

## **Anhang 1: Ergebnisse der Ringversuchsserie „Bakterien- und Pilzgenom-Nachweis (PCR/NAT)“ Juni 2017**

Anhang 1 zu:

Reischl U, Schneider W, Ehrenschwender M, Hiergeist A, Maaß M, Baier M, Frangoulidis D, Grass G, von Buttlar H, Scholz H, Fingerle V, Sing A, Jacobs E, Reiter-Owona I, Anders A. „Bakterien- und Pilzgenom-Nachweis PCR/NAT“: Auswertung des Ringversuchs Juni 2017 von INSTAND e.V. zur externen Qualitätskontrolle molekularbiologischer Nachweisverfahren in der bakteriologischen Diagnostik. *GMS Z Forder Qualitätssich Med Lab.* 2017;8:Doc03.  
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## **Attachment 1: Results of the proficiency testing scheme “Bacterial and Fungal Genome Detection (PCR/NAT)” June 2017**

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Reischl U, Schneider W, Ehrenschwender M, Hiergeist A, Maaß M, Baier M, Frangoulidis D, Grass G, von Buttlar H, Scholz H, Fingerle V, Sing A, Jacobs E, Reiter-Owona I, Anders A. “Bacterial and fungal genome detection PCR/NAT”: comprehensive discussion of the June 2017 distribution for external quality assessment of nucleic acid-based protocols in diagnostic medical microbiology by INSTAND e.V. *GMS Z Forder Qualitätssich Med Lab.* 2017;8:Doc03.  
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# PCR-/NAT *C. trachomatis* & GO (RV 530) Juni 2017



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

	Erwartet / expected	61	Probenzusammensetzung / Sample composition
1715301	++ / ∅	61	<i>Chlamydia trachomatis</i> (~ 1x10 <sup>4</sup> IFU/mL)
1715302	++ / +++	62	<i>Chlamydia trachomatis</i> (~ 5x10 <sup>3</sup> IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 <sup>5</sup> CFU/mL)
1715303	+++ / (+)	62	<i>Chlamydia trachomatis</i> (~ 5x10 <sup>4</sup> IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 <sup>2</sup> CFU/mL)
1715304	∅ / ∅	64	<i>Escherichia coli</i> K12

**Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.**

*Absolute numbers of reported individual results.*

n = 237	Probennummer (Sample no.)				Inhibition				
	1715301	1715302	1715303	1715304	1715301	1715302	1715303	1715304	
Befund Result									
Positiv CT	236	1	14 <sup>1)</sup>	1	n.d.	0	0	0	0
Positiv CT & GO	1	235	221	1	nein / no	237	237	237	237
Positiv GO	0	1	0	5	ja / yes	0	0	0	0
Negativ	0	0	1	230					
Fraglich / questionable	0	0	1 <sup>1)</sup>	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 True positive results			NAT richtig negativ True negative results		
	Absolut Absolute	Relativ Relative	%	Absolut Absolute	Relativ Relative	%
GenProbe CT/NG [20] (n = 7)	13	13 / 21	62	6	6 / 7	86
LightMix CT/NG [21] (n = 6)	18	18 / 18	100	6	6 / 6	100
Roche COBAS [22] (n = 59)	176	176/ 176 <sup>§</sup>	100	57	57 / 59	97
Cepheid Xpert CT/NG [23] (n = 28)	83	83 / 84	99	26	26 / 28	93
BD ProbeTec [24] (n = 8)	24	24 / 24	100	7	7 / 8	88
Artus CT/NG [25] (n = 3)	9	9 / 9	100	3	3 / 3	100
Abbott RealTime CT/NG [26] (n = 31)	91	91 / 93	98	29	29 / 31	93
Other commercial tests [27] (n = 83)	243	243/ 249	98	82	82 / 83	99
In house PCR assay [28] (n = 18)	54	54 / 54	100	18	18 / 18	100
Andere / k.A. / other [29] (n = 5)	14	14 / 15	93	5	5 / 5	100

<sup>§</sup> 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:** <sup>1)</sup> As sample #1715303 contained a low number of *Neisseria gonorrhoeae* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.

**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*

<i>n</i> = 237	Probennummer (Sample no.)				Inhibition				
	1715301	1715302	1715303	1715304	1715301	1715302	1715303	1715304	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	237	236	236	2	n.d.	0	0	0	0
<b>Negativ</b>	0	1	1	235	nein / no	237	237	237	237
<b>Fraglich</b> <i>Questionable</i>	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.*

<b>NAT-Methode (nur CT)</b> [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 = 7)	20	20 / 21	95	7	7 / 7	100
LightMix CT/NG [21] (n = 6)	18	18 / 18	100	6	6 / 6	100
Roche COBAS [22] (n = 59)	177	177 / 177	100	59	59 / 59	100
Cepheid Xpert CT/NG [23] (n = 28)	84	83 / 84	100	28	28 / 28	100
BD ProbeTec [24] (n = 8)	24	24 / 24	100	8	8 / 8	100
Artus CT/NG [25] (n = 3)	9	9 / 9	100	3	3 / 3	100
Abbott RealTime CT/NG [26] (n = 31)	92	92 / 93	99	30	30 / 31	97
Other commercial tests [27] (n = 83)	249	249 / 249	100	82	82 / 83	99
<i>In house</i> PCR assay [28] (n = 18)	54	54 / 54	100	18	18 / 18	100
Andere / k.A. / <i>other</i> [29] (n = 5)	15	15 / 15	100	5	5 / 5	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*

**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 = 237	Probennummer (Sample no.)				Inhibition				
	1715301	1715302	1715303	1715304	1715301	1715302	1715303	1715304	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	1	236	221	6	n.d.	0	0	0	0
<b>Negativ</b>	236	1	15 <sup>1)</sup>	231	nein / no	237	237	237	237
<b>Fraglich</b> <i>Questionable</i>	0	0	1	0	ja / yes	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 *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 ( <b>nur GO</b> ) [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 = 7)	7	7 / 14	50	13	13 / 14	93
LightMix CT/NG [21] (n = 6)	12	12 / 12	100	12	12 / 12	100
Roche COBAS [22] (n = 59)	117	117/ 117 <sup>§</sup>	100	116	116 / 118	98
Cepheid Xpert CT/NG [23] (n = 28)	55	55 / 56	98	54	54 / 56	96
BD ProbeTec [24] (n = 8)	16	16 / 16	100	15	15 / 16	94
Artus CT/NG [25] (n = 3)	6	6 / 6	100	6	6 / 6	100
Abbott RealTime CT/NG [26] (n = 31)	61	61 / 62	98	61	61 / 62	98
Other commercial tests [27] (n = 83)	160	160 / 166	96	166	166 / 166	100
<i>In house</i> PCR assay [28] (n = 18)	36	36 / 36	100	36	36 / 36	100
Andere / k.A. / other [29] (n = 5)	9	9 / 10	90	10	10 / 10	100

<sup>§</sup> 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:** <sup>1)</sup> As sample #1715303 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) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715311	++	61	<i>Chlamydia trachomatis</i> (~ 1x10 <sup>4</sup> IFU/mL)
1715312	∅	62	<i>Escherichia coli</i> K12
1715313	+++	61	<i>Chlamydia trachomatis</i> (~ 5x10 <sup>4</sup> IFU/mL)
1715314	++	61	<i>Chlamydia trachomatis</i> (~ 5x10 <sup>3</sup> IFU/mL)

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

<i>n</i> = 97	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
<i>Befund Result</i>	1715311	1715312	1715313	1715314	1715311	1715312	1715313	1715314	
<b>Positiv</b>	97	0	97	97	n.d.	0	0	0	0
<b>Negativ</b>	0	97	0	0	nein no	97	97	97	97
<b>Fraglich</b> <i>Questionable</i>	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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
Hain FluoroType CT [20] (n = 15)	45	45 / 45	100	15	15 / 15	100
TIB Molbiol LightMix CT [21] (n = 6)	18	18 / 18	100	6	6 / 6	100
Roche COBAS CT [22] (n = 20)	60	60 / 60	100	20	20 / 20	100
Cepheid Xpert CT/NG [23] (n = 5)	15	15 / 15	100	5	5 / 5	100
BD ProbeTec [24] (n = 10)	30	30 / 30	100	10	10 / 10	100
Artus CT [25] (n = 1)	3	3 / 3	100	1	1 / 1	100
Abbott CT/NG [26] (n = 3)	9	9 / 9	100	3	3 / 3	100
Other commercial tests [27] (n = 27)	81	81 / 81	100	27	27 / 27	100
<i>In house</i> PCR assay [28] (n = 11)	33	33 / 33	100	11	11 / 11	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) Juni 2017



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715321	++++	61	<i>Bordetella pertussis</i> (~ 1x10 <sup>5</sup> CFU/mL)
1715322	∅	62	<i>Escherichia coli</i> K12
1715323	∅	62	<i>Bordetella holmesii</i> (IS481-pos.) (~ 1x10 <sup>5</sup> CFU/mL)
1715324	∅	62	<i>Bordetella parapertussis</i> (~ 1x10 <sup>5</sup> CFU/mL)

**Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.**

*Absolute numbers of reported individual results.*

<i>n</i> = 155	Probennummer (Sample no.)				Inhibition				
	1715321	1715322	1715323	1715324	1715321	1715322	1715323	1715324	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	148	2	103 <sup>1)</sup>	5	n.d.	1	1	1	1
<b>Negativ</b>	7	153	51	149	nein <i>no</i>	154	154	154	154
<b>Fraglich</b> <i>Questionable</i>	0	0	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>	%
TIB Molbiol LightMix BP [20] (n = 11)	11	11 / 11	100	22	22 / 33	67
Diagenode <i>B.pertussis</i> [21] (n = 10)	10	10 / 10	100	20	20 / 30	67
GenoQuick <i>Bordetella</i> [22] (n = 6)	6	6 / 6	100	12	12 / 18	67
RIDAGENE <i>Bordetella</i> [23] (n = 18)	18	18 / 18	100	50	50 / 54	92
Other commercial tests [27] (n = 51)	47	47 / 51	92	117	117 / 152 <sup>§</sup>	77
<i>In house</i> PCR assay [28] (n = 57)	54	54 / 57	95	127	127 / 170 <sup>§</sup>	75
Andere / k.A. / other [29] (n = 3)	3	3 / 3	100	7	7 / 9	78

<sup>§</sup> 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:** <sup>1)</sup> Due to the well-known cross-reaction of *B. holmesii* in IS 481-specific PCR assays for *B. pertussis*, positive PCR results with sample #1715323 were not rated as false-positive.

## PCR-/NAT *Helicobacter pylori* (RV 533) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715331	+++	61/71	<i>Helicobacter pylori</i> (~ 5x10 <sup>5</sup> CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1715332	++	61/71	<i>Helicobacter pylori</i> (~ 5x10 <sup>4</sup> CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1715333	∅	62	<i>Escherichia coli</i> K12
1715334	+	61/71	<i>Helicobacter pylori</i> (~ 5x10 <sup>3</sup> CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)

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

<i>n = 50</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1715331	1715332	1715333	1715334		1715331	1715332	1715333	1715334
<i>Befund Result</i>									
<b>Positiv</b>	50 <sup>1)</sup>	50 <sup>1)</sup>	1	49 <sup>1)</sup>	n.d.	1	1	1	1
<b>Negativ</b>	0	0	49	1	nein no	49	49	49	49
<b>Fraglich</b> <i>Questionable</i>	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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
Hain GenoType Helico [20] (n = 21)	63	63 / 63	100	21	21 / 21	100
Ingenetix ClariRes [21] (n = 1)	3	3 / 3	100	0	0 / 1	0
r-Biopharm RIDAGENE [22] (n = 5)	15	15 / 15	100	5	5 / 5	100
Commercial assay [27] (n = 4)	11	11 / 12	92	4	4 / 4	100
<i>In house</i> PCR assay [28] (n = 20)	60	60 / 60	100	20	20 / 20	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:** <sup>1)</sup> Thirty-nine of the 50 participants reported results for molecular Clarithromycin-susceptibility testing. All reported results were correct.



# PCR-/NAT EHEC / STEC (RV 534) Juni 2017



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715341	+++	61 / 74	EHEC (~1x10 <sup>5</sup> CFU/mL) ( <i>stx-2d</i> positive)
1715342	++	61 / 71,72,77,78	EHEC (~1x10 <sup>4</sup> CFU/mL) ( <i>stx-1, stx-2, eae, hlyA</i> and O157 positive)
1715343	∅	62	<i>Shigella sonnei</i> (~ 1x10 <sup>5</sup> CFU/mL)
1715344	∅	62	<i>Escherichia coli</i> K12

**Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.**

*Absolute numbers of reported individual results.*

<i>n = 133</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	<i>1715341</i>	<i>1715342</i>	<i>1715343</i>	<i>1715344</i>	<i>1715341</i>	<i>1715342</i>	<i>1715343</i>	<i>1715344</i>	
<i>Befund Result</i>									
<b>Positiv</b>	124 <sup>1)</sup>	125 <sup>1)</sup>	4	1	n.d.	1	1	1	1
<b>Negativ</b>	7	8	127	132	nein no	132	132	132	132
<b>Fraglich Questionable</b>	2	0	2	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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
Hain GenoType EHEC [20] (n = 25)	49	49 / 50	98	50	50 / 50	100
Hyplex EHEC [21] (n = 1)	2	2 / 2	100	2	2 / 2	100
r-Biopharm RIDAGENE [22] (n = 42)	72	72 / 83 §	87	80	80 / 82 §	98
Other commercial tests [27] (n = 21)	42	42 / 42	100	41	41 / 42	98
<i>In house</i> PCR assay [28] (n = 46)	86	86 / 90 §	96	92	92 / 92	100
Anderer/ k.A. / other [29] (n = 2)	4	4 / 4	100	3	3 / 4	75

§ 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 112 laboratories. With the exception of 2 laboratories, all reported results were correct.



## PCR-/NAT *Borrelia burgdorferi* (RV 535) Juni 2017



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715351	++	61	<i>Borrelia garinii</i> OspA Typ3 (~ 5x10 <sup>4</sup> organisms/mL)
1715352	∅	62	<i>Escherichia coli</i> K12
1715353	+++	61	<i>Borrelia garinii</i> OspA Typ3 (~ 5x10 <sup>5</sup> organisms/mL)
1715354	+	61	<i>Borrelia garinii</i> OspA Typ3 (~ 5x10 <sup>3</sup> organisms/mL)

**Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.**

*Absolute numbers of reported individual results.*

<i>n = 127</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1715351	1715352	1715353	1715354	1715351	1715352	1715353	1715354	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	123	1	125	114	n.d.	1	1	1	1
<b>Negativ</b>	3	126	2	13 <sup>1)</sup>	nein <i>no</i>	126	126	126	126
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
artus <i>Borrelia</i> LC Kit [20] (n = 23)	69	69 / 69	100	23	23 / 23	100
Demeditec GenFlow [21] (n = 3)	9	9 / 9	100	3	3 / 3	100
LightMix <i>Borrelia</i> [22] (n = 6)	12	12 / 18 §	67	6	6 / 6	100
Other/commercial tests [27] (n = 41)	120	120 / 123	98	40	40 / 41	98
<i>In house</i> PCR assay [28] (n = 56)	159	159 / 168	95	56	56 / 56	100
Andere/ 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*

**Comments:** <sup>1)</sup> As sample #1715354 contained a low number of *Borrelia burgdorferi* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.

# PCR-/NAT *Legionella pneumophila* (RV 536) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715361	+++	61	<i>Legionella pneumophila</i> SG2 (~ 5x10 <sup>4</sup> CFU/mL)
1715362	∅	62	<i>Escherichia coli</i> K12
1715363	+	61	<i>Legionella pneumophila</i> SG2 (~ 5x10 <sup>2</sup> CFU/mL)
1715364	++	61	<i>Legionella pneumophila</i> SG2 (~ 5x10 <sup>3</sup> CFU/mL)

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

<i>n</i> = 119	Probennummer (Sample no.)					Inhibition			
	1715361	1715362	1715363	1715364		1715361	1715362	1715363	1715364
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	119	2	62	106	n.d.	1	1	1	1
<b>Negativ</b>	0	117	55 <sup>1)</sup>	12	nein <i>no</i>	118	118	118	118
<b>Fraglich</b> <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 <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 = 11)	27	27 / 33	82	11	11 / 11	100
GeneProof <i>L.pneumophila</i> [21] (n = 5)	15	15 / 15	100	5	5 / 5	100
r-Biopharm RIDAGENE [22] (n = 6)	14	14 / 18	78	6	6 / 6	100
Other commercial tests [27] (n= 56)	134	134/ 166 <sup>§</sup>	81	55	55 / 56	98
<i>In house</i> PCR assay [28] (n= 42)	101	101/ 125 <sup>§</sup>	81	41	41 / 42	98
Anderer/ k.A. / <i>other</i> [29] (n = 2)	5	5 / 6	83	2	2 / 2	100

<sup>§</sup> 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:** <sup>1)</sup> As sample #1715363 contained a low number of *Legionella pneumoniae* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.

## PCR-/NAT *Salmonella enterica* (RV 537) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715371	+++	61	<i>S. enterica</i> ser. typhimurium (~ 5x10 <sup>4</sup> CFU/mL)
1715372	+	61	<i>S. enterica</i> ser. typhimurium (~ 5x10 <sup>2</sup> CFU/mL)
1715373	∅	62	<i>Escherichia coli</i> K12
1715374	++	61	<i>S. enterica</i> ser. typhimurium (~ 5x10 <sup>3</sup> CFU/mL)

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

<i>n = 27</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1715371	1715372	1715373	1715374		1715371	1715372	1715373	1715374
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	27	21	2	25	n.d.	0	0	0	0
<b>Negativ</b>	0	6 <sup>1)</sup>	25	2	nein <i>no</i>	27	27	27	27
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
Other commercial tests [27] (n = 18)	49	49 / 54	91	17	17 / 18	94
In house PCR assay [28] (n = 8)	22	22 / 24	92	7	7 / 8	88
Anderer/ k.A. / other [29] (n = 1)	2	2 / 3	67	1	1 / 1	100

**Comments:** <sup>1)</sup> As sample #1715372 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) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715381	+++	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 <sup>4</sup> CFU/mL)
1715382	∅	62	<i>Escherichia coli</i> K12
1715383	++	61 /71	<i>Listeria monocytogenes</i> (~ 5x10 <sup>3</sup> CFU/mL)
1715384	+++	61 /72	<i>Listeria ivanovii</i> (~ 5x10 <sup>4</sup> CFU/mL)

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

<i>n = 46</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1715381	1715382	1715383	1715384		1715381	1715382	1715383	1715384
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	46	0	45	10	n.d.	0	0	0	0
<b>Negativ</b>	0	46	1	35 <sup>1)</sup>	nein <i>no</i>	46	46	46	46
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
TIB Molbiol LightMix LM [21] (n = 2)	4	4 / 6	67	2	2 / 2	100
Ingenetix BactoReal LM [22] (n = 4)	9	9 / 12	75	4	4 / 4	100
Other commercial tests [27] (n = 12)	25	25 / 36	69	12	12 / 12	100
<i>In house</i> PCR assay [28] (n = 28)	64	64 / 83 §	77	28	28 / 28	100
Anderer/ k.A. / other [29] (n = 1)	2	2 / 3	67	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*

**Comments:** <sup>1)</sup> Due to the predominant use of *L. monocytogenes*-specific PCR assays, negative PCR results with sample # 1715384 were not rated as “false negative”.

# PCR-/NAT MRSA / cMRSA (RV 539) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715391	++	61 / 72	MRSA ( <i>S. aureus</i> , oxa <sup>R</sup> , PVL-neg) (~1x10 <sup>4</sup> CFU/mL)
1715392	∅	62 / 72	MSSA ( <b>SCCmec pos, mecA neg</b> ) ( <i>S. aureus</i> , oxa <sup>S</sup> , PVL-neg, spa:t 310) (~ 1x10 <sup>4</sup> CFU/mL)
1715393	∅	62	<i>Escherichia coli</i> K12
1715394	+++	61 / 72	MRSA ( <i>S. aureus</i> , oxa <sup>R</sup> , PVL-neg) (~1x10 <sup>5</sup> CFU/mL)

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

<i>n = 302</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1715391</i>	<i>1715392</i>	<i>1715393</i>	<i>1715394</i>		<i>1715391</i>	<i>1715392</i>	<i>1715393</i>	<i>1715394</i>
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	301	47	3	298	n.d.	2	2	2	2
<b>Negativ</b>	1	254	296	3	nein <i>no</i>	300	300	299	300
<b>Fraglich</b> <i>Questionable</i>	0	1	3	1	ja <i>yes</i>	0	0	1	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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
BD MAX/BD GeneOhm MRSA [20] (n=42)	82	82 / 84	98	76	76 / 84	90
Hain FT MRSA [21] (n=29)	58	58 / 58	100	52	52 / 58	90
Roche COBAS [22] (n=1)	2	2 / 2	100	1	1 / 2	50
r-Biopharm RIDAGENE [23] (n=32)	64	64 / 64	100	61	61 / 63 §	97
Cepheid Xpert / GeneXpert [24] (n=131)	261	261 / 262	99	255	255 / 260§	98
LC MRSA Advanced (Roche) [25] (n=14)	27	27 / 27 §	100	15	15 / 27 §	56
TIB Molbiol LightMix MRSA [26] (n=2)	4	4 / 4	100	3	3 / 4	75
Commercial assay kit [27] (n=22)	44	44 / 44	100	39	39 / 44	89
<i>In house</i> PCR assay [28] (n=25)	50	50 / 50	100	41	41 / 50	82
Andere / k.A. / other [29] (n=18)	35	35 / 36	97	34	34 / 36	94

§ 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) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715401	∅	62	<i>Escherichia coli</i> K12
1715402	+++	61	<i>Chlamydia pneumoniae</i> (~ 5x10 <sup>5</sup> IFU/mL)
1715403	+	61	<i>Chlamydia pneumoniae</i> (~ 1x10 <sup>4</sup> IFU/mL)
1715404	++	61	<i>Chlamydia pneumoniae</i> (~ 5x10 <sup>4</sup> IFU/mL)

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

<i>n = 134</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1715401</i>	<i>1715402</i>	<i>1715403</i>	<i>1715404</i>		<i>1715401</i>	<i>1715402</i>	<i>1715403</i>	<i>1715404</i>
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	1	134	129	132	n.d.	1	1	1	1
<b>Negativ</b>	133	0	4	2	nein <i>no</i>	133	133	133	133
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
TIB Molbiol LightMix CP [21] (n = 14)	42	42 / 42	100	14	14 / 14	100
Diagenode MP/CP [22] (n = 8)	23	23 / 24	96	8	8 / 8	100
AmpliGnost CP PCR Kit [23] (n = 6)	17	17 / 18	94	6	6 / 6	100
Other commercial tests [27] (n = 63)	186	186 / 188 §	99	62	62 / 63	98
<i>In house</i> PCR assay [28] (n = 42)	124	124 / 126	98	42	42 / 42	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.*



# PCR-/NAT *Mycoplasma pneumoniae* (RV 541) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715411	∅	62	<i>Escherichia coli</i> K12
1715412	+++	61	<i>Mycoplasma pneumoniae</i> (~ 1x10 <sup>5</sup> genome copies/mL)
1715413	++	61	<i>Mycoplasma pneumoniae</i> (~ 1x10 <sup>4</sup> genome copies/mL)
1715414	∅	62	<i>Haemophilus influenzae</i> (~ 1x10 <sup>4</sup> CFU/mL)

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

<i>n = 149</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1715411</i>	<i>1715412</i>	<i>1715413</i>	<i>1715414</i>		<i>1715411</i>	<i>1715412</i>	<i>1715413</i>	<i>1715414</i>
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	0	149	133	2	n.d.	1	1	1	1
<b>Negativ</b>	149	0	15	147	nein <i>no</i>	148	148	148	148
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
LightMix <i>M.pneumoniae</i> [20] (n = 15)	26	26 / 29 §	90	30	30 / 30	100
Minerva Biolabs Venor Mp [22] (n = 1)	2	2 / 2	100	2	2 / 2	100
AmpliGnost MP PCR Kit [23] (n = 5)	10	10 / 10	100	10	10 / 10	100
Diagenode MP/CP [24] (n = 7)	13	13 / 14	93	13	13 / 14	93
r-Biopharm RIDAGENE Mp [25] (n = 7)	13	13 / 14	93	14	14 / 14	100
Commercial assay / kit [27] (n = 67)	127	127 / 134	95	133	133 / 134	99
In house PCR assay [28] (n = 46)	88	88 / 92	96	92	92 / 92	100
Andere / 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.*



# PCR-/NAT *C. burnetii* & *B. anthracis* (RV 542) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715421	+++ / +++	62	<i>Coxiella burnetii</i> (~ 1x10 <sup>5</sup> genome copies/mL) <i>B. anthracis</i> UR-1 Stamm (~ 1x10 <sup>5</sup> genome copies/mL)
1715422	∅ / ∅	64	<i>Escherichia coli</i> K12
1715423	++ / ∅	61	<i>Coxiella burnetii</i> (~ 1x10 <sup>4</sup> genome copies/mL)
1715424	∅ / ++++	63	<i>B. anthracis</i> Stamm STI* (~ 1x10 <sup>6</sup> genome copies/mL)

\* *B. anthracis* Stamm STI: *rpoB* (*dhp61*)- und *pagA*-positiv aber *capB* 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> = 39	Probennummer (Sample no.)				Inhibition				
	1715421	1715422	1715423	1715424	1715421	1715422	1715423	1715424	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	39	0	38	0	n.d.	0	0	0	0
<b>Negativ</b>	0	39	0	39	nein <i>no</i>	39	39	39	39
<b>Fraglich</b> <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. 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 = 11)	22	22 / 22	100	22	22 / 22	100
In house PCR assay [28] (n = 32)	63	63 / 64 §	98	64	64 / 64	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.*

§ 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> = 22	Probennummer (Sample no.)				Inhibition				
	1715421	1715422	1715423	1715424	1715421	1715422	1715423	1715424	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	22	0	0	22	n.d.	0	0	0	0
<b>Negativ</b>	0	22	22	0	nein <i>no</i>	22	22	22	22
<b>Fraglich</b> <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 ***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)	6	6 / 6	100	6	6 / 6	100
Commercial assay / kit [27] (n = 5)	10	10 / 10	100	10	10 / 10	100
In house PCR assay [28] (n = 20)	40	40 / 40	100	40	40 / 40	100

\* 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:** <sup>1)</sup> Twenty two of the 44 participants performed only *Coxiella burnetii* detection, 5 of the 44 participants performed only *Bacillus anthracis*-specific assays, whereas the other 17 laboratories reported the use of PCR/NAT assays to detected both species.

# PCR-/NAT *Francisella tularensis* (RV 543) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715431	+++	61	<i>Francisella tularensis tularensis</i> (~ 1x10 <sup>5</sup> CFU/mL)
1715432	++	61	<i>Francisella tularensis holarctica</i> (~ 1x10 <sup>4</sup> CFU/mL)
1715433	∅	62	<i>Escherichia coli</i> K12
1715434	+++	61	<i>Francisella tularensis novicida</i> (~ 1x10 <sup>5</sup> CFU/mL)

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

<i>n</i> = 26	Probennummer (Sample no.)				Inhibition					
Befund <i>Result</i>	1715431	1715432	1715433	1715434	1715431	1715432	1715433	1715434		
Positiv	25	18	0	24	n.d.	0	0	0	0	
Negativ	1	7 <sup>1)</sup>	26	2	nein <i>no</i>	26	26	26	26	
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.**  
*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)	12	12 / 15	80	5	5 / 5	100
Commercial assay / kit [27] (n = 2)	4	4 / 6	67	2	2 / 2	100
In house PCR assay [28] (n = 17)	47	47 / 51 §	94	17	17 / 17	100
Andere / k.A. / other [29] (n = 2)	4	4 / 6	67	2	2 / 2	100

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

**Comments:** <sup>1)</sup> As sample #1715432 contained a low number of *F. tularensis* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.

# PCR-/NAT Carbapenemasen (RV 544) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715441	+++	61 / 72	<i>K. pneumoniae</i> VIM-2 (~ 1x10 <sup>7</sup> genome copies/mL)
1715442	+++	61 / 71,73	<i>K. pneumoniae</i> KPC-2, OXA-48 (~ 1x10 <sup>7</sup> genome copies/mL)
1715443	∅	62	<i>Escherichia coli</i> K12
1715444	+++	61 / 75	<i>S. marcescens</i> NDM-1 (~ 1x10 <sup>7</sup> genome copies/mL)

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

<i>n</i> = 77	Probennummer (Sample no.)				Inhibition				
Befund <i>Result</i>	1715441	1715442	1715443	1715444	1715441	1715442	1715443	1715444	
Positiv	74	75 <sup>2)</sup>	2 <sup>3)</sup>	76	n.d.	1	1	1	1
Negativ	3 <sup>1)</sup>	1	75	1 <sup>4)</sup>	nein no	76	76	76	76
Fraglich <i>Questionable</i>	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>	%
Check MDR Caba test [20] (n=2)	6	6 / 6	100	2	2 / 2	100
Check direct CPE oder MDR [21] (n=7)	20	20 / 21	95	6	6 / 7	86
Hyplex Superbug [22] (n=1)	3	3 / 3	100	1	1 / 1	100
Hyplex Eazyplex [23] (n=5)	14	14 / 15	93	5	5 / 5	100
LightMix (TIB Molbiol) [24] (n=6)	18	18 / 18	100	6	6 / 6	100
GeneXpert CarbaR [25] (n=37)	111	111 / 111	100	37	37 / 37	100
Commercial assay / kit [27] (n=8)	22	22 / 23 §	96	8	8 / 8	100
<i>In house</i> PCR assay [28] (n=15)	43	43 / 45	96	14	14 / 15	93

§ 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) Three participants have missed the VIM-2 gene in sample # 1715441.
  - 2) Six participants have missed the KPC-2 gene in sample # 1715442.
  - 3) One participant reported a false-positive result for KPC in sample # 1715443.
  - 4) One participant has missed the NDM-1 gene in sample # 1715444.

# PCR-/NAT *Clostridium difficile* (RV 545) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715451	+++	61 / 71,72	<i>Clostridium difficile</i> O27 deletion (~ 1x10 <sup>5</sup> CFU/mL)
1715452	∅	62	<i>Escherichia coli</i> K12
1715453	++	61 / 71,72	<i>Clostridium difficile</i> O27 deletion (~ 1x10 <sup>4</sup> CFU/mL)
1715454	++	61 / 71,72	<i>Clostridium difficile</i> O27 deletion (~ 1x10 <sup>4</sup> CFU/mL)

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

<i>n = 130</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1715451	1715452	1715453	1715454		1715451	1715452	1715453	1715454
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	130	4	128	129	n.d.	1	1	1	1
<b>Negativ</b>	0	126	2	1	nein <i>no</i>	129	129	129	129
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
Cepheid Xpert <i>C.difficile</i> [20] (n=41)	121	121 / 123	98	41	41 / 41	100
BD MAX <i>C.difficile</i> [21] (n =14)	42	42 / 42	100	14	14 / 14	100
r-Biopharm RIDAGENE Cdif [22] (n =16)	48	48 / 48	100	16	16 / 16	100
Commercial assay / kit [27] (n =40)	119	119 / 120	99	38	38 / 40	95
<i>In house</i> PCR assay [28] (n = 17)	51	51 / 51	100	16	16 / 17	94
Andere / k.A. / other [29] (n = 5)	15	15 / 15	100	4	4 / 5	80

\* 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 VRE**  
(RV 546) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715461	++	61 / 71	<i>Enterococcus faecalis</i> <b>vanA</b> (~ 1x10 <sup>5</sup> CFU/mL)
1715462	+++	61 / 72	<i>Enterococcus faecium</i> <b>vanB</b> (~ 1x10 <sup>5</sup> CFU/mL)
1715463	+++	62 / 71	<i>E. avium</i> <b>vanA</b> (~ 1x10 <sup>5</sup> CFU/mL)
1715464	∅	62	<i>Escherichia coli</i> K12

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

<i>n = 50</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<b>1715461</b>	<b>1715462</b>	<b>1715463</b>	<b>1715464</b>		<b>1715461</b>	<b>1715462</b>	<b>1715463</b>	<b>1715464</b>
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	48 <sup>1)</sup>	47 <sup>1)</sup>	43 <sup>1)</sup>	0	n.d.	1	1	1	1
<b>Negativ</b>	2	3	7	50	nein <i>no</i>	49	49	49	49
<b>Fraglich</b> <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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>			<b>NAT richtig negativ</b> <i>True negative results</i>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
Cepheid Xpert vanA / vanB [20] (n=15)	<b>44</b>	44 / 45	<b>98</b>	<b>15</b>	15 / 15	<b>100</b>
Commercial assay / kit [27] (n =20)	<b>57</b>	57 / 60	<b>95</b>	<b>20</b>	20 / 20	<b>100</b>
In house PCR assay [28] (n = 14)	<b>37</b>	37 / 42	<b>88</b>	<b>14</b>	14 / 14	<b>100</b>
Andere / k.A. / other [29] (n = 1)	<b>0</b>	0 / 3	<b>0</b>	<b>1</b>	1 / 1	<b>100</b>

**Comments:** <sup>1)</sup> Forty seven participants reported dedicated vanA / vanB identification. All reported results were correct.



# PCR-/NAT *Pneumocystis jirovecii* (RV 560) Juni 2017



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1715601	+++	61	<i>Pneumocystis jirovecii</i> (~ 1x10 <sup>5</sup> CFU/mL)
1715602	∅	62	<i>Escherichia coli</i> K12
1715603	++	61	<i>Pneumocystis jirovecii</i> (~ 1x10 <sup>4</sup> CFU/mL)
1715604	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 102	Probennummer (Sample no.)				Inhibition				
	1715601	1715602	1715603	1715604	1715601	1715602	1715603	1715604	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	102	1	100	1	n.d.	0	0	0	0
<b>Negativ</b>	0	101	1	100	nein <i>no</i>	102	102	102	102
<b>Fraglich</b> <i>Questionable</i>	0	0	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>	%
TIB Molbiol LightMix PJ [21] (n =13)	26	26 / 26	100	26	26 / 26	100
r-Biopharm RIDAGENE PJ [22] (n =19)	38	38 / 38	100	36	36 / 37 §	97
AmpliGnost PJ PCR Kit [23] (n =7)	14	14 / 14	100	14	14 / 14	100
Sacace PJ RealTM [24] (n =3)	6	6 / 6	100	6	6 / 6	100
Commercial assay / kit [27] (n =14)	28	28 / 28	100	28	28 / 28	100
<i>In house</i> PCR assay [28] (n = 45)	88	88 / 89 §	99	89	89 / 90	99
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.