

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



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
530 230523 01	++ / +	<i>Chlamydia trachomatis</i> (~ 5x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ³ CFU/mL)
530 230523 02	+ / +++	<i>Chlamydia trachomatis</i> (~ 2x10 ⁴ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁵ CFU/mL)
530 230523 03	∅ / ∅	<i>Escherichia coli</i> K12
530 230523 04	++ / ++	<i>Chlamydia trachomatis</i> (~ 1x10 ⁵ IFU/mL) <i>Neisseria gonorrhoeae</i> (~ 5x10 ⁴ 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.

<i>n</i> = 298	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	298	294	4	297	n.d.	4	4	4	4
Negativ	0	4	294	1	nein / no	294	294	294	294
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 Anwenden 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		04		03	
	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 = 14)	14	100	14	100	14	100	14	100
Abbott RealTime CT (n = 17)	17	100	17	100	17	100	17	100
Amplex eazyplex STD complete (n = 1)	1	100	1	100	1	100	1	100
AmpliSens CT FRT PCR Kit (n = 2)	2	100	2	100	2	100	2	100
BD MAX CT (n = 24)	24	100	24	100	23	96	24	100

BD ProbeTec (n = 2)	2	100	2	100	2	100	2	100
BIORON RealLine CT (n = 2)	2	100	2	100	2	100	2	100
Bruker-HAIN FluoroType CT (n = 12)	12	100	12	100	12	100	12	100
Cepheid Xpert CT (n = 30)	30	100	28	93	30	100	27	90
CerTest VIASURE STD (n = 2)	2	100	2	100	2	100	2	100
DNA-Technology CT Real Time (n = 1)	1	100	1	100	1	100	1	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 = 2)	2	100	2	100	2	100	2	100
artus CT/NG QS-RGQ Kit (n = 2)	2	100	2	100	2	100	2	100
Roche COBAS 4800 CT (n = 23)	23	100	23	100	23	100	23	100
COBAS 5800, 6800, 8800 CT (n = 51)	51	100	51	100	51	100	50	98
Sacace C. trachomatis Real TM (n = 5)	5	100	5	100	5	100	5	100
Seegene Allplex CT/NG/MG/TV (n = 9)	9	100	9	100	9	100	9	100
Seegene Allplex STI Essential (n = 23)	23	100	22	96	23	100	23	100
Seegene Anyplex II STI-7 (n = 2)	2	100	2	100	2	100	2	100
LightMix CT (n = 5)	5	100	5	100	5	100	5	100
Aprimeo/BOSCH Vivalytic STI (n = 2)	2	100	2	100	2	100	2	100
In house PCR assay (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 18)	18	100	17	94	18	100	18	100

Comments:

- The following tests are listed under "Other commercial tests": Immundiagnostik MutaPLEX STI-1 (2x), AB Analytica RQ-STI CT (2x), AB Analytica REALQUALITY RQ-SevenSTI (1x), Bruker-Hain FluoroType STI (2x), Goffin Presto CT/NG Assay (2x), GeneProof CT/NG/MG Multiplex PCR Kit (1x), BeGenius STI Plus (1x), Anatolia Gene works Bosphore C. trach. Detection Kit V1 (1x), Astra Biotech C.trach. PCR Kit (1x), Roche COBAS CT/NG (1x), ELITech STI Mix (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 = 297	Proben Nr. (Sample no.)			
Befund Result	01	02	03	04
Positiv	295	295	13	297
Negativ	2	2	283	0

	Inhibition			
	01	02	03	04
n.d.	4	4	4	4
nein / no	293	293	293	293

Fraglich <i>Questionable</i>	0	0	1	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 *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		02		04		03	
	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 = 13)	13	100	13	100	13	100	12	92
Abbott RealTime NG (n = 18)	18	100	18	100	18	100	15	83
Amplex eazyplex STD complete (n = 1)	1	100	1	100	1	100	1	100
AmpliSens NG FRT PCR Kit (n = 2)	2	100	2	100	2	100	1	50
BD MAX NG (n = 24)	23	96	24	100	24	100	24	100
BD ProbeTec (n = 2)	2	100	2	100	2	100	2	100
BIORON RealLine NG (n = 2)	2	100	2	100	2	100	2	100
Bruker-HAIN FluoroType NG (n = 10)	10	100	10	100	10	100	10	100
Cepheid Xpert NG (n = 30)	30	100	28	93	30	100	28	93
CerTest VIASURE STD (n = 2)	2	100	2	100	2	100	2	100
DNA-Technology NG Real Time (n = 2)	2	100	2	100	2	100	2	100
EUROIMMUN EUROArray STI (n = 6)	5	83	6	100	6	100	6	100
GeneProof N. gonorrhoeae (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	8	89
Qiagen NeuMoDx CT/NG (n = 2)	2	100	2	100	2	100	2	100
artus CT/NG QS-RGQ Kit (n = 2)	2	100	2	100	2	100	2	100
Roche COBAS 4800 CT (n = 23)	23	100	23	100	23	100	23	100
COBAS 5800, 6800, 8800 CT (n = 51)	51	100	51	100	51	100	49	96
Sacace N. gonorrhoeae Real TM (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex CT/NG/MG/TV (n = 9)	9	100	9	100	9	100	7	78
Seegene Allplex STI Essential (n = 23)	23	100	23	100	23	100	21	91
Seegene Anyplex II STI-7 (n = 2)	2	100	2	100	2	100	2	100
LightMix NG (n = 5)	5	100	5	100	5	100	5	100

Aprimeo/BOSCH Vivalytic STI (n = 2)	2	100	2	100	2	100	2	100
In house PCR assay (n = 8)	8	100	8	100	8	100	8	100
Other commercial tests (n = 18)	18	100	18	100	18	100	18	100

Comments:

1. The following tests are listed under "Other commercial tests": Immundiagnostik MutaPLEX STI-1 (2x), AB Analitica RQ-STI NG (1x), AB Analitica REALQUALITY RQ-SevenSTI (1x), Bruker-Hain FluoroType STI (2x), Goffin Presto CT/NG Assay (2x), GeneProof CT/NG/MG Multiplex PCR Kit (1x), Anatolia Gene works Bosphore N. gonorrh. Detection Kit V1 (1x), Astra Biotech N. gonorrh. PCR Kit (1x), Roche COBAS CT/NG (1x), ELITech STI Mix (1x) and IFFMEDIC (1x).