

Anhang 1: Ergebnisse der Ringversuchsserie „Bakterien- und Pilzgenom-Nachweis (PCR/NAT)“ 2013

Anhang 1 zu: *Reischl U, Straube E, Maaß M, Jacobs E, Schneider W, Fingerle V, Busch U, Frangoulidis D, Splettstösser W, Grass G, Reiter-Owona I. Bakterien- und Pilzgenom-Nachweis PCR/NAT: Auswertung des Ringversuchs Mai 2013 von INSTAND e.V. zur externen Qualitätskontrolle molekularbiologischer Nachweisverfahren in der bakteriologischen Diagnostik. GMS Z Forder Qualitätssich Med Lab. 2013;4:Doc03. DOI: 10.3205/lab000010, URN: urn:nbn:de:0183-lab0000102*

Attachment 1: Results of the proficiency testing scheme “Bacterial and Fungal Genome Detection (PCR/NAT)” 2013

Attachment 1 to: *Reischl U, Straube E, Maaß M, Jacobs E, Schneider W, Fingerle V, Busch U, Frangoulidis D, Splettstösser W, Grass G, Reiter-Owona I. Bakterien- und Pilzgenom-Nachweis PCR/NAT: Auswertung des Ringversuchs Mai 2013 von INSTAND e.V. zur externen Qualitätskontrolle molekularbiologischer Nachweisverfahren in der bakteriologischen Diagnostik. GMS Z Forder Qualitätssich Med Lab. 2013;4:Doc03. DOI: 10.3205/lab000010, URN: urn:nbn:de:0183-lab0000102*

**PCR-/NAT *C. trachomatis* & GO
(RV 530) Mai 2013**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315301	++/+	62	<i>Chlamydia trachomatis</i> (~ 5x10 ³ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 1x10 ³ CFU/mL)
1315302	∅/++	63	<i>Neisseria gonorrhoeae</i> (~ 1x10 ⁴ CFU/mL)
1315303	+/∅	61	<i>Chlamydia trachomatis</i> (~ 1x10 ³ IFU/mL)
1315304	∅/++	63	<i>Neisseria gonorrhoeae</i> (~ 1x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 170</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
<i>Befund Result</i>	1315301	1315302	1315303	1315304	1315301	1315302	1315303	1315304	
Positiv CT	22	0	164	0	n.d.	0	0	0	0
Positiv CT & GO	140	0	2	1	nein/no	170	170	170	170
Positiv GO	4	166	0	165	ja/yes	0	0	0	0
Negativ	3	4	3	4					
Fraglich /questionable	1	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.

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)	28	28/36	78	0	0/0	0
LightMix CT/NG [21] (n = 12)	47	47/48	98	0	0/0	0
Roche COBAS [22] (n = 34)	128	128/136	94	0	0/0	0
Cepheid Xpert CT/NG [23] (n = 2)	7	7/8	88	0	0/0	0
BD ProbeTec [24] (n = 20)	77	77/80	96	0	0/0	0
Artus CT [25] (n = 4)	15	15/16	94	0	0/0	0
Abbott RealTime CT/NG [26] (n =32)	128	128/128	100	0	0/0	0
Other commercial tests [27] (n = 46)	171	171/184	93	0	0/0	0
<i>In house</i> PCR assay [28] (n = 18)	66	66/70 §	94	0	0/0	0
Andere/k.A./other [29] (n = 9)	31	31/36	86	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 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 <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)	18	18/18	100	18	18/18	100
LightMix CT/NG [21] (n = 12)	24	24/24	100	24	24/24	100
Roche COBAS [22] (n = 34)	67	67/68	99	68	68/68	100
Cepheid Xpert CT/NG [23] (n = 2)	3	3/4	75	4	4/4	100
BD ProbeTec [24] (n = 20)	38	38/40	95	40	40/40	100
Artus CT [25] (n = 4)	8	8/8	100	8	8/8	100
Abbott RealTime CT/NG [26] (n =32)	64	64/64	100	64	64/64	100
Other commercial tests [27] (n = 46)	86	86/92	93	92	92/92	100
<i>In house</i> PCR assay [28] (n = 18)	34	34/36	94	36	36/36	100
Andere/k.A./other [29] (n = 9)	18	18/18	100	17	17/18	94

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

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 (nur GO) [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)	19	19/27	70	9	9/9	100
LightMix CT/NG [21] (n = 12)	35	35/36	97	12	12/12	100
Roche COBAS [22] (n = 34)	94	94/102	92	34	34/34	100
Cepheid Xpert CT/NG [23] (n = 2)	6	6/6	100	2	2/2	100
BD ProbeTec [24] (n = 20)	59	59/60	98	20	20/20	100
Artus CT [25] (n = 4)	11	11/12	92	4	4/4	100
Abbott RealTime CT/NG [26] (n =32)	96	96/96	100	32	32/32	100
Other commercial tests [27] (n = 46)	129	129/138	93	44	44/46	96
<i>In house</i> PCR assay [28] (n = 18)	51	51/53 §	96	17	17/17 §	100
Andere/k.A./other [29] (n = 9)	22	22/27	81	9	9/9	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) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315311	∅	62	<i>Escherichia coli</i> K12
1315312	++	61	<i>Chlamydia trachomatis</i> (~ 5x10 ³ IFU/mL)
1315313	∅	62	<i>Escherichia coli</i> K12
1315314	+	61	<i>Chlamydia trachomatis</i> (~ 1x10 ³ IFU/mL)

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

<i>n</i> = 115	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1315311	1315312	1315313	1315314	1315311	1315312	1315313	1315314	
Befund <i>Result</i>									
Positiv	2	115	1	113	n.d.	2	2	2	2
Negativ	112	0	112	2	nein <i>no</i>	112	113	112	113
Fraglich <i>Questionable</i>	1	0	2	0	ja <i>yes</i>	1	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.

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 GenoQuick CT [20] (n = 20)	38	38/40	95	36	36/39 §	92
TIB Molbiol LightMix CT [21] (n = 3)	6	6/6	100	6	6/6	100
Roche COBAS CT [22] (n = 32)	64	64/64	100	64	64/64	100
Cepheid Xpert CT/NG [23] (n = 3)	6	6/6	100	4	4/4 §	100
BD ProbeTec [24] (n = 14)	28	28/28	100	28	28/28	100
Artus CT [25] (n = 10)	20	20/20	100	20	20/20	100
Abbott CT/NG [26] (n = 4)	8	8/8	100	8	8/8	100
Other commercial tests [27] (n = 15)	30	30/30	100	30	30/30	100
<i>In house</i> PCR assay [28] (n = 13)	26	26/26	100	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.

PCR-/NAT *Bordetella pertussis* (RV 532) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315321	∅	62	<i>Escherichia coli</i> K12
1315322	+++	61	<i>Bordetella pertussis</i> (~ 1x10 ⁵ CFU/mL)
1315323	+	61	<i>Bordetella pertussis</i> (~ 1x10 ³ CFU/mL)
1315324	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 145	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1315321	1315322	1315323	1315324	1315321	1315322	1315323	1315324	
Befund <i>Result</i>									
Positiv	1	145	139	2	n.d.	3	3	3	3
Negativ	144	0	6	142	nein <i>no</i>	142	142	142	142
Fraglich <i>Questionable</i>	0	0	0	1	ja <i>yes</i>	0	0	0	0

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>			NAT richtig negativ <i>True negative results</i>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
TIB Molbiol LightMix BP [20] (n =15)	29	29/30	96	28	28/29 §	97
Diagenode <i>B.pertussis</i> [21] (n = 5)	10	10/10	100	10	10/10	100
GenoQuick <i>Bordetella</i> [22] (n = 11)	22	22/22	100	22	22/22	100
Other commercial tests [27] (n = 43)	86	86/86	100	85	85/86	99
<i>In house</i> PCR assay [28] (n = 69)	135	135/138	98	136	136/137 §	99
<i>Andere/k.A./other</i> [29] (n = 4)	6	6/8	75	8	8/8	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 *Helicobacter pylori* (RV 533) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315331	+++	61/72	<i>Helicobacter pylori</i> (~ 1x10 ⁶ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1315332	∅	62	<i>Escherichia coli</i> K12
1315333	+	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin resistant (GGA +GTA mut. in 23S rDNA)
1315334	∅	62	<i>Campylobacter jejuni</i> (~ 1x10 ⁵ CFU/mL)

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

<i>n = 48</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1315331	1315332	1315333	1315334		1315331	1315332	1315333	1315334
Befund <i>Result</i>									
Positiv	48 ¹⁾	1	48 ¹⁾	0	n.d.	1	1	1	1
Negativ	0	47	0	48	nein <i>no</i>	47	47	47	47
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

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

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

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>			NAT richtig negativ <i>True negative results</i>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Hain GenoType Helico [25] (n = 8)	16	16/16	100	15	15/16	94
Ingenetix ClariRes [26] (n = 2)	4	4/4	100	4	4/4	100
Commercial assay [27] (n = 9)	18	18/18	100	18	18/18	100
<i>In house</i> PCR assay [28] (n = 28)	56	56/56	100	56	56/56	100
Andere/k.A./other [29] (n = 1)	2	2/2	100	2	2/2	100

Comments:

¹⁾ Thirty two of the 48 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 5 laboratories, all reported results were correct.

PCR-/NAT EHEC/STEC (RV 534) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315341	∅	62	<i>Salmonella enterica serovar typhi</i> (~1x10 ⁴ CFU/mL)
1315342	∅	62	<i>Escherichia coli</i> K12 (negative for <i>eae</i> and <i>hlyA</i>)
1315343	++	61/72,73	EHEC (~1x10 ⁴ CFU/mL) (<i>stx-2c</i> and EAEC positive)
1315344	+++	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)

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

<i>n</i> = 110	Probennummer (Sample no.)				Inhibition				
	1315341	1315342	1315343	1315344	1315341	1315342	1315343	1315344	
Befund <i>Result</i>									
Positiv	0	1	103 ¹⁾	107 ¹⁾	n.d.	3	3	3	3
Negativ	110	109	5	3	nein <i>no</i>	107	107	107	107
Fraglich <i>Questionable</i>	0	0	2	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 = 27)	51	51/52 §	98	54	54/54	100
Hyplex EHEC [21] (n = 6)	11	11/12	92	11	11/12	92
r-Biopharm RIDAGENE [22] (n = 14)	24	24/28	86	28	28/28	100
Other commercial tests [27] (n = 9)	17	17/18	94	18	18/18	100
<i>In house</i> PCR assay [28] (n = 52)	104	104/104	100	104	104/104	100
Anderer/ k.A./other [29] (n = 2)	3	3/4	75	4	4/4	100

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

Comments:

¹⁾ Partial or complete shiga-toxin subtyping, *eae*-, and *hlyA*-detection was performed by 99 laboratories.

PCR-/NAT *Borrelia burgdorferi* (RV 535) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315351	+	61	<i>Borrelia garinii</i> OspA Typ3 (~1x10 ⁴ organisms/mL)
1315352	++	61	<i>Borrelia garinii</i> OspA Typ3 (~1x10 ⁵ organisms/mL)
1315353	+++	61	<i>Borrelia garinii</i> OspA Typ3 (~1x10 ⁶ organisms/mL)
1315354	(+)	61	<i>Borrelia garinii</i> OspA Typ3 (~1x10 ³ organisms/mL)

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

<i>n = 119</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1315351	1315352	1315353	1315354		1315351	1315352	1315353	1315354
Befund Result									
Positiv	108	112	117	83	n.d.	2	2	2	2
Negativ	10	6	2	33¹⁾	nein no	117	117	117	117
Fraglich Questionable	1	1	0	3¹⁾	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>	%
artus <i>Borrelia</i> LC Kit [20] (n = 21)	84	84/84	100	0	0/0	0
Demeditec GenFlow [21] (n = 9)	33	33/36	92	0	0/0	0
LightMix <i>Borrelia</i> [22] (n = 4)	12	12/16	75	0	0/0	0
Other/commercial tests [27] (n = 27)	95	95/106 §	90	0	0/0	0
<i>In house</i> PCR assay [28] (n = 57)	192	192/225 §	85	0	0/0	0
Anderel/ k.A./other [29] (n = 1)	4	4/4	100	0	0/0	0

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

Comments:

¹⁾ As sample #1315374 contained a very low number of *B. garinii* target organisms, negative PCR results were not rated as "false negative", but the participants may consider to improve the analytical sensitivity of their corresponding PCR assays.

PCR-/NAT *Legionella pneumophila* (RV 536) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315361	∅	62	<i>Escherichia coli</i> K12
1315362	∅	62	<i>Legionella micdadei</i> (~ 5x10 ⁴ CFU/mL)
1315363	++	61	<i>Legionella pneumophila</i> SG3 (~ 1x10 ⁵ CFU/mL)
1315364	+	61	<i>Legionella pneumophila</i> SG3 (~ 1x10 ⁴ CFU/mL)

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

<i>n</i> = 98	Probennummer (Sample no.)				Inhibition				
	1315361	1315362	1315363	1315364	1315361	1315362	1315363	1315364	
Befund <i>Result</i>									
Positiv	1	6	98	92	n.d.	2	2	2	2
Negativ	96	91	0	5	nein <i>no</i>	95	95	96	95
Fraglich <i>Questionable</i>	1	1	0	1	ja <i>yes</i>	1	1	0	1

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 Legionella [25] (n = 8)	16	16/16	100	16	16/16	100
GeneProof <i>L.pneumophila</i> [26] (n = 3)	6	6/6	100	6	6/6	100
Other commercial tests [27] (n= 32)	62	62/63 §	98	62	62/62 §	100
<i>In house</i> PCR assay [28] (n= 53)	103	103/106	97	99	99/106	93
Andere/k.A./other [29] (n= 4)	7	7/8	88	8	8/8	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.

PCR-/NAT *Salmonella enterica* (RV 537) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315371	++	61	<i>S. enterica</i> ser. Typhi (~ 1x10 ⁵ CFU/mL)
1315372	+	61	<i>S. enterica</i> ser. Typhi (~ 1x10 ⁴ CFU/mL)
1315373	∅	62	<i>Escherichia coli</i> K12
1315374	++	61	<i>S. enterica</i> ser. Enteritidis (~ 5x10 ⁵ CFU/mL)

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

<i>n = 11</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1315371</i>	<i>1315372</i>	<i>1315373</i>	<i>1315374</i>		<i>1315371</i>	<i>1315372</i>	<i>1315373</i>	<i>1315374</i>
Befund <i>Result</i>									
Positiv	11	9	1	10	n.d.	0	0	0	0
Negativ	0	2	10	1	nein <i>no</i>	11	11	11	11
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>	%
Other commercial tests [27] (n = 2)	6	6/6	100	2	2/2	100
In house PCR assay [28] (n = 8)	21	21/24	88	7	7/8	88
Andere/k.A./other [29] (n= 1)	3	3/3	100	1	1/1	100

**PCR-/NAT *Listeria spp.*
(RV 538) Mai 2013**



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315381	+++	61 /72	<i>Listeria ivanovii</i>
1315382	Ø	62	<i>Escherichia coli</i> K12
1315383	Ø	62	<i>Escherichia coli</i> K12
1315384	+	61 /71	<i>Listeria monocytogenes</i> (~ 1x10 ⁴ CFU/mL)

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

<i>n</i> = 31	Probennummer (Sample no.)					Inhibition			
	1315381	1315382	1315383	1315384		1315381	1315382	1315383	1315384
Befund <i>Result</i>									
Positiv	3	0	0	30	n.d.	0	0	0	0
Negativ	27 ¹⁾	30	31	1	nein <i>no</i>	31	31	31	31
Fraglich <i>Questionable</i>	1	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>	%
TIB Molbiol LightMix LM [21] (n = 2)	2	2/4	50	4	4/4	100
Ingenetix BactoReal LM [22] (n = 1)	1	1/2	50	2	2/2	100
Other commercial tests [27] (n = 4)	3	3/7 §	43	8	8/8	100
<i>In house</i> PCR assay [28] (n = 23)	25	25/46	54	45	45/45 §	100
Anderer/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.

Comments:

¹⁾ Due to the predominant use of *L. monocytogenes*-specific PCR assays, negative PCR results with sample # 1315381 were not rated as "false negative".

**PCR-/NAT MRSA/cMRSA
(RV 539) Mai 2013**



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315391	+++	61/72	MRSA (<i>S. aureus</i> , oxa ^R , PVL-neg) (~ 1x10 ⁴ CFU/mL)
1315392	∅	62	<i>Escherichia coli</i> K12
1315393	+	61/72	LaMRSA (<i>S. aureus</i> , oxa ^R , PVL-neg) (~ 1x10 ³ CFU/mL)
1315394	∅	62/74	CoNS (<i>S. haemolyticus</i> , oxa ^R) (~ 1x10 ⁴ CFU/mL)

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

<i>n = 259</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>1315391</i>	<i>1315392</i>	<i>1315393</i>	<i>1315394</i>		<i>1315391</i>	<i>1315392</i>	<i>1315393</i>	<i>1315394</i>
Befund <i>Result</i>									
Positiv	256 ¹⁾	1	246 ¹⁾	7	n.d.	0	0	0	0
Negativ	2	257	10 ²⁾	252	nein <i>no</i>	258	258	259	259
Fraglich <i>Questionable</i>	1	1	3 ²⁾	0	ja <i>yes</i>	1	1	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 GeneOhm MRSA [20] (n=29)	57	57/58	98	57	57/58	98
GT MRSA Direct/GQ MRSA [21] (n=39)	77	77/78	99	78	78/78	100
Hyplex <i>StaphyloResist</i> [22] (n=5)	10	10/10	100	10	10/10	100
LightCycler Kits [23] (n=5)	10	10/10	100	10	10/10	100
Cepheid Xpert/GeneXpert [24] (n=85)	169	169/169 [§]	100	167	167/169 [§]	99
LC MRSA Advanced (Roche) [25] (n=28)	54	54/54 [§]	100	56	56/56	100
TIB Molbiol LightMix MRSA [26] (n=1)	1	1/2	50	2	2/2	100
Commercial assay kit [27] (n=27)	52	52/53 [§]	98	53	53/54	98
<i>In house</i> PCR assay [28] (n=39)	73	73/78	94	74	74/78	95
Anderer/k.A./other [29] (n=16)	29	29/32	91	32	32/32	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.

Comments:

- 1) A dedicated cMRSA identification (lukFS gene detection) was performed by some laboratories, but obviously only positive results (if observed) were reported. With the exception of 1 laboratory, all reported results for cMRSA were correct.
- 2) As sample #1315393 contained this time a low number of MRSA target organisms, negative PCR results were not rated as "false negative", but the participants may consider to improve the analytical sensitivity of their corresponding PCR assays.

PCR-/NAT *Chlamydia pneumoniae* (RV 540) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315401	∅	62	<i>Legionella pneumophila</i> SG3 (~ 1x10 ⁶ CFU/mL)
1315402	+++	61	<i>Chlamydia pneumoniae</i> (~ 1x10 ⁶ IFU/mL)
1315403	∅	62	<i>Escherichia coli</i> K12
1315404	(+)	61	<i>Chlamydia pneumoniae</i> (~ 1x10 ³ IFU/mL)

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

<i>n</i> = 109	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1315401	1315402	1315403	1315404	1315401	1315402	1315403	1315404	
Befund Result									
Positiv	0	109	2	104	n.d.	1	1	1	1
Negativ	109	0	107	5 ¹⁾	nein no	108	108	108	108
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>	%
TIB Molbiol LightMix CP [21] (n = 13)	26	26/26	100	26	26/26	100
Diagenode MP/CP [22] (n = 8)	15	15/16	94	16	16/16	100
AmpliGnost CP PCR Kit [23] (n = 2)	4	4/4	100	4	4/4	100
Other commercial tests [27] (n = 33)	64	64/66	97	65	65/66	98
<i>In house</i> PCR assay [28] (n = 51)	100	100/102	98	101	101/102	99
Andere/k.A./other [29] (n = 3)	6	6/6	100	6	6/6	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 #1315404 contained a very low number of *Chlamydia pneumoniae* target organisms, negative PCR results were not rated as "false negative", but the participants may consider to improve the analytical sensitivity of their corresponding PCR assays.

PCR-/NAT *Mycoplasma pneumoniae* (RV 541) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315411	∅	62	<i>Escherichia coli</i> K12
1315412	++	61	<i>Mycoplasma pneumoniae</i> (~ 10 ⁵ genome copies/mL)
1315413	+	61	<i>Mycoplasma pneumoniae</i> (~ 10 ⁴ genome copies/mL)
1315414	+++	61	<i>Mycoplasma pneumoniae</i> (~ 10 ⁶ genome copies/mL)

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

<i>n</i> = 119	Probennummer (Sample no.)				Inhibition				
	1315411	1315412	1315413	1315414	1315411	1315412	1315413	1315414	
Befund <i>Result</i>									
Positiv	1	119	109	118	n.d.	1	1	1	1
Negativ	118	0	8 ¹⁾	1	nein <i>no</i>	118	118	118	118
Fraglich <i>Questionable</i>	0	0	2 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>	%
LightMix <i>M.pneumoniae</i> [20] (n = 10)	29	29/29 [§]	100	10	10/10	100
Minerva Venor Mp [22] (n = 1)	3	3/3	100	1	1/1	100
AmpliGnost MP PCR Kit [23] (n = 2)	6	6/6	100	2	2/2	100
Diagenode MP/CP [24] (n = 9)	26	26/27	96	9	9/9	100
Commercial assay/kit [27] (n = 34)	96	96/102	94	33	33/34	97
<i>In house</i> PCR assay [28] (n = 58)	172	172/174	99	58	58/58	100
Anderer/k.A./other [29] (n = 6)	17	17/17 [§]	100	6	6/6	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⁾ As sample #1315413 contained a low number of *Mycoplasma pneumoniae* target organisms, negative PCR results were not rated "false negative", but the participants may consider to improve the analytical sensitivity of corresponding PCR assays.

**PCR-/NAT *C. burnetii* & *B. anthracis*
(RV 542) Mai 2013**



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315421	(+)/+	62	<i>Coxiella burnetii</i> (~ 1x10 ³ genome copies/mL) <i>Bacillus anthracis</i> (~ 5x10 ³ genome copies/mL)
1315422	++/∅	61	<i>Coxiella burnetii</i> (~ 1x10 ⁵ genome copies/mL)
1315423	∅/∅	64	<i>Escherichia coli</i> K12
1315424	∅/++	63	<i>Bacillus anthracis</i> (~ 5x10 ⁴ genome copies/mL)

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 = 21</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1315421	1315422	1315423	1315424	1315421	1315422	1315423	1315424	
<i>Befund Result</i>									
Positiv	20	21	0	0	n.d.	0	0	0	0
Negativ	1	0	20	21	nein <i>no</i>	21	21	21	21
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. 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 = 2)	4	4/4	100	4	4/4	100
Commercial assay/kit [27] (n = 2)	4	4/4	100	4	4/4	100
<i>In house</i> PCR assay [28] (n = 19)	37	37/38	97	37	37/37 [§]	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 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> = 10	Probennummer (Sample no.)					Inhibition			
	1315421	1315422	1315423	1315424		1315421	1315422	1315423	1315424
Befund Result									
Positiv	10	0	0	10	n.d.	0	0	0	0
Negativ	0	10	10	0	nein no	10	10	10	10
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 ***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 True positive results			NAT richtig negativ True negative results		
	Absolut Absolute	Relativ Relative	%	Absolut Absolute	Relativ Relative	%
LightMix <i>B. anthracis</i> [21] (n = 2)	4	4/4	100	4	4/4	100
Commercial assay/kit [27] (n = 2)	4	4/4	100	4	4/4	100
In house PCR assay [28] (n = 8)	16	16/16	100	16	16/16	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⁾ Thirteen of the 23 participants performed only a *Coxiella burnetii* detection, two of the 23 participants performed only *Bacillus anthracis*-specific assays, whereas the other eight laboratories detected both species.

PCR-/NAT *Francisella tularensis* (RV 543) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315431	∅	62	<i>Escherichia coli</i> K12
1315432	+++	61	<i>Francisella tularensis holarctica</i> (~ 1x10 ⁶ CFU/mL)
1315433	+	61	<i>Francisella tularensis holarctica</i> (~ 1x10 ⁴ CFU/mL)
1315434	∅	62	<i>Escherichia coli</i> K12

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

<i>n = 11</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1315431	1315432	1315433	1315434		1315431	1315432	1315433	1315434
Befund <i>Result</i>									
Positiv	0	11	9	0	n.d.	0	0	0	0
Negativ	11	0	2	11	nein <i>no</i>	11	11	11	11
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 = 4)	7	7/8	88	8	8/8	100
Commercial assay/kit [27] (n = 1)	2	2/2	100	2	2/2	100
In house PCR assay [28] (n = 8)	14	14/16	88	16	16/16	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 *Pneumocystis jirovecii* (RV 560) Mai 2013



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
1315601	+++	61	<i>Pneumocystis jirovecii</i> (~ 3x10 ⁶ genome copies/mL)
1315602	++	61	<i>Pneumocystis jirovecii</i> (~ 4x10 ⁵ genome copies/mL)
1315603	+	61	<i>Pneumocystis jirovecii</i> (~ 3x10 ⁴ genome copies/mL)
1315604	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 66	Probennummer (Sample no.)					Inhibition			
	1315601	1315602	1315603	1315604		1315601	1315602	1315603	1315604
Befund <i>Result</i>									
Positiv	66	66	65	0	n.d.	1	1	1	1
Negativ	0	0	1	66	nein <i>no</i>	65	65	65	65
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>	%
Myconostica MycAssay [20] (n =2)	6	6/6	100	2	2/2	100
TIB Molbiol LightMix PJ [21] (n =6)	18	18/18	100	6	6/6	100
AmpliGnost PJ PCR Kit [22] (n =5)	15	15/15	100	5	5/5	100
Sacace PJ RealTM [23] (n =1)	3	3/3	100	1	1/1	100
Commercial assay/kit [27] (n =10)	30	30/30	100	10	10/10	100
In house PCR assay [28] (n = 41)	122	122/123	99	41	41/41	100
Andere/k.A./other [29] (n = 1)	3	3/3	100	1	1/1	100