

PCR-/NAT *C. trachomatis* & GO (RV 530) November 2010



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

Gruppe A	Erwartet / expected		Probenzusammensetzung / Sample composition
1025301	∅ / ∅	64	<i>Neisseria sicca</i>
1025302	+ / +	62	<i>Chlamydia trachomatis</i> (~ 1x10 ³ IFU/mL) & <i>Neisseria gonorrhoeae</i> (~ 1x10 ³ CFU/mL)
1025303	∅ / ∅	64	<i>Neisseria lactamica</i>
1025304	+ / ++	62	<i>Chlamydia trachomatis</i> (~ 1x10 ³ IFU/mL) & <i>Neisseria gonorrhoeae</i> (~ 1x10 ⁴ CFU/mL)

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

n = 128	Probennummer (Sample no.)				Inhibition				
	1025301	1025302	1025303	1025304	1025301	1025302	1025303	1025304	
Befund Result									
Positiv CT	0	6	0	2	n.d.	0	0	0	0
Positiv CT & GO	0	120	1	118	nein / no	128	128	127	128
Positiv GO	1	0	9	4	ja / yes	0	0	1	0
Negativ	127	2	116	3					
Fraglich / <i>questionable</i>	0	0	2	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>	%
GenProbe CT/NG [20] (n = 4)	4	4 / 8	50	8	8 / 8	100
LightMix CT/NG [21] (n = 7)	14	14 / 14	100	14	14 / 14	100
Roche Cobas TaqMan [22] (n = 18)	33	33 / 36	92	36	36 / 36	100
COBAS Amplicor [23] (n = 20)	40	40 / 40	100	39	39 / 40	98
BD ProbeTec [24] (n = 19)	37	37 / 38	97	36	36 / 38	95
Artus CT [25] (n = 5)	10	10 / 10	100	10	10 / 10	100
Abbott RealTime CT/NG [26] (n = 28)	55	55 / 56	98	56	56 / 56	100
Other commercial tests [27] (n = 25)	48	48 / 49 [§]	98	45	45 / 48 [§]	94

In house PCR assay [28] (n = 20)	34	34 / 40	85	35	35 / 40	88
Andere / k.A. / other [29] (n = 4)	7	7 / 8	88	7	7 / 8	88

Legend for Table 3:

* 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) have been reduced.

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 = 4)	5	5 / 8	63	8	8 / 8	100
LightMix CT/NG [21] (n = 7)	14	14 / 14	100	14	14 / 14	100
Roche Cobas TaqMan [22] (n = 18)	35	35 / 36	97	36	36 / 36	100
COBAS Amplicor [23] (n = 20)	40	40 / 40	100	39	39 / 39 §	100
BD ProbeTec [24] (n = 19)	37	37 / 38	97	38	38 / 38	100
Artus CT [25] (n = 5)	10	10 / 10	100	10	10 / 10	100
Abbott RealTime CT/NG [26] (n = 28)	56	56 / 56	100	56	56 / 56	100
Other commercial tests [27] (n = 25)	48	48 / 49 §	98	49	49 / 49 §	100
In house PCR assay [28] (n = 20)	37	37 / 40	93	38	38 / 39 §	97
Andere / k.A. / other [29] (n = 4)	8	8 / 8	100	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) have been reduced.

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 = 4)	6	6 / 8	75	8	8 / 8	100
LightMix CT/NG [21] (n = 7)	14	14 / 14	100	14	14 / 14	100
Roche Cobas TaqMan [22] (n = 18)	34	34 / 36	94	36	36 / 36	100
COBAS Amplicor [23] (n = 20)	40	40 / 40	100	39	39 / 40	98
BD ProbeTec [24] (n = 19)	38	38 / 38	100	36	36 / 38	95
Artus CT [25] (n = 5)	10	10 / 10	100	10	10 / 10	100
Abbott RealTime CT/NG [26] (n = 28)	55	55 / 56	98	56	56 / 56	100
Other commercial tests [27] (n = 25)	50	50 / 50	100	46	46 / 49 [§]	94
In house PCR assay [28] (n = 20)	34	34 / 40	85	35	35 / 40	88
Andere / k.A. / other [29] (n = 4)	7	7 / 8	88	7	7 / 8	88

* 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: Falsch-positive und falsch-negative NAT-Befunde nach Methode

False-positive and -negative NAT results with commercial or in-house assays

NAT-Methode NAT method	Positive samples		Negative samples	
	1025302	1025304	1025301	1025303
GenProbe CT/NG (n = 4)	2/4 GO- 1/4 CT-	2/4 CT-	-	-
LightMix CT/NG (n = 7)	-	-	-	-
Roche Cobas TaqMan (n = 18)	1/18 GO-	2/18 GO- 1/18 CT-	-	-
COBAS Amplicor (n = 20)	-	-	-	1/20 GO+
BD ProbeTec (n = 19)	-	1/19 CT-	-	2/19 GO+
Artus CT (n = 5)	-	-	-	-
Abbott RealTime CT/NG (n = 28)	1/28 GO-	-	-	-
Other commercial tests (n = 25)	-	-	-	3/25 GO+
In house PCR assay (n = 20)	3/20 GO- 1/20 CT-	3/20 GO- 2/20 CT-	1/20 GO+	4/20 GO+
Andere / k.A. / other (n = 4)	1/4 GO-	-	-	-