalis</i> (~ 1x10 ⁵ CFU/mL)
1925472	++	<i>Gardnerella vaginalis</i> (~ 5x10 ⁴ CFU/mL)
1925473	++	<i>Mycoplasma genitalium</i> (~ 5x10 ⁴ CFU/mL)
1925474	∅	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma genitalium* dargestellt.

Absolute numbers of reported individual results.
*Note: only the **M.genitalium-specific results** are depicted in this table*

<i>n = 68</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1925471</i>	<i>1925472</i>	<i>1925473</i>	<i>1925474</i>		<i>1925471</i>	<i>1925472</i>	<i>1925473</i>	<i>1925474</i>
<i>Befund Result</i>									
Positiv	0	0	68	1	n.d.	0	0	0	0
Negativ	68	68	0	67	nein no	21	22	22	21
Fraglich Questionable	0	0	0	0	ja yes	1	0	0	1

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma genitalium* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.
*Note: only the **M.genitalium -specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	1925473		1925471		1925472		1925474	
	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>
Multiplex Kit [20] (n = 20)	20	100	20	100	20	100	19	95
Commercial assay [27] (n = 38)	38	100	38	100	38	100	38	100
In house PCR assay [28] (n = 10)	10	100	10	100	10	100	10	100

Tabelle 4: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

Absolute numbers of reported individual results.

*Note: only the **T.vaginalis-specific results** are depicted in this table*

<i>n</i> = 55	Probennummer (Sample no.)					Inhibition			
	1925471	1925472	1925473	1925474		1925471	1925472	1925473	1925474
Befund <i>Result</i>									
Positiv	53	1	0	1	n.d.	0	0	0	0
Negativ	2	54	55	54	nein <i>no</i>	55	55	55	55
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 5: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

*Note: only the **T.vaginalis-specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	1925471		1925472		1925473		1925474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Multiplex Kit [20] (n = 19)	19	100	19	100	19	100	19	100
Commercial assay [27] (n = 27)	25	93	26	96	27	100	26	96
<i>In house</i> PCR assay [28] (n = 9)	9	100	9	100	9	100	9	100

Tabelle 6: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Gardnerella vaginalis* dargestellt.

Absolute numbers of reported individual results.

*Note: only the **G.vaginalis-specific results** are depicted in this table*

<i>n</i> = 16	Probennummer (Sample no.)				Inhibition				
	1925471	1925472	1925473	1925474	1925471	1925472	1925473	1925474	
Befund <i>Result</i>									
Positiv	0	14	1	1	n.d.	0	0	0	0
Negativ	16	2	15	15	nein <i>no</i>	16	16	16	16
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 7: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Gardnerella vaginalis* dargestellt.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

*Note: only the **G.vaginalis-specific results** are depicted in this table.*

NAT-Methode [Code] (total number *)	NAT richtig positiv		NAT richtig negativ <i>True negative results</i>					
	1925472		1925471		1925473		1925474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Multiplex Kit [20] (n = 3)	3	100	3	100	2	67	3	100
Commercial assay [27] (n = 5)	3	60	5	100	5	100	5	100
<i>In house</i> PCR assay [28] (n = 8)	8	100	8	100	8	100	7	88

Comments: ¹⁾ *Mycoplasma hominis*-detection was performed by 64 laboratories. With the exception of 2 laboratories, with 1 false positive result, all reported results were correct.
²⁾ *Ureaplasma parvum*-detection was performed by 60 laboratories. All reported results were correct.
³⁾ *Ureaplasma urealyticum*-detection was performed by 63 laboratories. All reported results were correct.
⁴⁾ *Treponema pallidum*-detection was performed by 32 laboratories. With the exception of 1 laboratory, with 1 false positive result, all reported results were correct.

PCR-/NAT *Pneumocystis jirovecii* (RV 560) November 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1925601	+	61	<i>Pneumocystis jirovecii</i> (~ 5x10 ³ organisms/mL)
1925602	++	61	<i>Pneumocystis jirovecii</i> (~ 1x10 ⁵ organisms/mL)
1925603	+	61	<i>Pneumocystis jirovecii</i> (~ 1x10 ⁴ organisms/mL)
1925604	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n</i> = 120	Probennummer (Sample no.)					Inhibition			
	1925601	1925602	1925603	1925604		1925601	1925602	1925603	1925604
Befund <i>Result</i>									
Positiv	105	120	119	0	n.d.	1	1	1	1
Negativ	14 ¹⁾	0	1	120	nein <i>no</i>	119	119	119	119
Fraglich <i>Questionable</i>	1 ¹⁾	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.
Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	1925601		1925602		1925603		1925604	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
TIB Molbiol LightMix PJ [21] (n = 10)	9	90	10	100	10	100	10	100
r-Biopharm RIDAGENE PJ [22] (n = 33)	31	94	33	100	32	97	33	100
AmpliGnost PJ PCR Kit [23] (n = 9)	9	100	9	100	9	100	9	100
Sacace PJ Real TM [24] (n = 4)	4	100	4	100	4	100	4	100
Commercial assay / kit [27] (n = 33)	24	73	33	100	33	100	33	100
<i>In house</i> PCR assay [28] (n = 31)	28	93	31	100	31	100	31	100

Comments: ¹⁾ As sample #1925601 contained a low number of *Pneumocystis jirovecii* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.