

Anhang 1: Ergebnisse der Ringversuchsserie „Bakterien- und Pilzgenom-Nachweis (PCR/NAT)“ November 2016

Anhang 1 zu:

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Attachment 1: Results of the proficiency testing scheme “Bacterial and Fungal Genome Detection (PCR/NAT)” November 2016

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PCR-/NAT *C. trachomatis* & GO (RV 530) November 2016



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625301	++ / ∅	61	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL)
1625302	++ / (+)	62	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 1x10 ³ CFU/mL)
1625303	∅ / +++	63	<i>Neisseria gonorrhoeae</i> (~ 5x10 ⁶ CFU/mL)
1625304	+ / ++	62	<i>Chlamydia trachomatis</i> (~ 1x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 208</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1625301	1625302	1625303	1625304	1625301	1625302	1625303	1625304	
<i>Befund Result</i>									
Positiv CT	206	12	1	1	n.d.	1	1	1	1
Positiv CT & GO	1	195	2	207	nein / no	207	207	200	207
Positiv GO	1	1	198	0	ja / yes	0	0	7	0
Negativ	0	0	0	0					
Fraglich / questionable	0	0	7	0					

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

Abs. numbers and relative frequency of true positive and 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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
GenProbe CT/NG [20] (n = 9)	25	25 / 36	69	0	0 / 0	0
LightMix CT/NG [21] (n = 7)	28	28 / 28	100	0	0 / 0	0
Roche COBAS [22] (n = 55)	218	218 / 220	99	0	0 / 0	0
Cepheid Xpert CT/NG [23] (n = 25)	100	100 / 100	100	0	0 / 0	0
BD ProbeTec [24] (n = 10)	40	40 / 40	100	0	0 / 0	0
Abbott RealTime CT/NG [26] (n = 28)	112	112 / 112	100	0	0 / 0	0
Other commercial tests [27] (n = 66)	255	255 / 257 [§]	99	0	0 / 0	0
<i>In house PCR assay</i> [28] (n = 19)	76	76 / 76	100	0	0 / 0	0
<i>Andere / k.A. / other</i> [29] (n = 2)	7	7 / 8	88	0	0 / 0	0

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

* **Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.**
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

Tabelle 4: 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

n = 208	Probennummer (Sample no.)					Inhibition			
	1625301	1625302	1625303	1625304		1625301	1625302	1625303	1625304
Befund Result									
Positiv	207	207	3	208	n.d.	1	1	1	1
Negativ	1	1	205	0	nein / no	207	207	207	207
Fraglich Questionable	0	0	0	0	ja / yes	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 *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 in this table.

NAT-Methode (nur CT) [Code] (total number *)	NAT richtig positiv True positive results			NAT richtig negativ True negative results		
	Absolut Absolute	Relativ Relative	%	Absolut Absolute	Relativ Relative	%
GenProbe CT/NG [20] (n = 9)	26	26 / 27	97	8	8 / 9	89
LightMix CT/NG [21] (n = 7)	21	21 / 21	100	7	7 / 7	100
Roche COBAS [22] (n = 55)	164	164 / 165	99	54	54 / 55	98
Cepheid Xpert CT/NG [23] (n = 25)	75	75 / 75	100	25	25 / 25	100
BD ProbeTec [24] (n = 10)	30	30 / 30	100	10	10 / 10	100
Abbott RealTime CT/NG [26] (n = 28)	84	84 / 84	100	28	28 / 28	100
Other commercial tests [27] (n = 66)	198	198 / 198	100	64	64 / 65 §	98
In house PCR assay [28] (n = 19)	57	57 / 57	100	19	19 / 19	100
Andere / k.A. / other [29] (n = 2)	6	6 / 6	100	2	2 / 2	100

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

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

Tabelle 6: 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 = 208	Probennummer (Sample no.)					Inhibition			
	1625301	1625302	1625303	1625304		1625301	1625302	1625303	1625304
Befund Result									
Positiv	2	196	200	207	n.d.	1	1	1	1
Negativ	206	12	1	1	nein / no	207	207	200	207
Fraglich Questionable	0	0	7	0	ja / yes	0	0	7	0

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

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

NAT-Methode (<u>nur GO</u>) [Code] (total number *)	NAT richtig positiv True positive results			NAT richtig negativ True negative results		
	Absolut Absolute	Relativ Relative	%	Absolut Absolute	Relativ Relative	%
GenProbe CT/NG [20] (n = 9)	17	17 / 27	63	8	8 / 9	89
LightMix CT/NG [21] (n = 7)	21	21 / 21	100	7	7 / 7	100
Roche COBAS [22] (n = 55)	164	164 / 165	99	55	55 / 55	100
Cepheid Xpert CT/NG [23] (n = 25)	75	75 / 75	100	25	25 / 25	100
BD ProbeTec [24] (n = 10)	30	30 / 30	100	10	10 / 10	100
Abbott RealTime CT/NG [26] (n = 28)	84	84 / 84	100	28	28 / 28	100
Other commercial tests [27] (n = 66)	189	189/ 191 [§]	99	65	65 / 66	98
In house PCR assay [28] (n = 19)	57	57 / 57	100	19	19 / 19	100
Andere / k.A. / other [29] (n = 2)	5	5 / 6	83	2	2 / 2	100

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

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

PCR-/NAT *Chlamydia trachomatis* (RV 531) November 2016



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625311	++	61	<i>Chlamydia trachomatis</i> (~ 1x10 ⁴ IFU/mL)
1625312	∅	62	<i>Escherichia coli</i> K12
1625313	+	61	<i>Chlamydia trachomatis</i> (~ 1x10 ³ IFU/mL)
1625314	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 79	Probennummer (Sample no.)				Inhibition					
Befund <i>Result</i>	1625311	1625312	1625313	1625314	1625311	1625312	1625313	1625314		
Positiv	79	1	77	2	n.d.	0	0	0	0	
Negativ	0	78	2	77	nein <i>no</i>	79	79	79	79	
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Hain FluoroType CT [20] (n = 7)	14	14 / 14	100	14	14 / 14	100
TIB Molbiol LightMix CT [21] (n =6)	12	12 / 12	100	12	12 / 12	100
Roche COBAS CT [22] (n = 20)	40	40 / 40	100	40	40 / 40	100
Cepheid Xpert CT/NG [23] (n = 4)	8	8 / 8	100	8	8 / 8	100
BD ProbeTec [24] (n = 9)	17	17 / 18	94	18	18 / 18	100
Artus CT [25] (n = 2)	4	4 / 4	100	4	4 / 4	100
Abbott CT/NG [26] (n = 3)	6	6 / 6	100	6	6 / 6	100
Other commercial tests [27] (n =19)	37	37 / 38	97	35	35 / 38	92
<i>In house</i> PCR assay [28] (n = 9)	18	18 / 18	100	18	18 / 18	100
Andere / k.A. / other [29] (n = 1)	2	2 / 2	100	2	2 / 2	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

PCR-/NAT *Bordetella pertussis* (RV 532) November 2016



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625321	∅	62	<i>Escherichia coli</i> K12
1625322	++	61	<i>Bordetella pertussis</i> (~ 1x10 ⁴ CFU/mL)
1625323	∅	62	<i>Escherichia coli</i> K12
1625324	++++	61	<i>Bordetella pertussis</i> (~ 1x10 ⁶ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 133	Probennummer (Sample no.)					Inhibition			
	1625321	1625322	1625323	1625324		1625321	1625322	1625323	1625324
Befund <i>Result</i>									
Positiv	1	123	3	132	n.d.	2	2	2	2
Negativ	132	10	130	1	nein <i>no</i>	131	131	131	131
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
TIB Molbiol LightMix BP [20] (n = 8)	16	16 / 16	100	16	16 / 16	100
Diagenode <i>B.pertussis</i> [21] (n = 8)	16	16 / 16	100	16	16 / 16	100
GenoQuick <i>Bordetella</i> [22] (n = 6)	11	11 / 12	92	11	11 / 12	92
RIDAGENE <i>Bordetella</i> [23] (n = 23)	45	45 / 46	98	46	46 / 46	100
Other commercial tests [27] (n = 37)	69	69 / 74	93	72	72 / 74	97
<i>In house</i> PCR assay [28] (n = 50)	97	97 / 100	97	99	99 / 100	99
Andere / k.A. / <i>other</i> [29] (n = 2)	3	3 / 4	75	4	4 / 4	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

PCR-/NAT *Helicobacter pylori* (RV 533) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625331	∅	62	<i>Escherichia coli</i> K12
1625332	+	61/71	<i>Helicobacter pylori</i> (~ 1x10 ³ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1625333	++	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1625334	++	61/72	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

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

<i>n</i> = 38	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1625331	1625332	1625333	1625334		1625331	1625332	1625333	1625334
Befund <i>Result</i>									
Positiv	0	38 ¹⁾	38 ¹⁾	38 ¹⁾	n.d.	1	1	1	1
Negativ	38	0	0	0	nein <i>no</i>	37	37	37	37
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Hain GenoType Helico [20] (n = 17)	51	51 / 51	100	17	17 / 17	100
Ingenetix ClariRes [21] (n = 3)	9	9 / 9	100	3	3 / 3	100
Commercial assay [27] (n = 7)	21	21 / 21	100	7	7 / 7	100
<i>In house</i> PCR assay [28] (n = 13)	39	39 / 39	100	13	13 / 13	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

Comments: ¹⁾ Thirty-four of the 38 participants reported results for molecular Clarithromycin-susceptibility testing. All reported results were correct.

PCR-/NAT EHEC / STEC (RV 534) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625341	+++	61 / 73,77,78	EHEC (~1x10 ⁵ CFU/mL) (<i>stx-2c</i> , <i>eae</i> , <i>hlyA</i> and O26:H11 positive)
1625342	∅	62	<i>Escherichia coli</i> K12 (negative for <i>eae</i> and <i>hlyA</i>)
1625343	+++	61 / 71,72,77,78	EHEC (~1x10 ⁵ CFU/mL) (<i>stx-1</i> , <i>stx-2</i> , <i>eae</i> , <i>hlyA</i> and O157 positive)
1625344	∅	62	<i>S. enterica</i> ser. enteritidis (~ 1x10 ⁴ CFU/mL)

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

<i>n</i> = 123	Probennummer (Sample no.)				Inhibition				
	1625341	1625342	1625343	1625344	1625341	1625342	1625343	1625344	
Befund <i>Result</i>									
Positiv	122 ¹⁾	1	121 ¹⁾	1	n.d.	3	3	3	3
Negativ	1	122	1	122	nein <i>no</i>	120	120	120	120
Fraglich <i>Questionable</i>	0	0	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 <i>True negative results</i>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Hain GenoType EHEC [20] (n = 25)	49	49 / 50	98	49	49 / 50	98
Hyplex EHEC [21] (n = 2)	4	4 / 4	100	4	4 / 4	100
r-Biopharm RIDAGENE [22] (n = 34)	66	66 / 67 §	99	68	68 / 68	100
Other commercial tests [27] (n = 17)	34	34 / 34	100	34	34 / 34	100
<i>In house</i> PCR assay [28] (n = 49)	98	98 / 98	100	97	97 / 98	99
Anderer/ k.A. / other [29] (n = 2)	4	4 / 4	100	4	4 / 4	100

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

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

Comments: ¹⁾ Partial or complete shiga toxin subtyping, *eae*-, and *hlyA*-detection was performed by 106 laboratories. With the exception of 1 laboratory, all reported results were correct.

**PCR-/NAT *Borrelia burgdorferi*
(RV 535) November 2016**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625351	++	61	<i>Borrelia garinii</i> OspA Typ3 (~ 1x10 ⁴ organisms/mL)
1625352	∅	62	<i>Escherichia coli</i> K12
1625353	+++	61	<i>Borrelia valaisiana</i> (~ 1x10 ⁵ organisms/mL)
1625354	++	61	<i>Borrelia bisettiae</i> (~ 1x10 ⁴ organisms/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 103</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1625351</i>	<i>1625352</i>	<i>1625353</i>	<i>1625354</i>		<i>1625351</i>	<i>1625352</i>	<i>1625353</i>	<i>1625354</i>
<i>Befund Result</i>									
Positiv	101	0	97	99	n.d.	0	0	0	0
Negativ	2	103	6	4	nein <i>no</i>	103	103	103	103
Fraglich Questionable	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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
artus <i>Borrelia</i> LC Kit [20] (n = 20)	60	60 / 60	100	20	20 / 20	100
Demeditec GenFlow [21] (n = 3)	9	9 / 9	100	3	3 / 3	100
LightMix <i>Borrelia</i> [22] (n = 5)	15	15 / 15	100	5	5 / 5	100
Other/commercial tests [27] (n = 25)	73	73 / 75	97	25	25 / 25	100
<i>In house</i> PCR assay [28] (n = 53)	149	149 / 159	94	53	53 / 53	100
Anderer/ k.A. / other [29] (n = 1)	3	3 / 3	100	1	1 / 1	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

PCR-/NAT *Legionella pneumophila* (RV 536) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625361	++	61	<i>Legionella pneumophila</i> SG2 (~ 1x10 ⁴ CFU/mL)
1625362	+	61	<i>Legionella pneumophila</i> SG2 (~ 1x10 ³ CFU/mL)
1625363	∅	62	<i>Escherichia coli</i> K12
1625364	+++	61	<i>Legionella pneumophila</i> SG2 (~ 1x10 ⁵ CFU/mL)

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

<i>n = 103</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1625361</i>	<i>1625362</i>	<i>1625363</i>	<i>1625364</i>		<i>1625361</i>	<i>1625362</i>	<i>1625363</i>	<i>1625364</i>
<i>Befund Result</i>									
Positiv	97	67	1	101	n.d.	0	0	0	0
Negativ	6	35	102	2	nein no	103	103	103	103
Fraglich Questionable	0	1	0	0	ja yes	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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
LightMix <i>Legionella</i> [20] (n = 10)	27	27 / 30	90	10	10 / 10	100
GeneProof <i>L.pneumophila</i> [21] (n = 6)	14	14 / 18	78	6	6 / 6	100
Other commercial tests [27] (n= 44)	106	106 / 132	80	43	43 / 44	98
In house PCR assay [28] (n= 43)	118	118/ 128 [§]	92	43	43 / 43	100
Anderer/ k.A. / other [29] (n = 1)	3	3 / 3	100	1	1 / 1	100

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

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

PCR-/NAT *Salmonella enterica* (RV 537) November 2016



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625371	+	61	<i>S. enterica</i> ser. Enteritidis (~ 5x10 ³ CFU/mL)
1625372	++	61	<i>S. enterica</i> ser. Enteritidis (~ 5x10 ⁴ CFU/mL)
1625373	+++	61	<i>S. enterica</i> ser. Enteritidis (~ 5x10 ⁵ CFU/mL)
1625374	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 21</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1625371	1625372	1625373	1625374		1625371	1625372	1625373	1625374
Befund <i>Result</i>									
Positiv	18	20	21	0	n.d.	0	0	0	0
Negativ	3¹⁾	1	0	21	nein <i>no</i>	21	21	21	21
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
foodproof Salmonella Kit [21] (n = 1)	3	3 / 3	100	1	1 / 1	100
Other commercial tests [27] (n = 12)	36	36 / 36	100	12	12 / 12	100
<i>In house</i> PCR assay [28] (n = 8)	20	20 / 24	83	8	8 / 8	100
Andere/ k.A. / other [29] (n = 1)	3	3 / 3	100	1	1 / 1	100

Comments: ¹⁾ As sample #1625371 contained a low number of *Salmonella enterica* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

**PCR-/NAT *Listeria spp.*
(RV 538) November 2016**



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625381	+++	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 ⁵ CFU/mL)
1625382	∅	62	<i>Escherichia coli</i> K12
1625383	+	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 ³ CFU/mL)
1625384	++	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 ⁴ CFU/mL)

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

<i>n</i> = 36	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>					
<i>Befund Result</i>	1625381	1625382	1625383	1625384	1625381	1625382	1625383	1625384		
Positiv	36	0	35	36	n.d.	0	0	0	0	
Negativ	0	36	1	0	nein <i>no</i>	36	36	36	36	
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
TIB Molbiol LightMix LM [21] (n = 2)	6	6 / 6	100	2	2 / 2	100
Ingenetix BactoReal LM [22] (n = 4)	12	12 / 12	100	4	4 / 4	100
Other commercial tests [27] (n = 7)	20	20 / 21	95	7	7 / 7	100
<i>In house</i> PCR assay [28] (n = 23)	69	69 / 69	100	23	23 / 23	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

PCR-/NAT MRSA / cMRSA (RV 539) November 2016



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

	Erwartet / expected		Probenzusammensetzung / Sample composition
1625391	Ø	62 / 73	CoNS (<i>S. epidermidis</i> , oxa ^R) (~1x10 ⁵ CFU/mL)
1625392	+++	61 / 72	MRSA MREJ (right extremity junction) type IV (<i>S. aureus</i> , oxa ^R , PVL-neg) (~ 1x10 ⁵ CFU/mL)
1625393	Ø	62 / 72	MSSA (~ 1x10 ⁴ CFU/mL)
1625394	+++	61 / 71,72	cMRSA (<i>S. aureus</i> , oxa ^R , PVL-pos, spa:t 310) (~1x10 ⁵ CFU/mL)

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

n = 305	Probennummer (Sample no.)					Inhibition			
	1625391	1625392	1625393	1625394		1625391	1625392	1625393	1625394
Befund <i>Result</i>									
Positiv	5	283	7	302	n.d.	2	2	2	2
Negativ	299	21	297	2	nein <i>no</i>	303	303	303	303
Fraglich <i>Questionable</i>	1	1	1	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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
BD MAX/BD GeneOhm MRSA [20] (n=39)	77	77 / 78	99	78	78 / 78	100
Hain FT MRSA [21] (n=25)	50	50 / 50	100	50	50 / 50	100
RIDAGENE MRSA [23] (n=31)	61	61 / 62	98	60	60 / 62	97
Cepheid Xpert / GeneXpert [24] (n=138)	273	273/ 275 [§]	99	269	269 / 274 [§]	98
LC MRSA Advanced (Roche) [25] (n=19)	22	22 / 38	58	38	38 / 38	100
TIB Molbiol LightMix MRSA [26] (n=1)	1	1 / 2	50	2	2 / 2	100
Commercial assay kit [27] (n=22)	42	42 / 44	95	42	42 / 44	95
In house PCR assay [28] (n=27)	53	53 / 54	98	51	51 / 54	94
Andere / k.A. / other [29] (n=17)	33	33 / 33 [§]	100	33	33 / 34	97

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

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

PCR-/NAT *Chlamydia pneumoniae* (RV 540) November 2016



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625401	++	61	<i>Chlamydia pneumoniae</i> (~ 5x10 ⁴ IFU/mL)
1625402	+++	61	<i>Chlamydia pneumoniae</i> (~ 5x10 ⁵ IFU/mL)
1625403	+	61	<i>Chlamydia pneumoniae</i> (~ 5x10 ³ IFU/mL)
1625404	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 108</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1625401</i>	<i>1625402</i>	<i>1625403</i>	<i>1625404</i>		<i>1625401</i>	<i>1625402</i>	<i>1625403</i>	<i>1625404</i>
Befund <i>Result</i>									
Positiv	106	107	100	2	n.d.	0	0	0	0
Negativ	2	1	8 ¹⁾	106	nein <i>no</i>	108	108	108	108
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
TIB Molbiol LightMix CP [21] (n = 11)	33	33 / 33	100	11	11 / 11	100
Diagenode MP/CP [22] (n = 6)	17	17 / 18	94	6	6 / 6	100
AmpliGnost CP PCR Kit [23] (n = 7)	21	21 / 21	100	7	7 / 7	100
Other commercial tests [27] (n = 46)	132	132 / 138	96	45	45 / 46	98
<i>In house</i> PCR assay [28] (n = 38)	110	110 / 114	96	37	37 / 38	97
Andere / k.A. / other [29] (n = 1)	3	3 / 3	100	1	1 / 1	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

Comments: ¹⁾ As sample #1625403 contained a low number of *Chlamydia pneumoniae* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.

PCR-/NAT *Mycoplasma pneumoniae* (RV 541) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625411	+	61	<i>Mycoplasma pneumoniae</i> (~ 5x10 ³ genome copies/mL)
1625412	∅	62	<i>Mycoplasma genitalium</i> (~ 10 ⁴ genome copies/mL)
1625413	∅	62	<i>Escherichia coli</i> K12
1625414	+++	61	<i>Mycoplasma pneumoniae</i> (~ 1x10 ⁵ genome copies/mL)

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

<i>n = 123</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1625411	1625412	1625413	1625414		1625411	1625412	1625413	1625414
<i>Befund Result</i>									
Positiv	118	5	1	122	n.d.	0	0	0	0
Negativ	5	118	122	1	nein no	123	123	123	123
Fraglich Questionable	0	0	0	0	ja yes	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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
LightMix <i>M.pneumoniae</i> [20] (n = 13)	26	26 / 26	100	26	26 / 26	100
AmpliGnost MP PCR Kit [23] (n = 6)	12	12 / 12	100	12	12 / 12	100
Diagenode MP/CP [24] (n = 6)	12	12 / 12	100	12	12 / 12	100
Commercial assay / kit [27] (n = 55)	105	105 / 110	95	105	105 / 110	95
<i>In house</i> PCR assay [28] (n = 42)	83	83 / 84	99	83	83 / 84	99
Andere / k.A. / other [29] (n = 2)	4	4 / 4	100	4	4 / 4	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

**PCR-/NAT *C. burnetii* & *B. anthracis*
(RV 542) November 2016**



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625421	++ / ++	62	<i>C. burnetii</i> (~ 1x10 ⁴ genome copies/mL) <i>B. anthracis</i> UR-1 Stamm (~ 1x10 ⁴ genome copies/mL)
1625422	∅ / ∅	64	<i>Escherichia coli</i> K12
1625423	∅ / ++	63	<i>B. anthracis</i> Pasteur Stamm* (~ 5x10 ⁴ genome copies/mL)
1625424	+ / ∅	61	<i>C. burnetii</i> (~ 1x10 ³ genome copies/mL)

* *B. anthracis* Pasteur Stamm: *rpoB*- und *dhp61*-positiv aber *pagA* negativ !

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

Absolute numbers of reported individual results.

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

<i>n</i> = 36	Probennummer (Sample no.)				Inhibition				
	1625421	1625422	1625423	1625424	1625421	1625422	1625423	1625424	
Befund <i>Result</i>									
Positiv	36	0	0	34	n.d.	0	0	0	0
Negativ	0	36	36	1	nein <i>no</i>	36	36	36	35
Fraglich <i>Questionable</i>	0	0	0	1	ja <i>yes</i>	0	0	0	1

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwenden 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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
LightMix <i>C. burnetii</i> [20] (n = 1)	2	2 / 2	100	2	2 / 2	100
Commercial assay / kit [27] (n = 8)	15	15 / 16	94	16	16 / 16	100
<i>In house</i> PCR assay [28] (n = 28)	55	55 / 55 §	100	56	56 / 56	100
Andere / k.A. / other [29] (n = 2)	4	4 / 4	100	4	4 / 4	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

§ 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 *Bacillus anthracis* dargestellt.

Absolute numbers of reported individual results.

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

<i>n</i> = 17	Probennummer (Sample no.)				Inhibition				
	1625421	1625422	1625423	1625424	1625421	1625422	1625423	1625424	
Befund <i>Result</i>									
Positiv	16	0	15	0	n.d.	0	0	0	0
Negativ	0	17	2	17	nein <i>no</i>	17	17	17	17
Fraglich <i>Questionable</i>	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 <i>True negative results</i>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
LightMix <i>B. anthracis</i> [21] (n = 3)	5	5 / 5 §	100	6	6 / 6	100
Commercial assay / kit [27] (n = 3)	5	5 / 6	83	6	6 / 6	100
In house PCR assay [28] (n = 13)	25	25 / 26	96	26	26 / 26	100
Andere / k.A. / other [29] (n = 1)	2	2 / 2	100	2	2 / 2	100

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

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 4) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

Comments: ¹⁾ Twenty-two of the 39 participants performed only *Coxiella burnetii* detection, 3 of the 39 participants performed only *Bacillus anthracis*-specific assays, whereas the other 14 laboratories reported the use of PCR/NAT assays covering both species.

PCR-/NAT *Francisella tularensis* (RV 543) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625431	++	61	<i>F. tularensis holarctica</i> (~ 1x10 ⁴ CFU/mL)
1625432	+++	61	<i>F. tularensis holarctica</i> (~ 1x10 ⁵ CFU/mL)
1625433	∅	62	<i>Escherichia coli</i> K12
1625434	+++	61	<i>F. tularensis tularensis</i> (~ 1x10 ⁵ CFU/mL)

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

<i>n = 21</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1625431	1625432	1625433	1625434		1625431	1625432	1625433	1625434
Befund <i>Result</i>									
Positiv	19	21	2	20	n.d.	0	0	0	0
Negativ	2	0	19	1	nein <i>no</i>	21	21	21	21
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
LightMix <i>F. tularensis</i> [20] (n = 5)	15	15 / 15	100	5	5 / 5	100
Commercial assay / kit [27] (n = 1)	2	2 / 3	67	1	1 / 1	100
In house PCR assay [28] (n = 15)	43	43 / 45	96	13	13 / 15	87
Andere / k.A. / other [29] (n = 1)	3	3 / 3	100	1	1 / 1	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

PCR-/NAT Carbapenemase (RV 544) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625441	+++	61 / 71,72	<i>K. oxytoca</i> KPC-3, VIM-1 (~ 1x10 ⁷ genome copies/mL)
1625442	+++	61 / 73,75	<i>K. pneumoniae</i> NDM-1, OXA-48 (~ 1x10 ⁷ genome copies/mL)
1625443	+++	61 / 73	<i>K. pneumoniae</i> OXA-232 (~ 1x10 ⁷ genome copies/mL)
1625444	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 63	Probennummer (Sample no.)					Inhibition			
	1625441	1625442	1625443	1625444		1625441	1625442	1625443	1625444
Befund <i>Result</i>									
Positiv	63 ¹⁾	63 ²⁾	58 ³⁾	2 ⁴⁾	n.d.	0	0	0	0
Negativ	0	0	5	61	nein <i>no</i>	63	63	63	63
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.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>			NAT richtig negativ <i>True negative results</i>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Check direct CPE oder MDR [21] (n=7)	21	21 / 21	100	6	6 / 7	86
Hyplex Superbug [22] (n=2)	5	5 / 6	83	2	2 / 2	100
Hyplex Eazyplex [23] (n=4)	9	9 / 12	75	4	4 / 4	100
LightMix (TIB Molbiol) [24] (n=5)	15	15 / 15	100	5	5 / 5	100
GeneXpert CarbaR [25] (n=29)	87	87 / 87	100	28	28 / 29	97
Commercial assay / kit [27] (n=4)	12	12 / 12	100	4	4 / 4	100
<i>In house</i> PCR assay [28] (n = 13)	38	38 / 39	97	13	13 / 13	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

- Comments:**
- 1) One participant did not detect the VIM-1 gene in sample # 1625441 and one reported the (wrong) detection of the OXA gene.
 - 2) Three participants did not detect the NDM-1 gene in sample # 1625442 and one reported the (wrong) detection of the VIM gene.
 - 3) Two participants reported the (wrong) detection of the VIM gene in sample # 1625443.
 - 4) One participant reported the (wrong) detection of VIM and OXA genes in sample # 1625444 and another laboratory reported the (wrong) detection of KPC und VIM genes.

PCR-/NAT *Clostridium difficile* (RV 545) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625451	∅	62	<i>Escherichia coli</i> K12
1625452	++	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ⁴ CFU/mL)
1625453	+++	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ⁵ CFU/mL)
1625454	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 103	Probennummer (Sample no.)				Inhibition				
	1625451	1625452	1625453	1625454	1625451	1625452	1625453	1625454	
Befund <i>Result</i>									
Positiv	1	102	102	0	n.d.	0	0	0	0
Negativ	102	1	1	103	nein <i>no</i>	103	103	103	103
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Cepheid Xpert <i>C.difficile</i> [20] (n=29)	56	56 / 58	97	58	58 / 58	100
BD MAX <i>C.difficile</i> [21] (n=11)	22	22 / 22	100	21	21 / 22	95
Commercial assay / kit [27] (n=51)	102	102 / 102	100	102	102 / 102	100
<i>In house</i> PCR assay [28] (n=13)	26	26 / 26	100	26	26 / 26	100
Andere / k.A. / other [29] (n=2)	4	4 / 4	100	4	4 / 4	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

Comments: 39 participants reported dedicated identification of toxin genes. All reported results were correct.

PCR-/NAT VRE (RV 546) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625461	+++	61 / 71	<i>E. gallinarum</i> vanA und vanC (~ 1x10 ⁵ CFU/mL)
1625462	∅	62	<i>Escherichia coli</i> K12
1625463	+++	61 / 71	<i>Enterococcus faecium</i> vanA (~ 1x10 ⁵ CFU/mL)
1625464	∅	62	<i>Enterococcus faecium</i> (~ 1x10 ⁴ CFU/mL)

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

<i>n</i> = 39	Probennummer (Sample no.)					Inhibition			
	1625461	1625462	1625463	1625464		1625461	1625462	1625463	1625464
Befund <i>Result</i>									
Positiv	37 ¹⁾	0	39 ¹⁾	0	n.d.	2	2	2	2
Negativ	1	39	0	39	nein <i>no</i>	37	37	37	37
Fraglich <i>Questionable</i>	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 <i>True negative results</i>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Cepheid Xpert vanA / vanB [20] (n=11)	22	22 / 22	100	22	22 / 22	100
BD GeneOhm VanR [21] (n=1)	2	2 / 2	100	2	2 / 2	100
Commercial assay / kit [27] (n =14)	28	28 / 28	100	28	28 / 28	100
<i>In house</i> PCR assay [28] (n = 13)	24	24 / 25 §	96	26	26 / 26	100

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

Comments: ¹⁾ Thirty eight participants reported dedicated vanA / vanB identification. All reported results were correct.

PCR-/NAT *Pneumocystis jirovecii* (RV 560) November 2016



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625601	∅	62	<i>Escherichia coli</i> K12
1625602	+++	61	<i>Pneumocystis jirovecii</i> (~ 5x10 ⁵ organisms /mL)
1625603	+	61	<i>Pneumocystis jirovecii</i> (~ 5x10 ³ organisms /mL)
1625604	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 96	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>					
<i>Befund Result</i>	1625601	1625602	1625603	1625604	1625601	1625602	1625603	1625604		
Positiv	2	96	93	1	n.d.	1	1	1	1	
Negativ	94	0	3	95	nein <i>no</i>	95	95	95	95	
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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
TIB Molbiol LightMix PJ [21] (n=9)	18	18 / 18	100	18	18 / 18	100
r-Biopharm RIDAGENE PJ [22] (n=22)	43	43 / 44	98	43	43 / 44	98
AmpliGnost PJ PCR Kit [23] (n=8)	16	16 / 16	100	16	16 / 16	100
Sacace PJ RealTM [24] (n=3)	6	6 / 6	100	6	6 / 6	100
Commercial assay / kit [27] (n=10)	19	19 / 20	95	20	20 / 20	100
<i>In house</i> PCR assay [28] (n=42)	83	83 / 84	99	82	82 / 84	98
Andere / k.A. / other [29] (n=2)	4	4 / 4	100	4	4 / 4	100

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.