

**PCR-/NAT *C. trachomatis* & GO
 (RV 530) November 2023**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
530 231024 01	++ / ++	<i>Chlamydia trachomatis</i> (~ 1x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁴ CFU/mL)
530 231024 02	++ / ∅	<i>Chlamydia trachomatis</i> (~ 2x10 ⁴ IFU/mL)
530 231024 03	+++ / +	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ³ CFU/mL)
530 231024 04	∅ / +++	<i>Neisseria gonorrhoeae</i> (~ 5x10 ⁵ CFU/mL)

Tabelle 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.

n = 301	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	300	301	300	1	n.d.	4	4	4	4
Negativ	1	0	1	299	nein / no	297	297	297	296
Fraglich <i>Questionable</i>	0	0	0	1	ja / yes	0	0	0	1

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	
	01		02		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2110 STD (n = 2)	2	100	2	100	2	100	2	100
Abbott Alinity m STI Assay (n = 16)	16	100	16	100	16	100	16	100
Abbott RealTime CT (n = 13)	13	100	13	100	12	92	13	100
Amplex eazyplex STD complete (n = 1)	1	100	1	100	1	100	1	100
AmpliSens CT FRT PCR Kit (n = 1)	1	100	1	100	1	100	1	100
BD MAX CT (n = 22)	22	100	22	100	22	100	22	100
BD ProbeTec (n = 3)	3	100	3	100	3	100	3	100

BIORON RealLine CT (n = 1)	1	100	1	100	1	100	1	100
Bruker-HAIN FluoroType CT (n = 11)	11	100	11	100	11	100	11	100
Cepheid Xpert CT (n = 31)	31	100	31	100	31	100	30 [§]	97
CerTest VIASURE STD (n = 1)	1	100	1	100	1	100	1	100
DNA-Technology CT Real Time (n = 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI (n = 6)	6	100	6	100	6	100	6	100
GeneProof C. trachomatis (n = 8)	8	100	8	100	8	100	8	100
Hologic Aptima Combo 2 assay (n = 16)	16	100	16	100	16	100	16	100
ampliCube STD Panel 1 (n = 9)	9	100	9	100	9	100	9	100
Qiagen NeuMoDx CT/NG (n = 4)	4	100	4	100	4	100	4	100
artus CT/NG QS-RGQ Kit (n = 3)	3	100	3	100	3	100	3	100
Roche COBAS 4800 CT (n = 20)	20	100	20	100	20	100	20	100
COBAS 5800, 6800, 8800 CT (n = 56)	56	100	56	100	56	100	56	100
Sacace C. trachomatis Real TM (n = 5)	5	100	5	100	5	100	5	100
Seegene Allplex CT/NG/MG/TV (n = 12)	12	100	12	100	12	100	12	100
Seegene Allplex STI Essential (n = 25)	25	100	25	100	25	100	25	100
LightMix CT (n = 3)	3	100	3	100	3	100	3	100
Aprimeo/BOSCH Vivalytic STI (n = 3)	3	100	3	100	3	100	3	100
In house PCR assay (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 19)	18	95	19	100	19	100	19	100

[§] Fraglich Due to reporting questionable results, the number of true results has been reduced.

Comments:

- The following tests are listed under "Other commercial tests": Immundiagnostik MutaPLEX STI-1 (3x), AB Analytica RQ-STI CT/NG/MG (1x), AB Analytica REALQUALITY RQ-SevenSTI (1x), Bruker-Hain FluoroType STI (2x), Goffin Presto CT/NG Assay (1x), GeneProof CT/NG/MG Multiplex PCR Kit (3x), Astra Biotech C.trach. PCR Kit (1x), Roche COBAS CT/NG (1x), PANAGENE PANA RealTyper (1x), Gerbion diarellaSTI-1 (1x), ELITech STI Mix (1x), Genetic signatures EasyScreen STI Genital Pathogen Detection (1x), vitro master diagnostica STD direct flow Chip Kit (1x) and IFFMEDIC (1x).

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

n = 301	Proben Nr. (Sample no.)			
	01	02	03	04
Befund Result				
Positiv	301	8	297	299
Negativ	0	293	4	2
Fraglich Questionable	0	0	0	0

	Inhibition			
	01	02	03	04
n.d.	4	4	4	4
nein / no	297	297	297	297
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 *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	
	01		03		04		02	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
AID RDB 2110 STD (n = 2)	2	100	2	100	2	100	2	100
AID RDB 2335 STI (n = 1)	1	100	1	100	1	100	1	100
Abbott Alinity m STI Assay (n = 16)	16	100	16	100	16	100	15	94
Abbott RealTime NG (n = 13)	13	100	12	92	12	92	13	100
Amplex eazyplex STD complete (n = 1)	1	100	1	100	1	100	1	100
AmpliSens NG FRT PCR Kit (n = 1)	1	100	1	100	1	100	1	100
BD MAX NG (n = 22)	22	100	22	100	22	100	21	95
BD ProbeTec (n = 3)	3	100	3	100	3	100	3	100
BIORON RealLine NG (n = 1)	1	100	1	100	1	100	1	100
Bruker-HAIN FluoroType NG (n = 9)	9	100	9	100	9	100	9	100
Cepheid Xpert NG (n = 32)	32	100	31	97	32	100	29	91
CerTest VIASURE STD (n = 1)	1	100	1	100	1	100	1	100
DNA-Technology NG Real Time (n = 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI (n = 6)	6	100	6	100	6	100	6	100
GeneProof N. gonorrhoeae (n = 9)	9	100	9	100	9	100	9	100
Hologic Aptima Combo 2 assay (n = 16)	16	100	16	100	16	100	16	100
ampliCube STD Panel 1 (n = 9)	9	100	9	100	9	100	9	100
Qiagen NeuMoDx CT/NG (n = 4)	4	100	4	100	4	100	4	100
artus CT/NG QS-RGQ Kit (n = 3)	3	100	3	100	3	100	3	100
Roche COBAS 4800 CT (n = 20)	20	100	20	100	20	100	19	95
COBAS 5800, 6800, 8800 CT (n = 56)	56	100	56	100	56	100	56	100
Sacace N. gonorrhoeae Real TM (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex CT/NG/MG/TV (n = 12)	12	100	12	100	12	100	12	100
Seegene Allplex STI Essential (n = 25)	25	100	25	100	25	100	25	100
LightMix NG (n = 3)	3	100	3	100	3	100	3	100
Aprimeo/BOSCH Vivalytic STI (n = 3)	3	100	3	100	3	100	3	100
<i>In house</i> PCR assay (n = 7)	7	100	7	100	6	86	6	86

Other commercial tests (n = 20)	20	100	18	90	20	100	19	95
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Comments:

1. The following tests are listed under "Other commercial tests": Immundiagnostik MutaPLEX STI-1 (3x), AB Analitica RQ-STI CT/NG/MG (1x), AB Analitica REALQUALITY RQ-SevenSTI (1x), Bruker-Hain FluoroType STI (2x), Goffin Presto CT/NG Assay (1x), GeneProof CT/NG/MG Multiplex PCR Kit (3x), Anatolia Gene works Bosphore N. gonorrh. Detection Kit V1 (1x), Gerbion diarellaSTI-1 (1x), Astra Biotech N. gonorrh. PCR Kit (1x), Genetic signatures EasyScreen STI Genital Pathogen Detection (1x), Roche COBAS CT/NG (1x), vitro master diagnostica STD direct flow Chip Kit (1x) PANAGENE PANA RealTyper (1x), ELITech STI Mix (1x) and IFFMEDIC (1x).