

Anhang 1: Ergebnisse der Ringversuchsserie „Bakterien- und Pilzgenom-Nachweis (PCR/NAT)“ November 2020

Anhang 1 zu:

Reischl U, Ehrenschwender M, Hiergeist A, Maaß M, Baier M, Frangoulidis D, Grass G, von Buttlar H, Ehmann R, Scholz H, Fingerle V, Sing A, Dumke R, Reiter-Owona I, Anders A. Bakterien- und Pilzgenom-Nachweis PCR/NAT: Auswertung des Ringversuchs November 2020 von INSTAND e.V. zur externen Qualitätskontrolle molekularbiologischer Nachweisverfahren in der bakteriologischen Diagnostik. GMS Z Forder Qualitätssich Med Lab. 2021;12:Doc02. DOI: 10.3205/lab000042, URN: urn:nbn:de:0183-lab0000426

Attachment 1: Results of the proficiency testing scheme “Bacterial and fungal genome detection (PCR/NAT)” November 2020

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**PCR/NAT *C. trachomatis* & GO
(RV 530) Nov 2020**



Table 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>	<i>Probenzusammensetzung/Sample composition</i>
2025301	∅/+	<i>Neisseria gonorrhoeae</i> (~5x10 ³ CFU/mL)
2025302	++/∅	<i>Chlamydia trachomatis</i> (~5x10 ⁴ IFU/mL)
2025303	++/++	<i>Chlamydia trachomatis</i> (~5x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~5x10 ⁴ CFU/mL)
2025304	+/(+)	<i>Chlamydia trachomatis</i> (~5x10 ³ IFU/mL) <i>Neisseria gonorrhoeae</i> (~5x10 ² CFU/mL)

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

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

<i>n=239</i>	Probennummer (Sample no.)			
Befund <i>Result</i>	2025301	2025302	2025303	2025304
Positiv	3	239	237	238
Negativ	236	0	1	1
Fraglich <i>Questionable</i>	0	0	1	0

	Inhibition			
	2025301	2025302	2025303	2025304
n.d.	3	3	3	3
nein/ <i>no</i>	236	236	236	236
ja/ <i>yes</i>	0	0	0	0

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

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

NAT-Methode [Code] (total number*)	NAT richtig-positiv <i>True-positive results</i>						NAT richtig-negativ	
	2025302		2015303		2015304		2015301	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Abbott RealTime CT (n=28)	28	100	28	100	28	100	28	100
BD MAX CT (n=13)	13	100	13	100	13	100	13	100
Cepheid Xpert CT (n=29)	29	100	27	93	29	100	27	93
HAIN FluoroType CT (n=21)	21	100	21	100	21	100	21	100
Hologic Aptima Combo 2 assay (n=11)	11	100	11	100	11	100	11	100
MIKROGEN ampliCube STD 1 (n=6)	6	100	6	100	6	100	6	100
Roche COBAS 4800 CT (n=40)	40	100	40	100	39	98	39	98
Roche COBAS 6800 CT (n=20)	20	100	20	100	20	100	20	100
Seegene Allplex STI Essential (n=16)	16	100	16	100	16	100	16	100
Sacace CT Real-TM (n=5)	5	100	5	100	5	100	5	100
LightMix CT (n=7)	7	100	7	100	7	100	7	100
Other commercial tests (n=33)	33	100	33	100	33	100	33	100
<i>In house</i> PCR assay (n=10)	10	100	10	100	10	100	10	100

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

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

<i>n=237</i>	Probennummer (Sample no.)			
Befund <i>Result</i>	2025301	2025302	2025303	2025304
Positiv	235	3	233	225
Negativ	1	234	3	12 ¹⁾
Fraglich <i>Questionable</i>	1	0	1	0

	Inhibition			
	2025301	2025302	2025303	2025304
n.d.	3	3	3	3
nein/ <i>no</i>	234	234	234	234
ja/ <i>yes</i>	0	0	0	0

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

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.

NAT-Methode [Code] (total number*)	NAT richtig-positiv <i>True-positive results</i>						NAT richtig-negativ	
	2025301		2025303		2025304		2025302	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Abbott RealTime NG (n=28)	28	100	28	100	28	100	28	100
BD MAX NG (n=13)	13	100	13	100	13	100	13	100
Cepheid Xpert NG (n=28)	28	100	26	93	28	100	27	96
HAIN FluoroType NG (n=19)	19	100	19	100	19	100	19	100
Hologic Aptima Combo 2 assay (n=11)	9	82	10	91	1	9	11	100
MIKROGEN ampliCube STD 1 (n=6)	6	100	6	100	6	100	6	100
Roche COBAS 4800 NG (n=39)	39	100	38	97	38	97	38	97
Roche COBAS 6800 NG (n=21)	21	100	21	100	21	100	21	100
Sacace CT Real-TM (n=5)	5	100	5	100	5	100	5	100
Seegene Allplex STI Essential (n=16)	16	100	16	100	16	100	16	100
LightMix NG (n=7)	7	100	7	100	7	100	7	100
Other commercial tests (n=34)	34	100	34	100	34	100	33	97
<i>In house</i> PCR assay (n=10)	10	100	10	100	9	90	10	100

Comments: ¹⁾ As sample # 2025304 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) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025311	++	61	<i>Chlamydia trachomatis</i> (~5x10 ⁴ IFU/mL)
2025312	+	61	<i>Chlamydia trachomatis</i> (~5x10 ³ IFU/mL)
2025313	++	61	<i>Chlamydia trachomatis</i> (~5x10 ⁴ IFU/mL)
2025314	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=51</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
<i>Befund Result</i>	2025311	2025312	2025313	2025314	2025311	2025312	2025313	2025314	
Positiv	51	51	51	0	n.d.	0	0	0	0
Negativ	0	0	0	51	nein no	51	51	51	51
Fraglich <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

NAT-Methode [Code] (total number*)	NAT richtig-positiv <i>True-positive results</i>						NAT richtig-negativ	
	2025311		2025312		2025313		2025314	
	<i>Absolut Absolute</i>	%	<i>Absolut Absolute</i>	%	<i>Absolut Absolute</i>	%	<i>Absolut Absolute</i>	%
BD MAX CT (n=3)	3	100	3	100	3	100	3	100
BD ProbeTec (n=4)	4	100	4	100	4	100	4	100
HAIN FluoroType CT (n=9)	9	100	9	100	9	100	9	100
Cepheid Xpert CT (n=4)	4	100	4	100	4	100	4	100
GeneProof <i>C. trachomatis</i> (n=4)	4	100	4	100	4	100	4	100
LightMix CT (n=6)	6	100	6	100	6	100	6	100
Other commercial tests (n=15)	15	100	15	100	15	100	15	100
<i>In house</i> PCR assay (n=7)	7	100	7	100	7	100	7	100

**PCR/NAT *Bordetella pertussis*
(RV 532) Nov 2020**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025321	++++	61	<i>Bordetella pertussis</i> (~5x10 ⁵ CFU/mL)
2025322	∅	62	<i>Escherichia coli</i> K12
2025323	∅	62	<i>Bordetella holmesii</i> (~5x10 ⁴ CFU/mL)
2025324	+++	61	<i>Bordetella pertussis</i> (~5x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=146</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
<i>Befund Result</i>	<i>2025321</i>	<i>2025322</i>	<i>2025323</i>	<i>2025324</i>	<i>2025321</i>	<i>2025322</i>	<i>2025323</i>	<i>2025324</i>	
Positiv	145	2	91 ¹⁾	144	n.d.	1	1	1	1
Negativ	1	144	54	1	nein no	145	145	145	144
Fraglich Questionable	0	0	1 ¹⁾	1	ja yes	0	0	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>			
	2025321		2025324		2025322		2025323	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID CAP Bacteria (n=4)	4	100	4	100	4	100	0	0
BioGX Bord. Speciation plus toxin (n=4)	4	100	4	100	4	100	3	75
HAIN FluoroType Bordetella (n=10)	10	100	10	100	10	100	0	0
Diagenode B. pert./B. parapert. (n=4)	4	100	3	75	3	75	0	0
GeneProof B. pert./B. parapert. (n=5)	5	100	5	100	5	100	5	100
HOLOGIC Panther Fusion Bordet. (n=5)	5	100	5	100	5	100	1	20
ampliCube Resp. Panel 2 (n=10)	10	100	10	100	9	90	4	40
Meridian Alethia Pertussis (n=4)	3	75	3	75	4	100	1	25
Solana Bordetella Complete Assay (n=4)	4	100	4	100	4	100	0	0
Seegene Allplex Resp. Panel 4 (n=8)	8	100	8	100	8	100	8	100
LightMix B. pert. (n=7)	7	100	7	100	7	100	0	0
RIDAGENE Bordetella (n=19)	19	100	19	100	19	100	11	58
Other commercial tests (n=24)	24	100	24	100	24	100	7	29
<i>In house</i> PCR assay (n=38)	38	100	38	100	38	100	14	37

Comments: ¹⁾ Due to the well-known cross-reaction of *B. holmesii* in IS 481-specific PCR assays for *B. pertussis*, positive PCR results with sample # 2025323 were not rated as false-positive.

PCR/NAT *Helicobacter pylori* (RV 533) Nov 2020



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025331	++	61/71	<i>Helicobacter pylori</i> (~1x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
2025332	∅	62	<i>Escherichia coli</i> K12
2025333	∅	62	<i>Helicobacter salomonis</i> (~5x10 ⁴ CFU/mL)
2025334	(+)	61/72	<i>Helicobacter acinonyx</i> (~5x10 ⁴ CFU/mL) + <i>Helicobacter pylori</i> (~1x10 ³ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

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

<i>n=45</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	2025331	2025332	2025333	2025334	2025331	2025332	2025333	2025334	
Befund <i>Result</i>									
Positiv	44 ¹⁾	1	5	37	n.d.	0	0	0	0
Negativ	1	44	40	6	nein <i>no</i>	45	45	45	44
Fraglich <i>Questionable</i>	0	0	0	2	ja <i>yes</i>	0	0	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>			
	2025331		2025334		2025332		2025333	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
HAIN GenoType HelicoDR (n=18)	17	94	11	61	17	94	17	94
Ingenetix H. pylori ClariRes (n=4)	4	100	4	100	4	100	4	100
Seegene Allplex H. pylori + ClariR (n=3)	3	100	3	100	3	100	3	100
LightMix Helicobacter 23S (n=2)	2	100	2	100	2	100	1	50
RIDAGENE H. pylori (n=4)	4	100	4	100	4	100	4	100
Other commercial tests (n=3)	3	100	3	100	3	100	2	67
<i>In house</i> PCR assay (n=11)	11	100	10	91	11	100	9	82

PCR/NAT EHEC/STEC (RV 534) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025341	∅	62	Shigella sonnei (~1x10 ⁴ CFU/mL)
2025342	+++	61/71,72,77,78	EHEC (~5x10 ⁴ CFU/mL) (stx-1, stx-2, eae, hlyA and O157 positive)
2025343	++	61/71,72,77,78	EHEC (~1x10 ⁴ CFU/mL) (stx-1, stx-2, eae, hlyA and O157 positive)
2025344	∅	62	Escherichia coli K12 (negative for eae and hlyA)

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>			
	<i>2025341</i>	<i>2025342</i>	<i>2025343</i>	<i>2025344</i>		<i>2025341</i>	<i>2025342</i>	<i>2025343</i>	<i>2025344</i>
Befund <i>Result</i>									
Positiv	7	126	125	2	n.d.	1	1	1	1
Negativ	119	1	2	125	nein <i>no</i>	126	126	126	126
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 true-positive and true-negative results

NAT-Methode [Code] (total number*)	NAT richtig-positiv <i>True-positive results</i>				NAT richtig-negativ <i>True-negative results</i>			
	2025342		2025343		2025341		2025344	
	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>
Amplex eazyplex EHEC complete (n=5)	5	100	5	100	5	100	5	100
HAIN GenoType EHEC (n=17)	17	100	17	100	15	88	17	100
Seegene Allplex Gast. Bacteria II (n=6)	6	100	6	100	6	100	6	100
LightMix Modular stx-1/stx-2/eae (n=6)	5	83	5	83	5	83	6	100
RIDAGENE (n=43)	43	100	42	98	40	93	43	100
Other commercial tests (n=15)	15	100	15	100	15	100	14	93
<i>In house</i> PCR assay (n=35)	35	100	35	100	33	94	34	97

PCR/NAT *Borrelia burgdorferi* (RV 535) Nov 2020



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025351	++	61	<i>Borrelia valaisiana</i> (~5x10 ⁴ organisms/mL)
2025352	∅	62	<i>Treponema phagedenis</i>
2025353	++	61	<i>Borrelia garinii</i> OspA Typ3 (~5x10 ⁴ organisms/mL)
2025354	∅	62	<i>Borrelia hispanica</i> (~1x10 ⁵ organisms/mL)

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

<i>n=98</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	<i>2025351</i>	<i>2025352</i>	<i>2025353</i>	<i>2025354</i>	<i>2025341</i>	<i>2025342</i>	<i>2025343</i>	<i>2025344</i>	
<i>Befund Result</i>									
Positiv	91	0	97	15	n.d.	1	1	1	1
Negativ	6	98	1	82	nein <i>no</i>	97	97	97	97
Fraglich <i>Questionable</i>	1	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>			
	2025351		2025353		2025352		2025354	
	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>
HAIN FluoroType <i>Borrelia</i> (n=6)	6	100	6	100	6	100	0	0
GeneProof <i>B. burgdorferi</i> (n=16)	16	100	16	100	16	100	16	100
Gerbion diarella <i>Borrelia</i> (n=4)	4	100	4	100	4	100	4	100
Mikrogen alphaCube <i>Borrelia</i> (n=7)	6	86	7	100	7	100	7	100
LightMix <i>Borrelia</i> (n=7)	7	100	7	100	7	100	5	71
Other commercial tests (n=14)	14	100	14	100	14	100	14	100
<i>In house</i> PCR assay (n=44)	38	86	43	98	44	100	36	82

PCR/NAT *Legionella pneumophila* (RV 536) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025361	+	61	<i>Legionella pneumophila</i> SG1 (~1x10 ⁴ CFU/mL)
2025362	∅	62	<i>Escherichia coli</i> K12
2025363	+++	61	<i>Legionella pneumophila</i> SG1 (~5x10 ⁵ CFU/mL)
2025364	+++	61	<i>Legionella pneumophila</i> SG1 (~5x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=109</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	2025361	2025362	2025363	2025364		2025361	2025362	2025363	2025364
Befund <i>Result</i>									
Positiv	106	0	107	107	n.d.	1	1	1	1
Negativ	3	109	2	2	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	
	2025361		2025363		2025364		2025362	
	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>
AID CAP Bacteria (n=5)	5	100	5	100	5	100	5	100
AmpliGnost <i>L. pneumophila</i> (n=4)	4	100	4	100	4	100	4	100
BioGx auf BD Max (n=5)	5	100	5	100	5	100	5	100
GeneProof <i>L. pneumophila</i> (n=5)	5	100	5	100	5	100	5	100
Seegene Allplex Resp. Panel 4 (n=13)	12	92	13	100	12	92	13	100
Tib Molbiol LightMix <i>Legionella</i> (n=8)	8	100	8	100	8	100	8	100
RIDAGENE <i>Legionella</i> (n=9)	9	100	9	100	9	100	9	100
Other commercial tests (n=27)	26	96	27	100	27	100	27	100
<i>In house</i> PCR assay (n=33)	32	97	31	94	32	97	33	100

PCR/NAT *Salmonella enterica* (RV 537) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025371	+++	61	<i>S. enterica</i> ser. typhimurium (~5x10 ⁵ CFU/mL)
2025372	∅	62	<i>Shigella sonnei</i> (~1x10 ⁵ CFU/mL)
2025373	∅	62	<i>Escherichia coli</i> K12
2025374	++	61	<i>S. enterica</i> ser. typhi (~1x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=24</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>2025371</i>	<i>2025372</i>	<i>2025373</i>	<i>2025374</i>		<i>2025371</i>	<i>2025372</i>	<i>2025373</i>	<i>2025374</i>
Befund <i>Result</i>									
Positiv	24	0	0	24	n.d.	0	0	0	0
Negativ	0	24	24	0	nein <i>no</i>	24	24	24	24
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

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

Absolute numbers and relative frequency of reported true-positive and true-negative results

NAT-Methode [Code] (total number*)	NAT richtig-positiv <i>True-positive results</i>				NAT richtig-negativ <i>True-negative results</i>			
	2025371		2025374		2025372		2025373	
	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>
BD MAX Enteric Bacterial Panel (n=5)	5	100	5	100	5	100	5	100
Seegene Allplex GI-Bacteria (I) (n=3)	3	100	3	100	3	100	3	100
RIDAGENE Bacterial Stool Panel (n=5)	5	100	5	100	5	100	5	100
Other commercial tests (n=5)	5	100	5	100	5	100	5	100
<i>In house</i> PCR assay (n=6)	6	100	6	100	6	100	6	100

**PCR/NAT *Listeria spp.*
(RV 538) Nov 2020**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025381	∅	62	<i>Escherichia coli</i> K12
2025382	+	61/71	<i>Listeria monocytogenes</i> (~5x10 ³ CFU/mL)
2025383	+++	61/71	<i>Listeria monocytogenes</i> (~5x10 ⁵ CFU/mL)
2025384	++	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=41</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	2025381	2025382	2025383	2025384		2025381	2025382	2025383	2025384
Befund <i>Result</i>									
Positiv	1	42	42	42	n.d.	0	0	0	0
Negativ	41	0	0	0	nein <i>no</i>	42	42	42	42
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

NAT-Methode [Code] (total number)	NAT richtig-positiv <i>True-positive results</i>						NAT richtig-negativ	
	2025382		2025383		2025384		2025381	
	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%
Ingenetix BactoReal <i>L. monocyt.</i> (n=5)	5	100	5	100	5	100	5	100
Seegene Allplex Meningitis-B (n=3)	3	100	3	100	3	100	3	100
LightMix <i>L. monocytogenes</i> (n=7)	7	100	7	100	7	100	7	100
Other commercial tests (n=10)	10	100	10	100	10	100	10	100
<i>In house</i> PCR assay (n=17)	17	100	17	100	17	100	16	94

PCR/NAT MRSA/cMRSA (RV 539) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025391	+++	61/72	MRSA (<i>S. aureus</i> , PVL-neg, pSA442 neg.) (~1x10 ⁵ CFU/mL)
2025392	∅	62/73	CoNS oxa ^S (~1x10 ³ CFU/mL)
2025393	+	61/71,72	cMRSA (<i>S. aureus</i> , oxa ^R , PVL-pos) (~5x10 ³ CFU/mL)
2025394	++	61/71,72	cMRSA (<i>S. aureus</i> , oxa ^R , PVL-pos) (~5x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=277</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	2025391	2025392	2025393	2025394	2025391	2025392	2025393	2025394	
<i>Befund Result</i>									
Positiv	250	5	273	275	n.d.	4	4	4	4
Negativ	24	272	3	2	nein no	273	273	273	273
Fraglich <i>Questionable</i>	3	0	1	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	
	2025391		2025393		2025394		2025392	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Amplex eazyplex MRSA plus (n=5)	4	80	5	100	5	100	5	100
BD MAX/BD GeneOhm MRSA (n=48)	48	100	47	97	48	100	45	94
HAIN FluoroType/GenoType (n=23)	17	74	22	96	23	100	23	100
Cepheid Xpert MRSA (n=142)	141	99	140	99	140	99	140	99
Immundiagnostik MutaPLEX MRSA(n=3)	3	100	3	100	3	100	3	100
r-Biopharm RIDAGENE MRSA (n=27)	11	41	27	100	27	100	27	100
Other commercial tests (n=12)	11	92	12	100	12	100	12	100
<i>In house</i> PCR assay (n=17)	15	88	17	100	17	100	17	100

PCR/NAT *Chlamydia pneumoniae* (RV 540) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025401	∅	62	<i>Escherichia coli</i> K12
2025402	+	61	<i>Chlamydia pneumoniae</i> (~5x10 ⁴ IFU/mL)
2025403	+++	61	<i>Chlamydia pneumoniae</i> (~1x10 ⁶ IFU/mL)
2025404	∅	62	<i>Escherichia coli</i> K12

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>				
	<i>2025401</i>	<i>2025402</i>	<i>2025403</i>	<i>2025404</i>	<i>2025401</i>	<i>2025402</i>	<i>2025403</i>	<i>2025404</i>	
Befund <i>Result</i>									
Positiv	1	119	118	3	n.d.	0	0	0	0
Negativ	118	0	1	116	nein <i>no</i>	119	119	119	119
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>			
	2025402		2025403		2025401		2025404	
	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>
AID CAP bacteria (n=5)	5	100	5	100	5	100	5	100
ARGENE C. pn/M. pn r-gene (n=6)	6	100	6	100	6	100	6	100
AmpliGnost C. pneumoniae (n=5)	5	100	5	100	5	100	5	100
BioGx auf BD Max (n=5)	5	100	5	100	5	100	5	100
GeneProof C. pneumoniae (n=9)	9	100	9	100	9	100	9	100
Mikrogen ampliCube Resp. Panel 1 (n=8)	8	100	8	100	8	100	8	100
Seegene Allplex Resp. Panel 4 (n=13)	13	100	13	100	13	100	13	100
LightMix C. pneumoniae (n=11)	11	100	11	100	11	100	11	100
Other commercial tests (n=23)	23	100	22	96	22	96	20	87
<i>In house</i> PCR assay (n=34)	34	100	34	100	34	100	34	100

**PCR/NAT *Mycoplasma pneumoniae*
(RV 541) Nov 2020**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025411	∅	62	<i>Escherichia coli</i> K12
2025412	++	61	<i>Mycoplasma pneumoniae</i> (~5x10 ⁴ genome copies/mL)
2025413	+	61	<i>Mycoplasma pneumoniae</i> (~5x10 ³ genome copies/mL)
2025414	+++	61	<i>Mycoplasma pneumoniae</i> (~5x10 ⁵ genome copies/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=136</i>	Probennummer (Sample no.)			
Befund Result	2025411	2025412	2025413	2025414
Positiv	3	134	128	135
Negativ	133	2	8	1
Fraglich Questionable	0	0	0	0

	Inhibition			
	2025411	2025412	2025413	2025414
n.d.	0	0	0	0
nein no	136	136	136	136
ja yes	0	0	0	0

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

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	
	2025412		2025413		2025414		2025411	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID CAP bacteria (n=5)	5	100	5	100	5	100	5	100
ARGENE C.pn/M.pn r-gene (n=7)	7	100	7	100	7	100	7	100
AmpliGnost M. pneumoniae (n=5)	5	100	5	100	5	100	5	100
BioGx auf BD Max (n=6)	6	100	6	100	6	100	6	100
GeneProof M. pneumoniae (n=8)	8	100	6	75	8	100	8	100
Mikrogen ampliCube Resp. Panel 1(n=9)	9	100	9	100	8	89	9	100
Alethia Mycoplasma direct (n=5)	5	100	4	80	5	100	5	100
Seegene Allplex Resp Panel 4 (n=12)	11	92	11	92	12	100	12	100
LightMix M. pneumoniae (n=12)	12	100	12	100	12	100	12	100
RIDAGENE M. pneumoniae (n=6)	6	100	6	100	6	100	6	100
Other commercial tests (n=25)	25	100	23	92	25	100	23	92
<i>In house</i> PCR assay (n=36)	35	97	34	94	36	100	35	97

PCR/NAT *C. burnetii* & *B. anthracis* (RV 542) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>	<i>Probenzusammensetzung/Sample composition</i>
2025421	+++ / +++	<i>Coxiella burnetii</i> (~5x10 ⁴ genome copies/mL) <i>B. anthracis</i> UR-1 Stamm (~1x10 ⁵ genome copies/mL)
2025422	∅ / +++	<i>B. anthracis</i> UR-1 Stamm (~5x10 ⁵ genome copies/mL)
2025423	∅ / ∅	<i>Escherichia coli</i> K12
2025424	+++ / ∅	<i>Coxiella burnetii</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.*

n=46	Probennummer (Sample no.)				Inhibition				
	2025421	2025422	2025423	2025424	2025421	2025422	2025423	2025424	
Befund <i>Result</i>									
Positiv	45	1	0	45	n.d.	0	0	0	0
Negativ	1	45	46	1	nein <i>no</i>	46	46	46	46
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. 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>			
	2025421		2025424		2025422		2025423	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Progenie RealCycler <i>C. burnetii</i> (n=2)	1	50	2	100	1	50	2	100
LightMix <i>C. burnetii</i> (n=3)	3	100	3	100	3	100	3	100
Other commercial tests (n=7)	7	100	7	100	7	100	7	100
<i>In house</i> PCR assay (n=34)	34	100	33	97	33	97	34	100

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.*

n=24	Probennummer (Sample no.)					Inhibition			
	2025421	2025422	2025423	2025424		2025421	2025422	2025423	2025424
Befund Result					n.d.	0	0	0	0
Positiv	24	24	0	0	nein no	24	24	24	24
Negativ	0	0	24	24	ja yes	0	0	0	0
Fraglich Questionable	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			
	2025421		2025422		2025423		2025424	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
Altona RealStar Anthrax (n=3)	3	100	3	100	3	100	3	100
LightMix B. anthracis (n=2)	2	100	2	100	2	100	2	100
Other commercial tests (n=1)	1	100	1	100	1	100	1	100
In house PCR assay (n=18)	18	100	18	100	18	100	18	100

PCR/NAT *F. tularensis* & *Brucella* (RV 543) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>	<i>Probenzusammensetzung/Sample composition</i>
2025431	++/++	<i>Francisella tularensis subsp. tul.</i> (~1x10 ⁴ CFU/mL) <i>Brucella melitensis</i> (~1x10 ⁴ CFU/mL)
2025432	∅/+++	<i>Brucella melitensis</i> (~1x10 ⁵ CFU/mL)
2025433	+++/∅	<i>Francisella tularensis subsp. tul.</i> (~1x10 ⁵ CFU/mL)
2025434	∅/∅	<i>Escherichia coli</i> K12

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

Absolute numbers of reported individual results.

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

n=27	Probennummer (Sample no.)				Inhibition				
	2025431	2025432	2025433	2025434	2025431	2025432	2025433	2025434	2025434
Befund <i>Result</i>									
Positiv	25	0	27	0	n.d.	0	0	0	0
Negativ	2	27	0	27	nein <i>no</i>	27	27	27	27
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. Anmerkung: In dieser Tabelle sind nur die Ergebnisse für *Francisella tularensis* dargestellt.

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

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

NAT-Methode [Code] (total number*)	NAT richtig-positiv <i>True-positive results</i>				NAT richtig-negativ <i>True-negative results</i>			
	2025431		2025433		2025432		2025434	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
LightMix <i>F.tularensis</i> (n=6)	6	100	6	100	6	100	6	100
Commercial assay/kit [27] (n=1)	0	0	1	100	1	100	1	100
<i>In house</i> PCR assay (n=20)	19	95	20	100	20	100	20	100

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

Absolute numbers of reported individual results.

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

n=25	Probennummer (Sample no.)					Inhibition			
	2025431	2025432	2025433	2025434		2025431	2025432	2025433	2025434
Befund Result									
Positiv	25	25	0	0	n.d.	0	0	0	0
Negativ	0	0	25	25	nein no	25	25	25	25
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 **Brucella** dargestellt.

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

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

NAT-Methode [Code] (total number*)	NAT richtig-positiv True-positive results				NAT richtig-negativ True-negative results			
	2025431		2025432		2025433		2025434	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
LightMix Brucella Genus (n=2)	2	100	2	100	2	100	2	100
Commercial assay/kit [27] (n=2)	2	100	2	100	2	100	2	100
In house PCR assay (n=21)	21	100	21	100	21	100	21	100

PCR/NAT Carbapenemase (RV 544) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025441	+++	61/72	<i>Serratia marcescens</i> VIM-4 (~1x10 ⁷ genome copies/mL)
2025442	∅	62	<i>Escherichia coli</i> K12
2025443	+++	61/73	<i>E. coli</i> OXA-162 (~1x10 ⁷ genome copies/mL)
2025444	+++	61/74	<i>C. freundii</i> complex GES-5 (~1x10 ⁷ genome copies/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=80</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>2025441</i>	<i>2025442</i>	<i>2025443</i>	<i>2025444</i>		<i>2025441</i>	<i>2025442</i>	<i>2025443</i>	<i>2025444</i>
<i>Befund Result</i>									
Positiv	80	1	80	21	n.d.	2	2	2	2
Negativ	0	79	0	58	nein <i>no</i>	78	78	78	78
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 Anwenden 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	
	2025441		2025443		2025444		2025442	
	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>
AID Carbapenemase (n=3)	3	100	3	100	0	0	3	100
Amplex eazypex SuperBug A/B/C(n=10)	10	100	10	100	6	60	10	100
Cepheid Xpert Carba-R (n=42)	42	100	42	100	4	10	42	100
Seegene Allplex Entero-DR (n=5)	5	100	5	100	1	20	4	80
LightMix Modular Carbapenemase (n=4)	4	100	4	100	2	50	4	100
Other commercial tests (n=6)	6	100	6	100	0	0	6	100
<i>In house</i> PCR assay (n=10)	10	100	10	100	8	80	10	100

**PCR/NAT *Clostridium difficile*
(RV 545) Nov 2020**



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

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025451	∅	62	<i>Escherichia coli</i> K12
2025452	++	61/71,73,75	<i>Clostridium difficile</i> (~5x10 ⁴ CFU/mL)
2025453	+++	61/71,73,75	<i>Clostridium difficile</i> (~5x10 ⁵ CFU/mL)
2025454	∅	62	<i>Escherichia coli</i> K12

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

<i>n=165</i>	<i>Probennummer (Sample no.)</i>			
<i>Befund Result</i>	2025451	2025452	2025453	2025454
Positiv	0	162	164	2
Negativ	164	3	1	163
Fraglich Questionable	1	0	0	0

	Inhibition			
	2025451	2025452	2025453	2025454
n.d.	4	4	4	4
nein no	161	161	161	161
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>			
	2025452		2025453		2025451		2025454	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Altona RealStar C. difficile (n=7)	7	100	7	100	7	100	7	100
Amplex eazyplex C. difficile (n=5)	5	100	5	100	5	100	5	100
BD MAX C.difficile (n=17)	17	100	17	100	17	100	17	100
HAIN GenoType/FluoroType (n=4)	4	100	4	100	4	100	4	100
Cepheid Xpert C.difficile (n=57)	56	98	57	100	57	100	56	98
Meridian Bioscience Alethia (n=7)	6	86	7	100	7	100	7	100
QUIDEL Solana C.difficile Assay (n=4)	4	100	4	100	4	100	4	100
Seegene Allplex GI Bacteria (n=5)	5	100	5	100	5	100	5	100
RIDAGENE C.diff. (n=27)	27	100	27	100	27	100	26	96
RIDAGENE Hospital Stool Panel (n=6)	6	100	6	100	6	100	6	100
Other commercial tests (n=15)	14	93	14	93	14	93	15	100
<i>In house</i> PCR assay (n=11)	11	100	11	100	11	100	11	100

PCR/NAT VRE (RV 546) Nov 2020



Table 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025461	+++	61/71	<i>Enterococcus faecium</i> vanA (~1x10 ⁵ CFU/mL)
2025462	∅	62	<i>Lactobacillus rhamnosus</i> (~1x10 ⁵ CFU/mL)
2025463	∅	62	<i>Escherichia coli</i> K12
2025464	++	61/72	<i>Enterococcus faecium</i> vanB (~5x10 ⁴ CFU/mL)

Table 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=63</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	<i>2025461</i>	<i>2025462</i>	<i>2025463</i>	<i>2025464</i>		<i>2025461</i>	<i>2025462</i>	<i>2025463</i>	<i>2025464</i>
<i>Befund Result</i>									
Positiv	63 ¹⁾	0	1	63 ¹⁾	n.d.	1	1	1	1
Negativ	0	63	62	0	nein <i>no</i>	62	62	62	62
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Table 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>			
	2025461		2025464		2025462		2025463	
	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>	<i>Absolut Absolute</i>	<i>%</i>
HAIN GenoType Enterococcus (n=10)	10	100	10	100	10	100	10	100
Cepheid Xpert vanA/vanB (n=26)	26	100	26	100	26	100	26	100
Seegene Allplex Entero-DR (n=5)	5	100	5	100	5	100	5	100
Other commercial tests (n=7)	7	100	7	100	7	100	7	100
<i>In house PCR assay (n=15)</i>	15	100	15	100	15	100	14	93

Comments: ¹⁾ All participants reported dedicated vanA/vanB identification. With the exception of 2 laboratories, all reported results were correct.

PCR/NAT Urogenital Panel (RV 547) Nov 2020



Table 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>	<i>Probenzusammensetzung/Sample composition</i>
2025471	++	<i>Ureaplasma parvum</i> (~5x10 ³ CFU/mL)
2025472	++	<i>Mycoplasma hominis</i> (~1x10 ⁴ CFU/mL)
2025473	++	<i>Trichomonas vaginalis</i> (~1x10 ⁴ CFU/mL)
2025474	++	<i>Gardnerella vaginalis</i> (~1x10 ⁴ CFU/mL)

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

Absolute numbers of reported individual results.

*Note: Only the **M. hominis-specific results** are depicted in this table*

<i>n=71</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	2025471	2025472	2025473	2025474	2025471	2025472	2025473	2025474	
Befund <i>Result</i>									
Positiv	2	71	1	3	n.d.	0	0	0	0
Negativ	69	0	70	68	nein <i>no</i>	71	71	71	71
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. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Mycoplasma hominis* dargestellt.

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

*Note: Only the **M. hominis** -specific results are depicted in this table.*

NAT-Methode [Code] (total number*)	NAT richtig-positiv		NAT richtig-negativ <i>True-negative results</i>					
	2025472		2025471		2025473		2025474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Amplex eazyplex STD complete (n=2)	2	100	2	100	2	100	2	100
BioGX Mycopl./Ureapl. (n=5)	5	100	5	100	5	100	4	80
EUROIMMUN EUROArray STI-11 (n=2)	2	100	2	100	2	100	2	100
MIKROGEN ampliCube STD 2 (n=7)	7	100	6	86	7	100	7	100
Seegene Allplex STI Essential (n=18)	18	100	18	100	18	100	17	94
Seegene Anyplex STI-5 Detection (n=2)	2	100	2	100	2	100	2	100
LightMix modular M.hominis (n=4)	4	100	4	100	4	100	4	100
RIDAGENE STI Myc. Panel (n=10)	10	100	10	100	10	100	10	100
Other commercial tests (n=13)	13	100	12	92	12	92	12	92
<i>In house</i> PCR assay (n=8)	8	100	8	100	8	100	8	100

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

Absolute numbers of reported individual results.

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

<i>n=63</i>	Probennummer (Sample no.)				Inhibition				
	2025471	2025472	2025473	2025474	2025471	2025472	2025473	2025474	
Befund <i>Result</i>									
Positiv	1	1	59	1	n.d.	0	0	0	0
Negativ	62	62	4	62	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 5: Häufigkeit richtig-positiver und richtig-negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Trichomonas vaginalis* dargestellt.

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

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

NAT-Methode [Code] (total number *)	NAT richtig-positiv		NAT richtig-negativ <i>True-negative results</i>					
	2025473		2025471		2025472		2025474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
BIORON RealLine T.vaginalis (n=2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI-11 (n=2)	2	100	2	100	2	100	2	100
MIKROGEN ampliCube STD 2 (n=7)	5	71	7	100	7	100	6	86
Roche COBAS TV/MG (n=3)	2	67	3	100	2	67	3	100
Seegene Allplex STI Essential (n=20)	19	95	20	100	20	100	20	100
LightMix modular M. vaginalis (n=2)	2	100	1	50	2	100	2	100
RIDAGENE T. vaginalis (n=2)	2	100	2	100	2	100	2	100
Other commercial tests (n=15)	15	100	15	100	15	100	15	100
<i>In house</i> PCR assay (n=10)	10	100	10	100	10	100	10	100

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

Absolute numbers of reported individual results.

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

<i>n=17</i>	Probennummer (Sample no.)					Inhibition			
	2025471	2025472	2025473	2025474		2025471	2025472	2025473	2025474
Befund <i>Result</i>									
Positiv	0	0	0	16	n.d.	0	0	0	0
Negativ	17	17	17	1	nein <i>no</i>	17	17	17	17
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

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

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

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

NAT-Methode [Code] (total number*)	NAT richtig-positiv		NAT richtig-negativ <i>True-negative results</i>					
	2025474		2025471		2025472		2025473	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID GenID STI (n=1)	1	100	1	100	1	100	1	100
BIORON RealLine G. vaginalis (n=1)	1	100	1	100	1	100	1	100
Seegene Allplex Bact. Vaginosis (n=5)	5	100	5	100	5	100	5	100
Other commercial tests (n=3)	2	67	3	100	3	100	3	100
<i>In house</i> PCR assay (n=7)	7	100	7	100	7	100	7	100

Tabelle 8: Häufigkeit der Mitteilung verschiedener Befunde. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Ureaplasma parvum* dargestellt.

Absolute numbers of reported individual results.

*Note: Only the **U. parvum** -specific results are depicted in this table*

n=53	Probennummer (Sample no.)					Inhibition			
	2025471	2025472	2025473	2025474		2025471	2025472	2025473	2025474
Befund <i>Result</i>									
Positiv	53	0	0	0	n.d.	0	0	0	0
Negativ	0	53	53	53	nein <i>no</i>	53	53	53	53
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 9: Häufigkeit richtig-positiver und richtig-negativer NAT-Befunde bei Anwendern verschiedener Methoden. Anmerkung: in dieser Tabelle sind nur die Ergebnisse für *Ureaplasma parvum* dargestellt.

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

Note: Only the *U. parvum* -specific results are depicted in this table.

NAT-Methode [Code] (total number*)	NAT richtig-positiv		NAT richtig-negativ <i>True-negative results</i>					
	2025471		2025472		2025473		2025474	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
BioGX Mycopl./Ureapl. (n=5)	5	100	5	100	5	100	5	100
EUROIMMUN EUROArray STI-11 (n=2)	2	100	2	100	2	100	2	100
Seegene Allplex STI Essential (n=20)	20	100	20	100	20	100	20	100
LightMix modular UU/UP (n=3)	3	100	3	100	3	100	3	100
RIDAGENE STI Mycop. Panel (n=2)	2	100	2	100	2	100	2	100
Other commercial tests (n=16)	16	100	16	100	16	100	16	100
<i>In house</i> PCR assay (n=6)	6	100	6	100	6	100	6	100

PCR/NAT *Pneumocystis jirovecii* (RV 560) Nov 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis

Sample composition and expected results

	<i>Erwartet/expected</i>		<i>Probenzusammensetzung/Sample composition</i>
2025601	++	61	<i>Pneumocystis jirovecii</i> (~1x10 ⁴ organisms/mL)
2025602	∅	62	<i>Escherichia coli</i> K12
2025603	+++	61	<i>Pneumocystis jirovecii</i> (~1x10 ⁵ organisms/mL)
2025604	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde

Absolute numbers of reported individual results

<i>n=111</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	<i>2025601</i>	<i>2025602</i>	<i>2025603</i>	<i>2025604</i>	<i>2025601</i>	<i>2025602</i>	<i>2025603</i>	<i>2025604</i>	
Befund <i>Result</i>									
Positiv	107	1	111	1	n.d.	0	0	0	0
Negativ	4	110	0	109	nein <i>no</i>	111	111	111	110
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 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>			
	2025601		2025603		2025602		2025604	
	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>	<i>Absolut</i> <i>Absolute</i>	<i>%</i>
Altona RealStar P. <i>jirovecii</i> (n=12)	12	100	12	100	12	100	12	100
Amplex eazyplex P. <i>jirovecii</i> (n=6)	5	83	6	100	6	100	6	100
AmpliGnost P. <i>jirovecii</i> (n=9)	9	100	9	100	9	100	9	100
BioGx P. <i>jirovecii</i> (n=5)	5	100	5	100	5	100	5	100
LightMix P. <i>jirovecii</i> (n=12)	12	100	12	100	12	100	12	100
RIDAGENE P. <i>jirovecii</i> (n=31)	29	94	31	100	31	100	31	100
Other commercial tests (n=8)	8	100	8	100	8	100	8	100
<i>In house</i> PCR assay (n=28)	27	96	28	100	27	96	26	93